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Pharmaceutical Advertising 2022

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CONTENTS

1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

FDA's Authority over Prescription Drug Advertising and Promotion

The Federal Food, Drug, and Cosmetic Act (FDCA) grants the US Food and Drug Administration (FDA) broad authority over the advertising and promotion of prescription drugs. FDA regulations, found in Title 21 of the Code of Federal Regulations (CFR), outline the requirements for prescription drug advertising and promotion. FDA guidance documents, found on the FDA's website and published in the Federal Register, describe specific FDA policies related to prescription drug marketing.

The FDA's Office of Prescription Drug Promotion (OPDP) is charged with ensuring that prescription drug advertising and promotion is truthful, balanced and not misleading. The OPDP provides written advisory comments on proposed promotional materials, reviews complaints about alleged violations, and issues untitled or warning letters citing false or misleading promotional materials.

FTC's Authority over Promotion of OTC Drugs

The Federal Trade Commission (FTC) Act (FTCA) prohibits "unfair or deceptive acts or practices in or affecting commerce", including the dissemination of false advertising for drugs. Under a joint FDA/FTC Memorandum of Understanding, the FDA holds primary jurisdiction over the labelling of all drugs and the advertising of prescription drugs, while the FTC maintains primary authority over the advertising of non-prescription drugs (also known as over-the-counter (OTC) drugs); see **2.1 Definition of Advertising**.

Other Sources of Oversight of Drug Promotion

State consumer protection laws, both civil and criminal, also prohibit false or misleading advertising.

The Lanham Act (15 USC 1125(a)) allows competitors and other entities that have suffered commercial harm to sue for false or misleading advertising.

Promotional activities may implicate the criminal Anti-Kickback Statute (42 USC 1320a-7b) and the Civil Money Penalties Statute (42 USC 1320a-7a); see **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals**. Violations of the Anti-Kickback Statute may also result in violations of the civil False Claims Act (31 USC 3729). The False Claims Act includes a whistle-blower provision allowing private citizens to bring claims on behalf of the United States and share in the government's recoveries resulting from such claims.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Pharmaceutical advertising and promotion are also subject to voluntary guidelines issued by trade associations or medical professional associations. These guidelines address a variety of issues, ranging from funding continuing medical education, engaging physicians as speakers or consultants, and giving gifts or items of value to physicians.

While the FDA's and FTC's rules are enforced through law, voluntary self-regulatory codes and professional guidelines establish standards of acceptable behaviour but hold no legal authority. The Pharmaceutical Research and Manufacturers of America (PhRMA) has a Code on Interactions with Healthcare Professionals

("PhRMA Code") which provides guidelines for pharmaceutical companies when interacting with healthcare professionals (HCPs). Though the code is voluntary, the US Department of Health and Human Services' Office of Inspector General (OIG) endorsed its use in a 2003 guidance document. Thus, many pharmaceutical companies adopt the PhRMA Code as company policy and some states have made it mandatory for pharmaceutical companies operating within their borders.

Other third-party guidelines relevant to communications about pharmaceuticals include:

- PhRMA's Direct to Consumer Advertising Principles;
- PhRMA's Principles on Responsible Sharing of Truthful and Non-Misleading Information;
- the Accreditation Council for Continuing Medical Education (ACCME) Guidelines; and
- the American Medical Association (AMA) Guidelines.

In addition, the National Advertising Division (NAD), a non-judicial, advertising industry self-regulatory body, adjudicates advertising disputes brought by consumers, competitors or the NAD itself. Although the NAD has jurisdiction to hear challenges to prescription and OTC drug advertising, historically, NAD challenges have primarily targeted OTC drug advertising.

2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

2.1 Definition of Advertising

The FDA's authority under the FDCA includes oversight of promotional labelling for all drugs and advertising for prescription drugs. Section 201(m) of the FDCA defines drug labelling as "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". Courts have defined "accompanying" broadly to include most types of promotional materials, including brochures, literature reprints, mailers, printed or digital sales aids, emails, slide decks, videos, websites, and social media posts.

The FDCA does not define advertising; however, FDA regulations provide examples such as "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems".

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

The FDA recognises certain limited categories of "non-promotional" communications that constitute neither labelling nor advertising and are, therefore, not subject to the requirements for prescription drug promotion under the FDCA.

One example of "non-promotional" information is disease awareness communications, which are communications disseminated to consumers or HCPs that discuss a particular disease or health condition, but do not mention any specific drug or make any representation or suggestions concerning a particular drug. The FDA's long-standing policy is that disease awareness communications should be perceptually different (eg, different colour schemes, graphics, etc) and should appear physically separate from any branded advertising and promotion to avoid converting the disease awareness communication into implied promotion and advertising.

For additional examples of "non-promotional" communications, see **3.3 Provision of Information to Healthcare Professionals**, **3.4 Provision of Information to Healthcare Institutions**

and **3.5 Publication of Compassionate Use Programmes**.

2.3 Restrictions on Press Releases regarding Medicines

In general, the FDA expects press releases discussing a specific approved drug to comply with FDA regulatory requirements for promotional labelling, including being truthful and not misleading, maintaining fair balance between risks and benefits, and providing full disclosure of relevant contraindications, warnings, precautions and adverse events.

Press releases about investigational drugs (eg, announcing significant clinical study results or the filing of a new drug application with the FDA) should be non-promotional in intent, tone and context, and avoid promotional claims and commercial objectives. The press release should truthfully and accurately present all material information. Press releases that make conclusory statements regarding the safety or efficacy of the investigational drug, mischaracterise study data, or fail to adequately disclose the investigational status of the drug, could be viewed as pre-approval promotion, and thus misbrand an investigational drug under the FDCA.

