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1 General - Medicinal Products

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

The primary body of law that governs the advertising of prescription medical products in the United States is the Food, Drug and Cosmetic Act, including its 1976 Medical Device Amendments. This Act is administered by the Food and Drug Administration (“FDA”), which has promulgated a detailed set of regulations that, among many other things, addresses advertising as “labelling.” The FDA has broadly interpreted what it considers “labelling” and thereby regulates most advertising, as well, including direct to consumer advertisements. The FDA’s jurisdiction overlaps with the general authority of the United States Federal Trade Commission (“FTC”) to regulate any false or deceptive advertising or unfair trade practices. The FDA and the FTC concluded a memorandum of understanding in 1971 that has been periodically updated. Under the most recent agreement, the FDA has primary authority to regulate prescription drug advertising, and the FTC has primary authority to regulate OTC drug advertising.

The fifty states also have concurrent power to regulate advertising as long as they do not conflict with federal law. State avenues include “Little FDC Acts,” consumer protection statutes, and various private tort causes of action.

1.2 How is “advertising” defined?

The FDA defines “advertising” very broadly to include material published in journals, magazines, other periodicals, and newspapers; and broadcast through media such as radio, television, and telephone communications systems. The regulation lists these as examples, and is not comprehensive. The FDA also regulates promotion of prescription medical products by company sales representatives, on computer programmes, through fax machines, or on electronic bulletin boards.

1.3 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?

Advertising, as opposed to labelling, need not be submitted

for advance FDA approval. However, any promotional materials that are either affixed to, or accompanying an FDA approved product are considered “labelling” and must be pre-approved. All labelling, and changes to labelling that impact on a product’s safety or effectiveness, must be submitted to the FDA by means of a “New Drug” Application” (or the administrative equivalent for devices and other FDA regulated products) or by way of a supplement to an existing application. The FDA has 180 days to act on such an application, although in practice it can take much longer. Minor labelling changes need not be pre-approved. Changes to labelling that strengthen warnings or otherwise increase safety information can be put into effect upon notice to the FDA and pending a final agency decision. There are FDA procedures for accelerated review of certain categories of products.

Informal communication between the FDA and regulated entities is encouraged, typically between the FDA reviewer or reviewers with ongoing responsibility for that product.

1.4 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?

The FDA has wide powers to address advertising that it considers in violation of its regulations and it exercises this power frequently. It can issue warning letters, require corrective advertising, impose fines, demand a recall, and in a serious case prohibit distribution of the product and have existing stocks seized. There are well-defined procedures for appealing adverse agency action, including eventual judicial review. Judicial review is typically under a deferential abuse of discretion standard.

1.5 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?

The FDA has a wide range of civil and criminal penalties available for enforcement of its regulations generally. False or misleading advertising that is considered labelling renders

the offending product misbranded. Typically the FDA starts with a “warning letter” stating what action it believes is required. This can be as simple as a change in the advertising. The FDA can require corrective statements, including corrective media advertising. If the FDA resorts to enforcement, it can seek civil or criminal fines and can prohibit distribution and seize product. In extreme cases, fines have exceeded \$100 million. The courts have also recently recognised the FDA’s power to demand disgorgement of profits. This is unusual in the advertising area unless there is a safety issue and the offender refuses to stop voluntarily.

The FDA issues numerous warning letters every year. These may be accessed on the FDA’s website.

Competing drug and device companies often prompt agency action by informing the FDA of practices they believe violate the agency’s regulations. Competitors may also file administrative citizen’s petitions to require the agency to act. There is no private right of action under the Food, Drug, and Cosmetic Act. Competitors have attempted to accuse one another of violating the Act in private actions brought under the United States’ Lanham Act, which governs unfair advertising generally, but to the extent that these claims would require the court to interpret FDA regulations, or determine whether violations have occurred, they have not been allowed.

1.6 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?

