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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2009

A practical insight to cross-border Pharmaceutical Advertising work

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USA

Harvey L. Kaplan

Jon A. Strongman

Shook, Hardy & Bacon L.L.P.

1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in the USA?

Prescription Drugs

Prescription drug advertising is governed by the Federal Food, Drug, and Cosmetic Act (FDCA) and corresponding US Food and Drug Administration (FDA) regulations.

The FDCA sets out broad requirements for prescription drug advertisements and authorises the FDA to promulgate related regulations. *See* 21 U.S.C. §352(n). The FDA regulations expand on these general requirements, adding details to the framework set forth in the FDCA. *See* 21 C.F.R. §202.1.

Non-Prescription Drugs

While the FDA regulates the labelling of non-prescription drugs, it does not regulate the advertising; that responsibility rests with the Federal Trade Commission (FTC). Under 15 U.S.C. §§52-57, the dissemination of false advertisements likely to induce the purchase of food, drugs, devices, services, or cosmetics is unlawful and subject to enforcement by the FTC.

1.2 How is "advertising" defined?

Advertising includes any descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to the drug. *See* 21 U.S.C. § 352(n). Advertising, however, does not include "labelling" as defined in §321(m). *Id.*

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and Codes of Practice on advertising, such as "sign off" of promotional copy requirements?

See questions 1.1 and 1.4.

1.4 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Generally, prescription drug advertisements do not need prior approval by the FDA. *See* 21 U.S.C. §352(n). However, in the case of accelerated approval products, all promotional materials (including advertisements) intended for dissemination within 120 days of approval must be submitted to the FDA during the pre-approval period. *See* 21 C.F.R. §314.550. Additionally, in special circumstances, advertisement pre-approval may be required as part of an enforcement action.

While pre-approval is not usually required, all advertisements must be submitted to the FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) at the time the advertisement is initially published. *See* 21 C.F.R. §314.81(b)(3)(i). DDMAC will also offer comments on any advertisements submitted prior to publication. *See* 21 C.F.R. §202.1(j)(4).

1.5 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

See question 1.4 above.

1.6 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

A prescription drug is considered "misbranded" if an advertisement fails to satisfy the requirements of the FDCA and FDA regulations. *See* 21 U.S.C. §352(n). The FDCA prohibits the introduction of a misbranded drug into interstate commerce or the misbranding of a drug already in interstate commerce. *See id.* at §331(a),(b). Potential penalties for misbranding violations include injunction proceedings, civil penalties, seizure proceedings, and even criminal prosecution. *See id.* at §§332-334. The US government is responsible for the enforcement of the FDCA and FDA regulations. *See* 21 U.S.C. 337(a).

Prescription drug advertising is constantly policed by DDMAC. Before pursuing the remedies listed above, DDMAC will often issue a warning letter to the manufacturer outlining any violations and requesting that certain actions be taken, including, in some circumstances, discontinuation of an advertisement.

While the FDCA does not provide for competitors to take action in court, the Lanham Act permits false advertising claims. *See* 15 U.S.C. §1051, et seq. A competitor has standing under the Lanham Act to challenge false or misleading advertising if such competitor believes that it is likely to be damaged. *See id.* at §1125(a)(1)(B).

1.7 What is the relationship between any self regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self- regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

While the FDA regulates the advertising of pharmaceutical products, professional organisations, such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the American Medical Association (AMA), provide additional guidance for the healthcare community and pharmaceutical manufacturers. *See* question 4.2. While there is some overlap between complaints raised with the regulatory agencies and professional organisations, each agency and organisation has its own mechanism to report such issues. For example, the FDA welcomes complaints regarding DTC advertisements and materials through DDMAC. Also, the AMA works with the various state medical boards to report complaints regarding violations of the AMA's Code of Ethics. One instance where a professional organisation reports complaints to the FDA is the PhRMA Office of Accountability. The PhRMA Office of Accountability is responsible for receiving comments from the general public and health care professionals regarding DTC advertisements. The PhRMA Office of Accountability issues periodic reports to the public regarding the nature of the comments and provides a copy of each report to the FDA.