2.4 Comparative Advertising for Medicines

Generally, the FDA requires that any comparative efficacy or safety claim be supported by adequate and well-controlled head-to-head studies or a large multi-centre trial. The FDA does not typically permit a claim of superior efficacy or safety based solely on the differences in the FDA-approved labelling of drugs or a comparison of results from two different studies. Comparative claims should be clinically relevant to indicated patients and must not be false or misleading.

3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The FDCA prohibits the introduction of a drug into interstate commerce that is intended for a use that has not been approved by the FDA. FDA regulations prohibit the promotion of an investigational (unapproved) drug as safe or effective for the purposes for which it is under investigation. This includes drugs that have never been approved, as well as unapproved indications for drugs that are approved for a different use.

Despite a broad prohibition on the promotion of unapproved drugs and indications, the FDA's current approach permits non-promotional communications about unapproved drugs and indications under the principles of scientific exchange. Importantly, a range of permissible communications qualify as scientific exchange, including scientific publications and presentations, support for independent scientific and medical education, responding to unsolicited requests for information, distributing scientific or medical publications on unapproved uses and/or risks, listing information on ClinicalTrials.gov, and communications with payors in advance of approval.

3.2 Provision of Information during a Scientific Conference

Factual and non-promotional presentations, posters, and abstracts about unapproved drugs or indications that are submitted to a scientific conference are typically regarded as legitimate scientific exchange.

In addition, it is common practice for pharmaceutical companies to host booths or exhibits at scientific conferences, which may include a medical information booth. A medical information booth should be non-promotional, staffed by scientific or medical personnel who may respond to unsolicited questions about unapproved drugs and off-label uses.

3.3 Provision of Information to Healthcare Professionals

As noted in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, although the FDA strictly prohibits the promotion of unapproved drugs and uses, it allows non-promotional scientific exchange, including the following limited "safe harbours" through which manufacturers can distribute or support information to HCPs about unapproved (off-label) uses of approved drugs.

FDA Off-Label Reprints Guidance – Proactive Distribution of Off-Label Reprints to HCPs

The FDA permits the proactive distribution of off-label reprints under recommendations stated in three guidance documents:

- "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices" (2009);
- "Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices" (draft guidance; 2014) (hereafter "Off-Label Reprints Guidance"); and
- "Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products — Recommended Practices" (draft guidance; 2014) (hereafter "Risk Information Reprints Guidance").

Off-Label Reprints Guidance

The Off-Label Reprints Guidance provides recommendations for the distribution of off-label scientific or medical journal articles, scientific or medical reference texts, and clinical practice guidelines. Each type of publication is subject to specific recommendations to ensure that distribution is appropriate.

Generally, off-label reprints should not be false or misleading and should not pose a significant risk to public health. The source of the publication should be considered, and should not be letters to the editor, special supplements funded by the manufacturer, or abstracts. Additionally, reprints should be provided in a complete and unabridged format, without alteration. Off-label reprints should be distributed in a non-promotional manner, and accompanied by a copy of the product's FDA-approved labelling – also known as the "prescribing information" or "package insert" (PI) – and a range of disclosures, including that the reprint discusses off-label uses of the company's product. Refer to the FDA's Off-Label Reprints Guidance for details.

Risk Information Reprints Guidance

The Risk Information Reprints Guidance permits the distribution of reprints about new risk information that may refute, mitigate, or refine risk information in the FDA-approved labelling. The reprint should meet the range of standards presented in the FDA's Risk Information Reprints Guidance, including that it is published in an independent, peer-reviewed journal and based on appropriate study design and methodology.

Risk information reprints should be distributed in a non-promotional manner, and accompanied by a copy of the product's PI and a range of disclosures, including that the information is not consistent with risk information in the FDA-approved labelling and the FDA has not reviewed the data.

Refer to the FDA's Risk Information Reprints Guidance for details.

FDA Unsolicited Requests Guidance – Reactive Distribution of Off-Label Information

Under the FDA's 2011 draft guidance, "Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices", the FDA permits companies to respond to unsolicited requests for information on unapproved, off-label uses of approved prescription drug products. The guidance outlines the FDA's position and recommendations on:

- distinguishing solicited versus unsolicited requests;
- distinguishing public versus non-public requests; and
- responding to unsolicited requests.

Independent Scientific Education

The FDA's 1997 guidance, "Industry-Supported Scientific and Educational Activities", makes clear that the FDA will not regulate industry-supported scientific activities that are independent of the influence and control of the supporting company. The guidance outlines a number of factors that the FDA will consider in evaluating the independence of industry-sponsored scientific activities, including those that may discuss unapproved drugs or off-label uses of approved drugs.

3.4 Provision of Information to Healthcare Institutions

The FDA's 2018 guidance, "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Other Similar Entities – Questions and Answers", established a safe harbour that expressly permits manufacturers to disseminate certain information about investigational drugs and unapproved uses of approved drugs to payor audiences prior to approval.

Communications disseminated in compliance with the guidance will not be considered violations of the prohibition on promotion of an investigational drug. The types of information about investigational drugs and unapproved uses of approved drugs that may be disseminated pre-approval to payors include: proposed indication, anticipated timeline for FDA approval, pricing, patient support programmes, patient utilisation projections, and results of clinical studies. All information provided must be "unbiased, factual, accurate and non-misleading" and must be accompanied by a clear statement of the drug's investigational status and stage of development.