The primary federal statute concerning unfair competition is the Lanham Act. It requires a commercial nexus to have standing to sue. The Lanham Act is thus available to competing businesses, but not to users of regulated products. As stated above, Lanham Act suits claiming violations of the FDCA are generally dismissed. If a pharmaceutical company misrepresents the existence of, or the extent of, FDA approval, that type of claim may be allowed.

Almost all of the fifty states have consumer protection statutes of some sort. Some of these allow suits by commercial competitors in addition to consumers, but a majority restrict relief to consumers who purchased a product. The state statutes vary widely in the elements that must be proven. The more liberal state consumer protection statutes do not require proof of either direct reliance by the plaintiff or specific monetary injury.

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?

A prescription medical product may not be promoted for an intended use that has not received prior FDA approval. The FDA looks at advertising to determine what the intended use

of a product is. The issue of “off-label” promotion at scientific and medical gatherings is controversial. FDA regulated companies may sponsor scientific gatherings at which researchers and practitioners discuss off-label uses. However, if they seek to influence the substantive content of the discussions or pay speakers directly, they run the risk of an FDA enforcement action.

The FDA allows regulated companies to disseminate reprints of scientific articles or textbooks concerning off-label uses under restrictive conditions, including a promise to submit a supplemental application to have the use in question approved. Such material must be conspicuously labelled as involving an off-label use, and must be submitted to the FDA for pre-approval.

Dissemination of scholarly articles involving off-label uses is permitted in response to a request from a licensed physician. Regulated entities are not permitted to solicit or encourage such requests.

The dissemination of truthful scientific information generally is subject to the free speech guarantees of the First Amendment to the US Constitution. The FDA was at one point enjoined from enforcing restrictions on the distribution of scholarly material concerning off-label uses, but the injunction was lifted when the FDA agreed not to consider such information as changing the intended use of regulated products. Other FDA restrictions upon the dissemination of truthful information about regulated products have been held unconstitutional, but the agency’s ability to restrict distribution of information about off-label uses currently remains intact.

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

Yes. There is no general restriction upon the publication of research involving off-label uses or upon discussion of off-label uses in books or in the popular press. To the extent that a regulated entity is paying for, or dictating the content of, such publications, however, they may be considered illegal promotion.

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

Yes. Companies routinely issue press releases about products under development, and in some cases may indeed be required to do so by other laws. FDA restrictions upon press releases are informal and developed on a case by case basis. To determine whether a press release constitutes illegal promotion the FDA looks to such factors as the phraseology of the release, its manner of distribution, and the scope of its distribution.

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

Information about off-label uses may be sent to licensed physicians only upon their request, which may not be solicited. Such information must be independently published and meet FDA standards for objectivity.

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?

Regulated entities may promote labelled uses as long as they do so truthfully. The FDA has not specifically approved the dissemination of information about off-label uses to anyone other than licensed physicians.

3 Advertisements to Health Professionals

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

Advertisements in medical publications are subject to the FDA's general requirements regarding printed advertising. The name and active ingredients of the product must be stated, as well as its manufacturer. The name of the product must appear on every printed page. The advertisement must also contain detailed prescribing information that parallels the relevant portions of the labelling that accompanies the product. Relevance is determined by the intended use(s) and dosage(s) that the advertisement describes. These uses and dosages must be FDA approved and must be prominently stated. If the product has more than one intended use or dosage, the required information need only concern the use(s) and dosage(s) that are the subject of the advertisement. The required prescribing information must address warnings, contraindications, side effects, precautions, and effectiveness. All advertising must also meet fair balance requirements mandating equal treatment of favourable and unfavourable information about the product.

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 statements that a manufacturer seeks to make that compare the safety or effectiveness of any drug or medical device product with any other product intended for the same indication must be supported by substantial scientific evidence, consisting of adequate and well-controlled studies, as defined by FDA regulations. Traditionally, the FDA has required two such studies, but the FDA may waive this requirement.

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 your country?