1.8 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

As stated in question 1.6, the Lanham Act provides standing to a competitor to bring a false advertising claim if such a competitor believes that it is likely to be damaged. 15 U.S.C. §1125(a)(1)(B).

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product?

New drugs cannot be marketed to physicians or other health care providers until they are approved by the FDA. Sharing scientific information, however, is not precluded. Specifically, FDA regulations provide that: "*A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialisation of the drug before it is approved for commercial distribution.*" 21 C.F.R. §312.7(a).

Additionally, manufacturers may provide health professionals with information on unapproved uses for already approved drugs so long as the information is in the form of a scientifically sound article or reference publication and it does not pose a significant risk to public health. *See* 21 C.F.R. §99.101(a).

Promoting prescription drugs for unapproved uses ("off-label promotion") can, however, have serious criminal and civil implications. For example, in *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass 2001), a whistle-blower brought a *qui tam* action alleging that the manufacturer's off-label promotion of Neurontin violated the False Claims Act and the Federal Anti-Kickback Act. Ultimately, the manufacturer paid $430 million to resolve all state and federal allegations of deceptive marketing related to the sale of Neurontin. This sum included $240 million to the U.S. Attorney's Office in Boston and $152 million to the states and federal government for Medicaid violations. In 2001, TAP Pharmaceuticals likewise paid $875 million to resolve charges of improper sales practices with respect to Lupron, a prostate cancer drug. Finally, in October of 2005, Serono agreed to pay $704 million in connection with allegations regarding the promotion of Serostim, a drug intended to treat weight loss associated with AIDs, also known as AIDs wasting.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Information on medicines that have not been approved by the FDA may be published so long as the publication is for the purpose of disseminating scientific information or findings. *See* 21 C.F.R. §312.7. Information on unapproved medicines may not be published for promotional or marketing purposes.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

See questions 2.1 and 2.2 above.

2.4 May such information be sent to health professionals by the company? If so, must the health professional request the information?

Manufacturers may send information to health professionals about medicines that have not been approved by the FDA if the information is distributed for scientific and not promotional purposes. *See* questions 2.1 and 2.2 above.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

Sending information on an unapproved drug to institutions for budget purposes could be construed as commercialising the drug, which is not allowed under FDA regulations. *See* question 2.1 above.

2.6 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Sending information on an unapproved drug to institutions for market research purposes could be construed as commercialising the drug, which is not allowed under FDA regulations. *See* question 2.1 above.

3 Advertisements to Health Professionals

3.1 What information must appear in advertisements directed to health professionals?

The statutes and regulations governing pharmaceutical advertising do not differentiate between advertisements aimed at health care providers and those aimed at consumers. As a result, the requirements are the same, regardless of the audience targeted by a particular advertisement. For further discussion of what information must appear in pharmaceutical advertisements, *see* questions 6.1 and 6.2 below.

3.2 Is it a requirement that there be data from any or a particular number of "head to head" clinical trials before comparative claims are made?

Any advertising claim that represents or suggests that one drug is safer or more efficacious that another drug must be supported by substantial evidence or substantial clinical experience. *See* 21 C.F.R. §202.1(e)(6)(ii). Substantial evidence of safety and efficacy consists of adequate and well-controlled investigations, including clinical investigations. *See id.* at §202.1(e)(4)(ii).

3.3 What rules govern comparator advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in the USA?

Prescription drug advertisements may not be false, unbalanced, or misleading. *See* 21 C.F.R. §202.1(e)(6). Under FDA regulations, a comparator advertisement is false, unbalanced or misleading if it: "*Contains 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.*" *Id.* at §202.1(e)(6)(ii). The fact that a comparison product has not yet been approved would not relieve a manufacturer of the requirements of § 202.1(e)(6).

3.4 What rules govern the distribution of scientific papers and/or proceedings of congresses to doctors?

The dissemination of scientific papers to doctors is appropriate, but is limited by the regulations discussed above in question 2.1. While providing scientific papers or information to doctors, pharmaceutical companies must be careful not to promote unapproved drugs or approved drugs for off-label uses, which can have serious criminal and civil implications.