3.5 Publication of Compassionate Use Programmes

Compassionate use or "expanded access" programmes establish a pathway for a patient with an imminently life-threatening condition or serious disease or condition to access an investigational drug when the treatment is unavailable in clinical trials and there are no other similar or sufficient therapy alternatives.

Under the 21st Century Cures Act, companies developing investigational drugs are required to publicly publish an expanded access policy on the company website and/or the Reagan-Udall Foundation's Expanded Access Navigator website for the investigational drug.

The published policy must include:

- contact information for the manufacturer or distributor;
- the procedure for submitting requests;
- the general criteria that the manufacturer or distributor uses to evaluate the requests;
- the length of time anticipated to respond to the request; and
- a hyperlink or other reference to the clinical trial record containing all the required information that must be submitted to ClinicalTri-

als.gov about expanded access availability for the drug.

4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Advertising to the general public, also commonly referred to as direct-to-consumer (DTC) advertising, is permitted in the United States. Companies may promote prescription drugs to the general public provided that the communication meets the following fundamental requirements.

- On-label or consistent with label: Advertising and promotion of prescription drugs must be consistent with the intended use for which the product is approved by the FDA, as established in the drug's FDA-approved labelling (ie, the PI). The labelling provides information on how to use the product safely and effectively for the approved indication, including but not limited to the patient population, dosage and administration. Advertising and promotion that discuss uses of the product that are not contained in or consistent with the FDA-approved labelling are regarded as unlawful "off-label" promotion. Refer to the FDA's 2018 guidance, "Medical Product Communications That Are Consistent With the FDA-Required Labeling – Questions and Answers" (CFL Guidance), for details; see **5.2 Reference to Data Not Included in the Summary of Product Characteristics**.
- Fair balance: The FDA regulations require prescription drug promotion and advertising to present a "fair balance" between product benefits and risks, ensuring that such information appears comparable in depth, detail and context. Promotional materials are misleading if they fail to present information about risks associated with a drug with a prominence and readability reasonably comparable with the presentation of information related to the effectiveness of the drug. Refer to the FDA's 2009 draft guidance, "Presenting Risk Information in Prescription Drug and Medical Device Promotion", for details.
- Adequately substantiated: Traditionally, all advertising and promotional claims about the safety or efficacy of a prescription drug have been required to be supported by substantial evidence or substantial clinical experience, which is the FDA's approval standard for prescription drug products. Under the CFL Guidance, claims should be supported by at least scientifically appropriate and statistically sound evidence.
- Otherwise truthful and not misleading: If prescription drug advertising and promotion is false or misleading in any particular, it will be considered misbranded under the FDCA and subject to enforcement.

Although not a requirement, the FDA strongly recommends the use of consumer-friendly language, and avoidance of technical language, scientific terms and medical jargon, in consumer-directed advertising and promotion.

The promotion of OTC drugs must also adhere to the product's approved labelling or monograph, as applicable. In addition, such promotion must be truthful and not misleading, including that all advertising claims are substantiated by competent and reliable scientific evidence. The FTC maintains regulations and guidelines governing consumer advertising to ensure that communications are not deceptive or misleading.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Consumer-directed prescription drug advertising and promotion must contain the following

core elements, as required by the FDCA and FDA regulations.

Core Elements

Proprietary and established names

The placement, size, prominence and frequency of the proprietary (brand or trade) and established (generic) names for prescription drugs are specified in FDA regulations, with additional recommendations in the FDA's 2017 guidance, "Product Name[,] Placement, Size, and Prominence in Promotional Labeling and Advertisements".

Quantitative composition

Advertising and promotion must include the quantitative amount of each ingredient of the advertised drug. Companies commonly include this information as part of the product logo.

Brief summary

Printed DTC advertisements must include information in "brief summary" that discloses each side effect, warning, precaution and contraindication. To fulfil this requirement, DTC print advertisements traditionally included the complete risk-related sections from the product's PI. To fulfil the adequate directions for use requirement, a copy of the PI has traditionally been provided. Contrary to these traditional approaches, the FDA's 2015 revised draft guidance, "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs", recommends that DTC printed promotional labelling and advertising utilise a "consumer brief summary" focused on the most important risk information, rather than an exhaustive list of product-related risks, presented in a way most likely to be understood by consumers. In addition, a copy of the PI is no longer recommended.

Major statement

Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in a clear, conspicuous and neutral manner in either audio or audio and visual. This is referred to as the "major statement". In addition, the advertisement must present a brief summary or, alternatively, make "adequate provision" for consumers to obtain the PI. The FDA's 1999 guidance documents, "Consumer-Directed Broadcast Advertisements" and "Consumer-Directed Broadcast Advertisements – Questions and Answers", provide recommendations for satisfying the adequate provision requirement through a toll-free telephone number, concurrent print ad in a widely distributed publication, on a website, and/or in consultation with an HCP.

Adverse event reporting disclosure statement

DTC print advertisements must include the following MedWatch statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088".

Reminder Labelling and Advertising

Under FDA regulations, reminder labelling and advertising is exempt from the general requirements above if it is limited to the proprietary and established names of the drug, and does not include any indications, disease state information, dosage, or other product representations. Additional optional information includes quantitative ingredient statements, dosage form, quantity of package contents, price, the name and address of the manufacturer, and price information.

Importantly, reminder labelling and advertising is not permitted for a prescription drug with a boxed warning in its FDA-approved labelling.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Interactions between pharmaceutical companies and patients and/or patient organisations are permitted in the United States, subject to the variety of limitations discussed in this chapter. For product-related advertising and promotion, communications must be on-label/CFL, fair and balanced, adequately substantiated and not otherwise false or misleading; see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public** and **4.2 Information Contained in Pharmaceutical Advertising to the General Public**. In addition, interactions must not implicate the Anti-Kickback Statute by inducing patient organisations or patients to recommend or use the advertised product; see **8. Pharmaceutical Advertising: Inducement/ Anti-bribery** and **9. Gifts, Hospitality, Congresses and Related Payments**.

Companies may also communicate with patients and patient organisations, such as patient advocacy groups, in a non-promotional manner to respond to unsolicited requests for information (see **3.3 Provision of Information to Healthcare Professionals**) or to provide information about clinical studies for recruitment purposes.

In addition, companies interacting with patients must abide by applicable federal and state privacy laws and avoid providing advice for the diagnosis, treatment, care or prognosis of an individual, which would be regarded as unlawfully engaging in the practice of medicine.

5. ADVERTISING TO HEALTHCARE PROFESSIONALS

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Rules for the advertising and promotion of prescription drugs to HCPs are generally the same as those that apply to advertising and promotion to consumers, including the fundamental requirements (see **4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public**):

- on-label or consistent with label;
- fair balance;
- adequately substantiated; and
- otherwise truthful and not misleading.

Prescription drug promotion and advertising to HCPs must also provide adequate directions for use, a requirement that is met by providing a copy of the FDA-approved labelling (ie, the PI).

Advertising and promotion targeting HCPs must also contain some of the same core elements as DTC advertising and promotion, including proprietary and established names and quantitative composition; see **4.2 Information Contained in Pharmaceutical Advertising to the General Public**. Unlike DTC advertising, a "brief summary" for HCP-directed print advertisements should follow the FDA's traditional approach, which includes reprinting the complete risk-related sections of the PI with the ad, but there is no requirement to include the MedWatch statement.

Promotion and Advertising to Payors

Under the FDCA, a company may provide healthcare economic information (HCEI) related to a product's indication to payor audiences, provided that it is supported by competent and

reliable scientific evidence. The pathway to promote HCEI to payors grants some flexibility from the standard approach, but is still subject to other rules of prescription drug promotion. Refer to the FDA's 2018 guidance, "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and other Similar Entities – Questions and Answers", for details.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

As previously mentioned, promotional communications for prescription drugs must include only information about the drug that is either within the drug's FDA-approved label (on-label) or consistent with the label (CFL). The CFL Guidance explains a three-factor test to determine whether product-related information is CFL. If a product communication fails any of the three factors below, it is not considered CFL and risks being off-label.

- How does the information in the communication compare to the information in the FDA-approved label – does it suggest a different indication, patient population, limitations and directions for use/handling, and/or dosing or usage regimen?
- Does the information suggest use of the drug in a manner that could increase the potential for harm to health relative to the information reflected in the drug's FDA-approved label?
- Do the directions for use in the FDA-approved label enable the product to be safely and effectively used under the conditions suggested in the communication?

In order to be distributed as CFL, the information must be substantiated by "scientifically appropriate and statistically sound" (SASS) evidence; be factually accurate; be presented with appropriate context, including disclosure of any limitations of the data, analyses and conclusions; and be otherwise truthful and not misleading. Examples of information that may be considered CFL include comparisons, adverse reactions, onset of action, long-term safety or efficacy, patient subgroups, patient compliance or adherence, and patient perceptions, convenience and mechanism of action.

5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

As noted, all promotional communications should be on-label or CFL. If the FDA-approved labelling of a combination product does not include details of each of the individual products in the combination, the company should evaluate the information under the CFL Guidance and consider potential off-label risks; see **5.2 Reference to Data Not Included in the Summary of Product Characteristics**.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

If a reprint is on-label or CFL, it may be used in a promotional manner, subject to the basic requirements for advertising and promotion directed at HCPs. If a reprint discusses an unapproved use of the product (ie, off-label), then it might be distributed under FDA's established safe harbour for off-label reprints; see **3.3 Provision of Information to Healthcare Professionals**.

5.5 Medical Science Liaisons

The primary responsibility of a Medical Science Liaison (MSL) is scientific engagement and education with HCPs, focusing on specific therapeutic areas, disease states and/or products in support of their company's product pipeline and portfolio. However, MSLs are often also used to help support scientific initiatives, such as identifying and recruiting potential sites and investigators for company-sponsored studies, scientific and medical advisory boards, and internal training and education, among others.

In general, an MSL may engage HCPs proactively or reactively consistent with the FDA's policy on off-label communications, but their interactions should not be promotional; see **3.3 Provision of Information to Healthcare Professionals** and **3.4 Provision of Information to Healthcare Institutions**. Specifically, MSLs may proactively discuss with HCPs therapeutic areas and disease states generally, as well as approved uses of approved products. Proactive discussions of investigational drugs or unapproved uses of approved drugs are generally not regarded as permissible activities for MSLs, as these proactive communications could be perceived as pre-approval or off-label promotion.

A significant role of MSLs is reactive interactions with HCPs, in which an MSL responds to unsolicited requests for scientific or medical information; see **3.3 Provision of Information to Healthcare Professionals**.

Importantly, the role and responsibilities of an MSL are neither commercial, nor promotional. The separation between medical and commercial functions is critical to preserving the legitimacy of MSL scientific exchange activities.