3.5 Are "teaser" advertisements permitted, which alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

FDA regulations do not forbid "teaser" advertisements as long as the drug at issue has been approved for marketing by the FDA. For example, FDA regulations allow the use of "reminder" advertisements (which only mention the name of the drug and not its use) and "help-seeking" advertisements (which encourage individuals with a particular condition to see a doctor without mentioning a specific product). *See* 21 C.F.R. §202.1(e).

4 Gifts and Financial Incentives

4.1 It is possible to provide health professionals with samples of products? If so, what restrictions apply?

Drug samples may be distributed to heath care professionals licensed to prescribe the sampled drug. FDA regulations allow samples to be distributed by: (1) mail or common carrier; or (2) direct delivery by a representative or detailer. *See* 21 C.F.R. §§203.30, 203.31. Under either form of distribution, the licensed practitioner must execute a written request and a written receipt. *Id.* When distribution occurs through a representative, the manufacture must conduct, at least annually, a physical inventory of all drug samples in the possession of each representative. *Id.* at §202.31(d). The manufacturer must also maintain a list of all representatives who distribute samples and the sites where those samples are stored. *Id.* at §202.31(e).

Drug samples may not be sold, purchased, or traded. *See* 21 U.S.C. §353(c)(1). However, under certain conditions, drug samples may be donated to a charitable institution. *See* 21 C.F.R. §203.39.

Of note, the TAP case, discussed in question 2.1 above, involved allegations that TAP provided doctors with free samples of Lupron and encouraged them to reap profits from the free samples by billing Medicare and Medicaid. Accordingly, sampling has become a highly inspected practice that can likewise lead to civil and criminal liability if not done properly.

4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

Offering any type of remuneration directly or indirectly 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 federal health care programme could violate the federal Anti-Kickback Statute if one purpose of the payment or gift to the health care professional is intended to induce Federal health care programme business. *See* 42 U.S.C. §1320a-7b(b). Pharmaceutical manufacturers must, therefore, carefully scrutinise sales and marketing practices involving gifts, donations or other forms of remuneration that may be given to medical professionals and/or facilities. Certain educational and practice-related items may, however, be offered to medical professionals under limited circumstances. Pharmaceutical manufacturers should be familiar with the "guidelines" regarding relationships with physicians and other persons or entities in a position to make or influence referrals published by the following three entities: the (i) The PhRMA Code on Interactions with Healthcare Professionals, available online at www.phrma.org/code_on_interactions_with_healthcare_professionals/; (ii) The HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) available online at http://oig.hhs.gov/authorities/docs/03/050503RCPGPharmac.pdf; and (iii) The AMA Guidelines on Gifts to Physicians from Industry, available online at http://www.ama-assn.org/ama/pub/category/4263.html. Generally, no gift may be given in exchange for prescribing products or a promise to continue prescribing products. Gifts should be primarily for the benefit of patients and of minor value (less than $100). Gifts of *de minimis* value to be used in the physician's practice such as pens and notepads are also allowed. Items intended for the personal benefit of the physician, including cash or cash equivalents, are inappropriate (except as compensation for *bona fide* services). So, for example, gift certificates, tickets to a sporting event, artwork, music, and floral arrangements would be prohibited under all three sets of guidelines.

As evidenced by *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass 2001) and the TAP case discussed in question 2.1 above, providing any benefits to physicians will increase governmental scrutiny and could result in civil and criminal liability, including hefty fines.

4.3 Is it possible to give gifts or donations of money to institutions such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

The Federal Anti-Kickback statute discussed above in question 4.2 applies to any remunerative relationship between the manufacturer and a person or entity in a position to generate Federal health care business for the manufacturer. Such persons or entities would also include institutions. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003). The OIG takes the position that goods and services provided by a manufacturer to a health care professional or institution that reduces or eliminates an expense the provider would otherwise have incurred (e.g., a business operational or overhead expense) implicates the Anti-Kickback statute if the arrangement is tied to the generation of federal healthcare programme business. Therefore, manufacturers must refrain from providing any form of remuneration to a health care professional for operational or overhead expenses.

4.4 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

As noted above in question 4.2, gifts may not be given in exchange for prescribing products or a promise to continue prescribing products. Any such gift may violate the Anti-Kickback statute, especially if it corresponds to changes in prescribing patterns.

If medical or educational goods provided to doctors are of *de minimus* value and primarily for the benefit of the patient, they may be considered appropriate if they are not tied to prescribing patterns in any way. For example, if a physician is provided medical literature that provides the doctor with information that causes him to alter his prescribing habits, then that would be permissible.

4.5 Do the rules on advertising and inducements permit the offer of a volume related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

To encourage price competition, the Federal Anti-Kickback statute contains both a statutory exception and regulatory safe harbour for discounts. *See* 42 U.S.C. §1320a-7b(b)(3)(A); 42 C.F.R. §1001.952(h). Both the statutory exception and regulatory safe harbour contain specific conditions that must be met. For example, all discounts must be disclosed and properly reported. Additionally, to qualify under the discount safe harbour, discounts must be in the form of a price reduction and must be given at the time of the sale (under certain circumstances the discount may be set at the time of the sale). *See* 42 C.F.R. §1001.952(h). Notably, the regulatory safe harbour provides that the term "discount" does not include: (i) cash payment or cash equivalents; (ii) supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care programme using the same methodology and the reduced charge is fully disclosed to the Federal health care programme and accurately reflected where appropriate to this reimbursement methodology; (iii) a reduction in price applicable to one payer **but not** to Medicare or a State health care programme; (iv) routine reduction or waiver of any co-insurance or deductible amount owed by a programme beneficiary; (v) warranties; (vi) services provided in accordance with a personal or management services contract; or (vii) any other remuneration, in cash or kind, not explicitly described in the regulation. *See* 42 C.F.R. §1001.952(h).

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

To ensure compliance with the Federal Anti-Kickback statute, no gift or payment should be made contingent on the purchase of medicinal products.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

The FDCA and FDA regulations do not specifically prohibit this practice with regard to prescription and over-the-counter medications. There is a "warranty" safe harbour in the Anti-Kickback law that excludes certain warranty payments from the definition of "remuneration" under the statute. *See* 42 C.F.R. §1001.952(g). The definition of warranty in the warranty safe harbour incorporates the Federal Trade Commission's definition of warranty which includes "any undertaking in writing... to refund, repair, replace, or take other remedial action with respect to such product in the event that such product fails to meet the specifications set forth in the undertaking." 15 U.S.C. §2301(6)(B). The warranty safe harbour only protects warranties on "items," so, a warranty on a combination of items and services does not technically qualify for protection. Safe harbour protection is available as long as the buyer complies with the standards of 42 C.F.R. §1001.952(g)(1)-(2) and the manufacturer or supplier complies with the following standards of 42 C.F.R. §1001.952(g)(3)-(4):

- The manufacturer or supplier must comply with either of the following two standards -- (i) The manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section. (ii) Where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.
- The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

It is permissible for pharmaceutical companies to support the education of the medical community through sponsoring Continuing Medical Education (CME). Pharmaceutical company-sponsored CME is customary and proper to the extent it contributes to the improved care of the patient. Since a pharmaceutical company's directly subsidising a healthcare professional may be considered an inappropriate gift, any financial support for CME, such as meetings or conferences, should be provided to the event's organiser to reduce the cost of attending for all attendees. If pharmaceutical companies provide financial support for medical conferences or meetings other than their own, control over the content and faculty of the meeting or conference must remain with the organisers. *See* The PhRMA Code on Interactions with Healthcare Professionals, available online at www.phrma.org/code_on_interactions_with_healthcare_professionals/.