6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

6.1 Requirements for Prior Notification/ Authorisation

In general, there is no requirement for prior notification or authorisation for prescription drug advertising and promotion; however, there are limited exceptions:

- companies whose advertisements have violated FDA or FTC standards in the past may be asked to pre-clear their advertisements in the future;
- prescription drugs approved under the accelerated approval process are subject to a "presubmission" requirement (ie, promotional materials must be submitted to the FDA prior to the intended date of dissemination or publication); and
- DTC television advertisments must be submitted for pre-dissemination review (in a 2012 draft guidance, "Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program", the FDA outlines the pre-dissemination review process and the category of television advertisements for which pre-dissemination review is required).

Importantly, companies always have the option to voluntarily submit proposed promotional labelling or advertising to the FDA for advisory review.

2253 Submission

The FDA's post-marketing reporting regulations require pharmaceutical companies to submit prescription drug promotional labelling and advertising materials to OPDP at the time of first use. This submission must be made using a completed Form FDA 2253 and must include a copy of the promotional material and the product's current PI.

6.2 Compliance with Rules on Medicinal Advertising

FDA regulations governing current Good Manufacturing Practices (CGMPs) require strict controls over labelling issued for use in drug product labelling operations. Although this regulation is typically applied to FDA-approved labelling (ie, PI), it should also be used for the development of promotional labelling.

It is best practice to adopt internal policies and standard operating procedures for managing the review, approval and use of promotional labelling and advertising. Typically, this is a cross-functional activity that includes representatives from legal, regulatory, medical and compliance departments within the company.

7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

7.1 Regulation of Advertising of Medicinal Products on the Internet

In general, the FDA's standard advertising and promotion rules apply to advertising and promotion on the internet. The FDA expects prescription drug websites to include risk information on the same screen as efficacy information; to provide a prominent link to the PI; to distinguish sites intended for US audiences and international audiences; to ensure that all claims, images and graphics are CFL; and to avoid links to off-label information.

Separately, the FTC has published several guides governing disclosures on the internet and social media, including ".com Disclosures: How to Make Effective Disclosures in Digital Advertising" (2013) and "Disclosures 101 for Social Media Influencers" (2019).

7.2 Advertising of Medicines on Social Media

The FDA permits advertising and promotion of prescription drugs on social media. Generally, the FDA's standard advertising and promotion rules apply, regardless of the social media platform being used.

The FDA has also issued guidance documents relevant to the use of social media for prescription pharmaceutical promotion.

- "Fulfilling Regulatory Requirements for Post-marketing Submissions of Interactive Promotional Media" (2014) describes when firms will be held responsible for social media content, including user-generated content (UGC), and how to submit interactive social media content via Form FDA 2253.
- "Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices" (2014) asserts that the FDA's long-standing rules regarding disclosure of risk information apply even in the context of character-limited communications (eg, Twitter, sponsored links). If there are insufficient characters to adequately communicate risk information for a particular drug, then character-limited communications may not be a "viable promotional tool" for that drug.
- "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices" (2014) describes how companies can address incorrect information posted about their products on social media or the internet by third parties unaffiliated with the company.

In addition, a number of FDA enforcement letters have cited companies for failing to adequately disclose risk information on social media, including Facebook, Instagram and YouTube. Notably, a 2014 warning letter to Zarbee's illustrates the potential for companies to be held responsible for independent UGC (eg, social media comments) if they endorse those statements by "liking", "sharing", or positively commenting on them.

7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

There is no requirement to include access restrictions on pharmaceutical promotional websites intended for HCPs. However, it is common

industry practice to include an interstitial page (eg, pop-up webpage) for viewers to confirm they are an HCP before accessing the page.

7.4 Provision of Disease Awareness Information to Patients Online

It is common practice in the USA for pharmaceutical companies to develop disease awareness websites, social media pages, or online advertising directed to consumers. In general, the same rules that apply to traditional forms of disease awareness communications apply to online disease awareness content; see **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information**.

7.5 Online Scientific Meetings

The same rules apply to promotion and advertising in online scientific meetings or congresses as in in-person settings. For virtual events, promotional materials should be reviewed according to traditional FDA advertising and promotion rules, but with the digital format in mind. In addition, given that geographic limitations are inherently more fluid in a virtual setting, companies should consider clear disclosures in materials and presentations regarding the intended audience, particularly if the product approval status or indication differs outside of the United States.

As with traditional in-person conferences, the AKS (see **8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals**) and PhRMA Code apply to the provision of items of value (eg, items for attendees) or other hospitality associated with a virtual scientific meeting or congress; see **9. Gifts, Hospitality, Congresses and Related Payments**.

8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

Anti-Kickback Statute

The Anti-Kickback Statute (AKS) (42 USC 1320a-7b) prohibits individuals and entities from knowingly and wilfully soliciting, receiving, offering or paying any remuneration (directly or indirectly, overtly or covertly, in cash or in kind), in order to induce the provision of a good or service that is reimbursable under a federal healthcare programme, including Medicare and Medicaid. The scope of the AKS is broad and applies to any individual or entity (including manufacturers, healthcare providers and organisations, and lay persons) that provides, offers, solicits or receives remuneration with improper intent. The courts have broadly interpreted the AKS to cover any arrangement where even one purpose of remuneration, though not its sole or primary purpose, is to provide value for the referral, purchase, use or recommendation of goods or services reimbursed by Medicare or Medicaid.

"Remuneration" includes anything of value and there is no de minimis exception. Remuneration includes gifts, payments and other things typically thought of as benefits, but also broadly includes price reductions (such as discounts or rebates) and free or below-cost products and services.

Safe Harbour Regulations

The OIG has promulgated final "safe harbour" regulations specifying certain types of arrangements/remuneration that will not be considered to contravene the AKS. The safe harbours include, among others, protection for certain

discounts/rebates, warranties, employment and services arrangements. If an arrangement satisfies all the criteria of a safe harbour, it will be immune from criminal prosecution and civil exclusion under the AKS. Failure to satisfy any safe harbour does not necessarily mean that the arrangement violates the AKS; however, arrangements falling outside a safe harbour present a legal risk and may be more likely to be scrutinised as violations of the kickback prohibition. There are both criminal and civil penalties for violating the AKS.

State Statutes

Various states have also enacted similar anti-kickback statutes that apply to inducements related to healthcare items and services (including drugs) reimbursed by private insurance, not just those reimbursed by a federal or state healthcare programme. Requirements under state law must be reviewed on a state-by-state basis.

Civil Monetary Penalties

Similar to the AKS, the Civil Monetary Penalties (CMP) provisions of the Social Security Act (42 USC 1320a-7a) prohibit the offering or provision of inducements to federal healthcare programme beneficiaries and impose monetary penalties on entities that offer or transfer remuneration to such a beneficiary, when they know or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of items or services paid for by certain government programmes.

Distinctions between the AKS and CMP

A few distinctions between the AKS and the CMP are notable. Firstly, the CMP law prohibits inducements only to Medicare and state healthcare programme beneficiaries (Medicaid), not all federal healthcare programme beneficiaries. Secondly, the CMP law may have indirect application (ie, the law is triggered if the person providing the remuneration knows or should know that it is likely to induce the beneficiary to order the item or service from a particular provider, practitioner or supplier). Thus, a pharmaceutical manufacturer, which is not a provider, practitioner, or supplier, could implicate the statute if it offered or gave remuneration to a beneficiary that it believed would be likely to induce the beneficiary to order an item or service from a particular provider, practitioner or supplier (eg, to choose a particular physician or pharmacy).

8.2 Legislative or Self-Regulatory Provisions

Because the penalties for violating the AKS and related civil statutes can be severe (including potentially leading to incarceration and/or exclusion from participation in federal healthcare programmes), there is a strong benefit to self-regulation.

Firstly, the OIG issued compliance guidance for pharmaceutical manufacturers – in part, to provide notice about activities that are likely to violate the AKS or CMP law. Companies self-regulate by developing internal policies and procedures that establish compliant practices and require auditing and monitoring of activities to ensure compliance. Secondly, the PhRMA Code sets forth voluntary guidelines for companies to stake out industry positions on common activities that should not be deemed to violate the AKS or CMP law. Finally, companies can adopt self-reporting protocols, consistent with guidelines from the OIG and the US Department of Justice, to self-report internally identified wrongdoing. Addressing potential fraud and corruption via internal policy and procedure, or by self-reporting to US authorities, can significantly help to mitigate potential allegations and/or penalties in the event of wrongdoing.

9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

9.1 Gifts to Healthcare Professionals

Under the PhRMA Code

The PhRMA Code expressly prohibits gifts that are intended for the personal benefit of HCPs, including practice-related items of de minimis value (eg, pens, pads, mugs, etc). Under the PhRMA Code, only items that "advance disease or treatment education" for patients may be furnished without charge to HCPs.

However, the PhRMA Code allows manufacturers to pay for or reimburse meals or travel expenses for HCPs in limited situations. Modest meals are generally permissible under the PhRMA Code only when they are provided in conjunction with an "informational presentation or discussion conducted by company representatives or their immediate managers working in field sales" in the HCP's office; in conjunction with an HCP's travel or meetings for consulting, training or speaking services on behalf of the manufacturer pursuant to a written agreement; or in conjunction with an HCP's attendance at a speaking or training event of the manufacturer. In these situations, meals should be modest, occasional, without attendance of spouses or guests, in a location that is conducive to educational or business content, subordinate in time and focus to the presentation, service or training at issue, and eaten on the premises (ie, no takeaway or two-hour meals for a 30-minute presentation). The PhRMA Code also prohibits companies from providing or paying for alcohol at meetings or presentations with HCPs.

Similarly, covering or paying for "reasonable" travel expenses is generally permissible under the PhRMA Code when made for an HCP's travel for meetings or services involving consulting, training or speaking services on behalf of the manufacturer pursuant to a written agreement. Travel expenses should not be covered for personal expenses or for individuals travelling with the HCP.

Under the AKS and Similar State Laws

Under the AKS and similar state laws, there are no express protections for remuneration in the form of gifts, free samples, grants or donations to support scientific meetings, research, or cultural, sporting, or other non-scientific events, or free or below-cost products or services, even when the value may be de minimis. Because many of these are common forms of business within the pharmaceutical industry, the PhRMA Code provides some level of protection for certain common arrangements in addition to specific regulatory safe harbour protections. Although it has been generally accepted by federal enforcement agencies, the PhRMA Code is not law or regulation. Thus, activities expressly condoned by the PhRMA Code, while not immune from prosecution, are less likely to be pursued by federal authorities, while activities prohibited by the PhRMA Code pose significant risks under the AKS.