Occasional meals (but no entertainment or recreational events) may be offered in conjunction with such medical conferences or meetings, so long as they: (a) are modest as judged by local standards; and (b) occur in a venue and manner conducive to informational communication and provide scientific or educational value. Pharmaceutical companies should only provide financial support for travel, lodging, and reasonable personal expenses of the conference or meeting faculty. *See id.*

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

Providing "hospitality," such as meals and social functions, to health professionals would also governed by the Federal Anti-Kickback statute. The guidelines set by the, OIG, AMA and PhRMA discussed above in question 4.2 would also be relevant. For example, under the PhRMA guidelines, a company may hold informational presentations that serve a valid scientific purpose and provide a "modest meal" by local standards. The company cannot, however, provide entertainment or a recreational outing and cannot pay for a spouse's or guest's meal. The AMA guidelines provide that subsidies for hospitality should not be accepted outside of modest meals or incidental social events held as part of a conference or meeting. *See* also question 5.2. It would not make a difference if the hospitality were in another country.

5.2 Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

Continuing medical education (CME), professional, and scientific conferences sponsored by third-parties can improve patient care, and as a result, financial support is allowed under the PhRMA, OIG and AMA guidelines in certain circumstances. A manufacturer's financial support may be appropriate if: (i) the subsidy is directly to the conference sponsor; (ii) the sponsor uses the subsidy to create an overall reduction in conference registration fees for all attendees; and (iii) the physician does not receive the subsidy directly. Non-faculty professionals should not be paid for the costs of travel, lodging, or any other personal expenses. A manufacturer may, however, offer financial support to sponsors for modest meals or receptions so long as the meals and receptions are provided for all attendees.

Funding should not, however, be offered to pay for the physician's time associated with attending the conference.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

The Federal Anti-Kickback statute governs the hospitality arrangements for scientific meetings. Usually, professional guidelines issued by groups such as the PhRMA, OIG and AMA, provide further guidance regarding the appropriateness of hospitality arrangements of meetings which are sponsored or subsidised by pharmaceutical companies.

5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

The Federal Anti-Kickback regulations also create a safe harbour for personal services, provided all of the requirements of the safe harbour are met. *See* 42 C.F.R. §1001.952(d). Manufacturers may enter into consulting agreements with physicians so long as the compensation reflects a fair market, commercially reasonable value, and there is a legitimate need for the services. As outlined in the PhRMA guidelines, there are several factors that are relevant in identifying the existence of a *bona fide* consulting arrangement: (i) the agreement is in writing and specifies the nature of the services to be provided and the basis for the payment of those services; (ii) a legitimate need for the services has been identified (and documented) in advance of the request for services and entering into arrangements with prospective consultants; (iii) the criteria for selecting the consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to decide if the consultant meets the criteria; (iv) the number of consultants retained is not greater than the number reasonably necessary to achieve the desired purpose; (v) the company maintains records of the services provided and makes appropriate use of the services provided; (vi) the venue and circumstances of any meeting with consultants is conducive to the consulting services provided and activities related to the services constitute the primary focus of the meeting, with any social or entertainment events clearly subordinate in terms of time and emphasis; and (vii) no payments are made for the consultant's spouse or significant other to attend the meeting.

In *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass 2001), Franklin alleged that Parke-Davis paid for inconsequential studies, paid physicians for minimal participation in consultations, and providing physicians with payment for small record-keeping tasks. As discussed in question 2.1 above, these allegations led to a large settlement. Manufacturers, therefore, must take all necessary steps to ensure that all such personal services are in fact legitimate.

5.5 Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

While it is possible to compensate doctors to participate as investigators in clinical trials, the compensation must comply with

the FDA regulations governing clinical trials. This includes a regulation requiring the disclosure of any financial arrangements between the clinical trial sponsor and the investigator that could cause, or be perceived as causing, bias. *See* 21 C.F.R. 54. Any such financial arrangement will be considered by the FDA when analysing the clinical trial.

The professional guidelines discussed in question 4.2 indicate that it is generally appropriate for doctors who perform bona fide services to receive reasonable compensation, including reasonable travel and lodging expenses. Token consulting arrangements are not appropriate to justify compensating a doctor for expenses. These guidelines do not delineate between scientific or market studies.