9.2 Limitations on Providing Samples to Healthcare Professionals

The Prescription Drug Marketing Act (PDMA) permits a manufacturer to provide samples directly to a licensed healthcare practitioner or institution that requests the samples, signs for or formally acknowledges receipt of the samples, agrees to legally prescribe and dispense the samples, and does not resell the samples or bill patients or health insurance for them. The purpose of facilitating samples should generally be to ensure that patients and HCPs can reasonably evaluate whether a particular drug is appropriate for a particular patient. Samples should not be used as gifts or improper inducements for HCPs to prescribe a particular product, as such uses could violate the AKS.

9.3 Sponsorship of Scientific Meetings

Pursuant to the PhRMA Code, a manufacturer may provide financial support to third parties hosting scientific or educational conferences or meetings, including those for continuing medical education (CME). The PhRMA Code specifically provides that "a company should develop objective criteria for making CME grant [or support] decisions to ensure that the program funded by the company is a bona fide educational program and that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment", such as by covering the cost of attendance for specific HCPs.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The PhRMA Code expressly prohibits the support of HCP participation in cultural, sports or other non-scientific events.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Grants or donations to HCPs or institutions, whether monetary or in-kind, generally fall within the broad definition of "remuneration" under the AKS. While it is not the policy of federal or state agencies to prosecute bona fide charitable donations and altruistic grants, these arrangements can raise serious issues under the AKS if any purpose of the funding is related to generating business from the recipient or individuals involved with the recipient. Because there are no protections for grants or donations under the statutory exceptions or regulatory safe harbours of the AKS, manufacturers should be mindful of the following:

- a grant or donation should be made only to charitable or non-profit organisations that would use the funding in accordance with their charitable/non-profit mission; and
- no purpose of the grant or donation should be to influence clinical or purchasing decision-making or to otherwise generate business for the manufacturer (some manufacturers demonstrate this by funding grants and donations from non-sales and marketing budgets; establishing and using a grants committee comprised of only non-commercial personnel; carefully documenting each grant and donation, including its intended purpose; and ensuring that there is no "return on investment" analysis with respect to grants or donations; among others).

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Discounts and rebates to HCPs and institutions are protected from violating the AKS if they meet all the requirements of a statutory exception (42 USC 1320a-7b(b)(3)(A)) or regulatory safe harbour (42 CFR 1001.952(h)). In general, to be protected, a discount or rebate must:

- be a reduction in the amount a purchaser is charged for an item or service based on an arm's length transaction;
- be disclosed to the purchaser in advance of any purchase being made and not paid prior to the purchase being made (ie, no upfront rebates or "pre-bates");
- not be paid in cash or cash equivalents (except for rebates paid by cheque);
- not be for the purpose of inducing the purchase of a different good or service, unless both items/services are reimbursed by the same federal healthcare programme using the same payment methodology, and the discount is fully disclosed to federal programmes;
- not be in exchange or payment for services;
- not result in the sale being made at a (net) price that is below the manufacturer's cost for

manufacturing, marketing and distributing the product(s); and
- be structured to provide the price reduction to the buyer within a year of the purchase of the product to which it relates.

In addition, the manufacturer must clearly inform the buyer of its obligations under the safe harbour to report the discount to federal agencies, as required, and must refrain from doing anything to impede the buyer from meeting its reporting obligations.

9.7 Payment for Services Provided by Healthcare Professionals

In order to receive AKS protection under the personal services and management contracts safe harbour (42 CFR 1001.952(d)), compensation for a services arrangement must meet all of the specific regulatory requirements, including:

- having a written agreement that expressly defines the services to be provided for a term of at least one year;
- that the contracted services are commercially reasonable in the absence of other business or referrals generated between the parties;
- the methodology for determining the compensation to be paid over the term of the agreement is set in advance, consistent with fair market value and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties; and
- the services must not involve any other violation of law.

The PhRMA Code provides additional guidance to help protect arrangements that cannot meet safe harbour protections, including factors that support the "existence of a bona fide consulting arrangement".

9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

The provision of products or services without charge by a manufacturer to an HCP may result in in-kind "remuneration" that implicates the broad scope of the AKS. In analysing whether or not services may constitute remuneration, a manufacturer should consider whether the services intended purely for the reasonable and expected support of the manufacturer's product for a patient, might instead be intended to take the place of internal services or efforts that the HCP would ordinarily be expected to provide at their own cost and expense. The former types of arrangements arguably would not result in remuneration under the AKS, while the latter may implicate the broad scope of the statute.

10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The federal Physician Payments Sunshine Act ("Sunshine Act") and its implementing regulations require certain pharmaceutical and biologic manufacturers to annually report to the Centers for Medicare and Medicaid Services (CMS) certain information about payments or transfers of value provided directly or indirectly to covered recipients during the previous calendar year. "Covered recipients" under the Sunshine Act and its implementing regulations include US physicians and teaching hospitals, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anaesthetists, and certified nurse midwives.

In addition to the federal reporting requirements, several states, including Connecticut, the District of Columbia, Massachusetts, Minnesota and Vermont, also require manufacturers to track and annually report certain information about payments or transfers of value provided to HCPs and healthcare organisations in the respective state. The specific transparency requirements vary from state to state. There are also several jurisdictions that require pharmaceutical representatives to be licensed/listed with local agencies, including Chicago, the District of Columbia, Nevada and Oregon. Many of these local requirements include transparency obligations for licensed/listed representatives, who are required to track and annually report certain information about their communications and interactions with HCPs.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The federal Sunshine Act requirements apply to foreign companies if the entity "operates in the United States" and meets the definition of an "applicable manufacturer". Determination of how transparency laws apply to entities based outside the United States should be conducted on a case-by-case basis considering the entity and any subsidiaries. Some state laws mirror the federal Sunshine Act requirements while other state laws are less clear but generally apply to manufacturers providing transfers of value to HCPs licensed by the state.