5.6 Is it possible to pay doctors to take part in market research involving promotional materials?

See question 5.5 above.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Non-prescription drugs may be advertised to the general public. Such advertising is known as direct-to-consumer advertising (DTC). As discussed above in question 1.1, non-prescription drug advertisements are regulated by the FTC, not the FDA. Federal statutes prohibit the dissemination of false advertisements. *See* 15 U.S.C. §52. This prohibition applies to non-prescription drug advertisements. A "false advertisement" is defined as an advertisement "which is misleading in a material respect." *Id.* at §55. In determining whether an advertisement is misleading, several factors will be considered, including the representations made or suggested by word, design, device, or sound and any material facts omitted.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

DTC advertising is also allowed for prescription drugs. Under FDA regulations, "advertisements" subject to the FDCA fall into two categories, print advertisements and broadcast advertisements. Print advertisements include "advertisements in published journals, magazines, other periodicals, and newspapers..." Broadcast advertisements include "advertisements broadcast through media such as radio, television, and telephone communication systems." 21 C.F.R. §202.1(l)(1). Both types of advertisements shall not be false or misleading and must present a fair balance between the efficacy of a drug and its risks. *Id.* at §202.1. Additional FDA requirements differ slightly depending on the type of advertisement.

Print Advertisements

The FDCA and FDA regulations require that all prescription drug advertisements discussing the effectiveness or indications of the drug must include a brief summary of side effects, contraindications, and effectiveness (known as the "brief summary" requirement). *See* 21 U.S.C. §352(n); 21 C.F.R. §202.1(e). This brief statement must include all risk information contained in the approved labelling, including all side effects, contraindications, warnings, precautions, and adverse reactions. *See* 21 C.F.R. §202.1(e)(3)(iii).

To satisfy the brief summary requirement, manufacturers will usually reprint the relevant sections of the package insert. The package insert is directed at health care providers and may be difficult for consumers to understand. As a result, the FDA has issued a Draft Guidance indicating that it does not intend to object to the use of FDA-approved patient labelling containing consumer-friendly language on contraindications, warnings, major precautions, and frequently occurring side effects. See Draft Guidance, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisement, January 2004. Additionally, the FDA has proposed an amendment to its regulations that would require FDA-approved professional labelling to contain a section entitled Highlights of Prescribing Information ("Highlights"). The FDA's Draft Guidance also indicates that the FDA does not intend to object to the use of the information that would appear in the Highlights section to satisfy the brief summary requirement. *See id.*

Two types of advertisements are not subject to the brief summary requirement:

- Reminder Advertisements; and
- Help-Seeking Advertisements.

Broadcast Advertisements

Broadcast advertisements have limitations that print advertisements do not. As a result, broadcast advertisements have different requirements.

First, a broadcast advertisement must include a statement of the most important risk information (known as the "major statement" requirement). Second, a broadcast advertisement must either include a brief summary, as discussed above, or make "adequate provision... for the dissemination of the approved or permitted package labelling in connection with the broadcast presentation" (known as the "adequate provision" requirement). 21 C.F.R. §202.1(e)(1). In a Guidance Document, the FDA indicated that a manufacturer can satisfy the adequate provision requirement by:

- providing a toll-free phone number for consumers to call for the approved labelling;
- referencing a printed advertisement or brochure that can be accessed with limited technology;
- providing reference to an internet website that contains the requisite labelling; and
- advising consumers to ask doctors or pharmacists for more information.

See Guidance for Industry, Consumer-Directed Broadcast Advertisements, August 1999.

6.3 If it is not possible to advertise prescription only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

While prescription drug advertisements are allowed, a manufacturer may use help-seeking or disease-oriented advertisements focused on raising awareness of a particular condition.

6.4 Is it possible to issue press releases concerning prescription only medicines to non-scientific journals? If so, what conditions apply?

There is no prohibition on such press releases so long as the drug has received marketing approval from the FDA. In some circumstances, a manufacturer may distribute scientific findings to the lay media prior to approval. *See* questions 2.1 and 2.2 above.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

There are no such restrictions on product descriptions and research initiatives, other than the prohibition against the promotion of off-label use.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

Prescription drug and medical device manufacturers may provide charitable funding to patient support groups. Currently, there are no reporting or disclosure requirements that are unique to pharmaceutical or medical device manufacturers regarding the funding or support of patient support groups.

7 The Internet

7.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

The FDA has yet to promulgate prescription drug advertising regulations specific to the internet. DDMAC is currently developing a FDA-wide policy to address promotion and advertising of prescription drugs on the internet. *See* http://www.fda.gov/cder/handbook/pol_guid.htm.

7.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for health professionals?

No specific level of security is required. Some prescription drug websites require the health care professional to register while others have no security at all.

7.3 What rules apply to the content of independent websites that may be accessed by link from a company sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

The FDA has yet to promulgate prescription drug advertising regulations specific to the internet. However, all restrictions and limitations discussed above on the promotion of prescription drugs would apply to the internet.

7.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

See question 7.3.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in the USA?

Like prescription medications, the FDCA and FDA govern the advertising of restricted medical devices. *See* 21 U.S.C. §352(q),(r). A restrictive device is one in which the sale, distribution, and use of the device must be authorised by a licensed practitioner. Advertisements regarding all other devices are regulated by the FTC.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

The restrictions on hospitality offered to physicians in connection with the promotion of a medical device are similar to the restrictions placed on the promotion of pharmaceutical products. *See* question 4.6 above. There are a few notable differences, however.

The Advanced Medical Technology Association (AdvaMed) has issued its own Code of Ethics on the Interactions with Health Care Professionals specific to medical devices, available at www.advamed.org/MemberPortal/About/code/codeofethics.htm. AdvaMed developed a code independent of the PhRMA code so that it could address issues specific to the medical device industry. The FDA requires medical device manufacturers to train and educate physicians on the safe and effective use of a particular device. This type of interaction is unique to the medical device context. As a result, medical device manufactures may fund product training and education programmes and may provide physicians with hospitality in the form of modest meals and receptions subordinate in time to the training purpose. Manufactures may also pay for reasonable travel expenses and lodging associated with these training programmes.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

While the regulations relating to pharmaceutical advertising have remained generally consistent over the last year, the pharmaceutical industry continues to come under close scrutiny for its method of advertising, especially the impact of DTC advertisements. Additionally, as the Internet has become an increasingly prevalent forum for communication, there has been ongoing dialogue as to how the FDA should regulate pharmaceutical advertising on the Internet.

DTC advertisements and the Internet have increased the amount of communication directly with consumers regarding pharmaceuticals. This increase in consumer communication has resulted in continued scrutiny regarding the learned intermediary doctrine. The learned intermediary doctrine provides that a pharmaceutical manufacturer discharges its duty by adequately warning the prescribing physician, therefore, the manufacturer has no duty to warn the patient directly. However, the increasing use of DTC advertising by pharmaceutical manufacturers may limit the uniform application of this important doctrine in prescription drug cases. *See* Harvey L. Kaplan and Jon A. Strongman, *Drug Advertising and the Learned Intermediary Doctrine*, The International Comparative Legal Guide to: Pharmaceutical Advertising 2008.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

While it is unclear if significant developments in pharmaceutical advertising will occur in the next year, DDMAC is currently

developing the following policies and guidances:

- *Revision of Previous Guidances*- DDMAC is revising all guidances it has issued since 1970 to determine if they are obsolete or need revision. A series of Federal Register notices will explain the changes and give the public an opportunity to comment.
- *DTC Advertising and Promotion*- With other FDA offices, DDMAC is examining whether the current advertising regulations should continue to apply to promotion directed to consumers, or whether there should be changes made in the requirements for this type of promotion.
- *Promotion on the Internet*- As part of an FDA working group, DDMAC is developing an agency-wide policy to address how advertising and promotion of FDA-regulated products will be regulated on the Internet.
- *Promotion to Managed Care Organizations*- DDMAC is developing a policy regarding pharmaceutical marketing, pharmacoeconomic claims, and information exchange in managed care environments.
- *Quality of Life Claims*- DDMAC is developing a policy regarding the claims made in labelling and advertising about the impact of pharmaceuticals on the quality of life.

See http://www.fda.gov/cder/handbook/pol_guid.htm.