As a general matter, the federal Sunshine Act and state transparency laws do not apply to companies that do not yet have marketed products.

11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

11.1 Pharmaceutical Advertising: Enforcement Bodies

See **1.1 Laws and Self-Regulatory Codes Regulating Advertising of Medicines** for information on regulatory and enforcement bodies for pharmaceutical advertising and promotion.

Both the Department of Justice (DOJ) and the OIG have authority to enforce the Anti-Kickback Statute, the Civil Money Penalties Law, and the False Claims Act. The DOJ has jurisdiction over both criminal and civil enforcement actions, while the OIG has authority with respect to civil actions. State attorneys general may take enforcement actions under similar state laws.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

In most instances, FDA enforcement against unlawful promotion and advertising begins with an enforcement letter issued by the OPDP of the FDA. Repeat or egregious violations may prompt the FDA and FTC to initiate enforcement proceedings in federal court to enjoin the behaviour and seek penalties.

Competitors and consumers may also challenge unlawful promotion and advertising. The FDCA and FTCA do not provide a right of action to competitors or consumers; however, the submission of trade complaints to the FDA and/or FTC may prompt the agencies to act. HCPs, consumers and competitors can also notify the FDA of unlawful pharmaceutical marketing through the FDA's "Bad Ad Program" hotline. In addition, competitors and/or consumers may seek to challenge advertising directly through state and/or other federal laws.

Companies may also challenge competitors' "false and misleading" advertising in court under the Lanham Act and before the self-regulatory body of the NAD of the Better Business Bureau (BBB), which is a voluntary process and not enforceable under law.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

FDA and FTC Enforcement

Penalties for unlawful pharmaceutical marketing and advertising vary depending on the statute used to challenge the activity. If the FDA or FTC pursue enforcement in federal courts, injunctions are common penalties; the FDA may also seize products. In more extreme cases, the FDA may co-ordinate with the DOJ to bring criminal charges. Misdemeanour convictions of "misbranding" a drug can result in a fine of USD1,000 and a year in prison. A felony conviction could result in a USD10,000 fine and three years in prison.

In a typical challenge under the Lanham Act, the court may award injunctive and/or monetary remedies, based on lost profits or loss of goodwill due to false advertising, or to reimburse the costs of corrective advertising. In extraordinary cases and in some jurisdictions, courts may also consider granting a preliminary injunction, disgorgement of profits, treble damages, and/or an award of attorney's fees.

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Under the AKS, criminal sanctions include a fine not to exceed USD250,000 or imprisonment for up to five years, or both, for each offence. In addition, monetary penalties for each offence may be increased to USD500,000 for organisations. Civil penalties include fines of up to USD50,000 for each violation, and monetary damages of up to three times the amount paid for referrals and/or exclusion from the Medicare programme. Furthermore, any claims submitted to Medicare or Medicaid as a result of an illegal kickback now automatically constitute false or fraudulent claims under the federal False Claims Act.

False Claims Act

Penalties for violating the False Claims Act can be civil and/or criminal, with statutory civil penalties between USD5,000 and USD10,000 (which can be increased to up to USD23,607) per false claim and triple the amount of the damage to the government. The criminal False Claims Act can be enforced with imprisonment and/or criminal fines.

11.4 Relationship between Regulatory Authorities and Courts

Regulatory authorities such as the FDA and FTC may pursue enforcement against unlawful advertising and promotion in federal court, while state enforcement occurs in a state court. Self-regulation through the NAD is a voluntary process. Although NAD decisions are not binding in court; some cases may be referred to the FTC for potential enforcement.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Based on OPDP enforcement letters issued over the past few years, the FDA is focusing on a range of digital and broadcast advertising and promotional activities, including DTC television advertisements, consumer videos, websites, emails, sponsored links, and social media. Consistent with past enforcement letters, the most cited violation continues to be false or misleading presentation of risk information; however, there is also a strong focus on false or misleading efficacy claims. Products with boxed warnings in their labelling are a frequent target of OPDP letters.

For both the FDA and FTC, marketing by physicians, celebrity spokespeople and influencers is

a key focus area for both prescription and OTC drugs. Recent enforcement related to influencer and spokesperson marketing has cited omission or minimisation of risk information, overstatement of efficacy, and lack of adequate disclosure of the relationship between the influencer and the sponsoring company. Finally, due to the COVID-19 pandemic, both agencies have regularly issued enforcement letters against products marketed with fraudulent claims for the treatment or prevention of COVID-19.

King & Spalding LLP has more than 1,200 lawyers in its 22 global offices and helps companies advance business interests in more than 160 countries. The firm's FDA and life sciences practice plays a critical role within this context. With over 40 lawyers and professionals in the US and Europe, the group counsels more than 250 large, mid-cap and start-up drug, biotech and medical device companies, food manufacturers, distributors, healthcare providers and technology ventures. The EU team focuses on EU and national (French, Belgian and German) issues associated with the legal requirements for pharmaceuticals/biologics, medical devices, cosmetics and foods. The firm's clients receive tremendous synergy from the interaction of the FDA/regulatory and healthcare teams with the product liability, government investigations, discovery, appellate, intellectual property, corporate and litigation teams. More than 400 lawyers and professionals in 17 areas devote all or a substantial portion of their practices to the life sciences industry.

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