9.3 Are there any general practice or enforcement trends that have become apparent in the USA over the last year or so?

See question 9.1.

9.4 Has your national code been amended in order to implement the current version of the EFPIA Code of October 2007?

Not applicable.

Harvey L. Kaplan

Shook, Hardy & Bacon L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108-2613
USA

Tel: +1 816 474 6550
Fax: +1 816 421 5547
Email: hkaplan@shb.com
URL: www.shb.com

Harvey Kaplan is a partner of Shook, Hardy & Bacon L.L.P. in Kansas City, Missouri. He Chairs the firm's Pharmaceutical and Medical Device Litigation Division and is well-known nationally and internationally for defending pharmaceutical companies. Harvey has tried and won high profile cases in many jurisdictions, involving such drugs and devices as DES, the Cu-7 IUD, the Dalkon Shield IUD, and the FenPhen diet drug combination. In 2008, Mr. Kaplan was named by *Who's Who Legal: The International Who's Who of Business Lawyers as Product Liability Lawyer of the Year*; and he was selected as the World's Leading Product Liability Lawyer for 2009 by *The Legal Media Group Guide to the World's Leading Product Liability Lawyers*. He was also featured in *The American Lawyer* where SHB was selected as the 2008 Product Liability Litigation Department of the Year and in a profile of SHB in the October 2008 *ABA Journal*.

Jon A. Strongman

Shook, Hardy & Bacon L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108-2613
USA

Tel: +1 816 474 6550
Fax: +1 816 421 5547
Email: jstrongman@shb.com
URL: www.shb.com

Jon is an associate attorney in the Pharmaceutical and Medical Device Litigation Division of Shook, Hardy & Bacon L.L.P. Jon was an articles editor for the Kansas Law Review and a national quarterfinalist in the National Moot Court Competition. He is a member of Order of the Coif.
Jon is admitted to practice before the state and federal courts of Missouri as well as the U.S. District Court for the District of Kansas. He graduated from the University of Kansas (B.A. 1999, with distinction) and from the University of Kansas School of law (J.D. 2002).

Shook, Hardy & Bacon L.L.P. (SHB) is an international law firm that was established in Kansas City, Mo., in 1889. Today, SHB has grown to nearly 1,800 employees worldwide, including more than 500 attorneys and 250 research analysts and paraprofessionals in nine offices: Geneva, Switzerland; Houston, Texas; Kansas City, Missouri; London, England; Miami, Florida; Orange County, California; San Francisco, California; Tampa, Florida; and Washington, D.C.

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SHB's vast litigation experience and ability to handle national and international litigation sets it apart from other firms. Several recent accolades attest to our standing as a premier litigation law firm in the United States and around the globe. In January 2008, The American Lawyer named SHB the Product Liability Litigation Department of the Year. In 2007, SHB was selected as Global Product Liability Firm of the Year (for the third consecutive year) by Who's Who Legal: The International Who's Who of Business Lawyers; and we were included on The National Law Journal's 2007 "Defense Hot List."

Additionally, many SHB attorneys have been recognised for their outstanding professional skills and abilities by: Chambers USA: America's Leading Lawyers for Business; The Best Lawyers in America; The Legal 500 United States; Lawdragon: The 500 Leading Lawyers in America; Lawdragon: The 500 Leading Litigators in America; Who's Who Legal: The International Who's Who of Business Lawyers; and Who's Who Legal: The International Who's Who of Product Liability Lawyers.

In addition to our work in the courtroom and boardroom, SHB has been singled out for its innovative diversity efforts. Clients, including The Coca-Cola Company and DuPont, and organizations such as the Minority Corporate Counsel Association have honored SHB for our commitment to building an inclusive environment for attorneys and employees.

For more information, contact:

Harvey L. Kaplan, Chair, Pharmaceutical and Medical Device Litigation Division, Shook, Hardy & Bacon L.L.P.
2555 Grand Boulevard, Kansas City, Missouri 64108, USA
Tel: +1 816 474 6550, Fax: +1 816 421 5547, Email: hkaplan@shb.com, URL: www.shb.com