In general, comparative claims are only appropriate if there are data resulting from head-to-head comparative studies. There are two types of comparative claims - superiority and equivalence. For superiority claims, the required scientific evidence should include adequate and well-controlled trials designed to establish superiority of one product over another. For claims of similar effectiveness, the required evidence should include adequate and well-controlled trials designed to demonstrate that one product is not inferior to another and that the difference between the two is not clinically significant.

The FDA does not restrict express references to competing products, if those products have in fact been compared in acceptable clinical studies. As long as references to the competing product are not unfair or misleading under the general law respecting advertisements, references to competing products are allowed.

A product that has no FDA approval at all may not be promoted for any health-related use, and thus could not be referenced in a comparative advertisement.

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

Scholarly publications concerning FDA approved uses may be distributed without restriction, as long as the source of the reprint is identified. Scholarly publications concerning off-label uses may be distributed only upon unsolicited request, or if the company complies with the limited statutory safe harbour that requires pre-approval and a commitment to submit the off-label use in question to the FDA for approval.

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 permit so-called "reminder," advertisements, which call attention to the name of the product but do not mention either its indications or dosage recommendations. Because such "reminder" advertisements cannot discuss the product's safety or effectiveness, they are also exempt from requirements that they discuss the product's risks. Reminder advertisements are prohibited if the product carries a boxed warning, with the exception of advertisements limited solely to the price of the product.

4 Gifts and Financial Incentives

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

Yes. Such samples may be distributed but cannot be sold. Samples must be specially prepared and labelled. They must be recorded and accounted for by lot. Samples may be given to physicians licensed to prescribe the product in question or to pharmacies. Samples cannot be distributed without prior written request, and no single request can be for more than six months. All samples require a written receipt. The contents of both the request and the receipt are specified by the FDA. A sampling manufacturer must keep records and follow written procedures. It obligates itself to conduct an annual inventory of each physician or pharmacy to which it provides samples to ensure that samples are being used properly. A sampling manufacturer must report suspected diversion or theft to the FDA.

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

The FDA does not regulate the giving of gifts or donations to medical practitioners. However, such practices are also subject to the ethical prohibitions and limitations issued by

the American Medical Association and similar professional medical associations of medical specialists. While these ethical restrictions are not themselves legally binding, in many states they may serve as the basis for disciplinary actions against a licensed physician.

However, if a gift or donation is intended to influence a physician's decision to prescribe a particular drug, it may constitute an illegal gratuity under the criminal anti-kickback provisions of statutes governing the operation of federal healthcare reimbursement programmes such as Medicare and Medicaid.

It is permissible to pay physicians who participate in clinical trials based upon the number of patients they recruit to participate in a given trial.

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 same considerations apply to gifts and donations to institutions that apply to similar payments to physicians.

4.4 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?

Volume discounts are not regulated by the FDA. However actual wholesale prices must be reported to the federal government and figure into the average wholesale prices mandated under so-called "best price programmes" that determine how reimbursements and rebates to governmental medical assistance programmes are calculated. Thus an inducement of this nature can lead to adverse legal action if not properly reported.

A discount that is properly disclosed under federal best price/wholesale price regulations cannot constitute an improper gratuity under federal anti-kickback legislation. An irregular discount, however, can constitute an anti-kickback violation.

4.5 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?

Contingent payments of this sort are not regulated by the FDA. Free goods contingent upon other purchase requirements must be factored in when calculating the "best price" for the purpose of price-based rebates to governmental medical assistance programmes. Thus this type of programme is subject to federal reporting requirements. If such inducements are not properly reported they could become an improper gratuity under federal anti-kickback legislation.

4.6 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?

There is no general legal prohibition against a manufacturer of prescription medical products voluntarily offering a refund if its product is ineffective, or indeed for any other reason. Thus, a refund policy is a matter of the manufacturer's choice and its competitive position. It is possible that a particular refund programme could be structured in such a way as to run afoul of anti-trust statutes. The FDA has explicit statutory authority to order refunds for medical devices that fail to function as intended, and most courts have recognised that general power to order refunds with respect to any regulated product. The agency, however, has issued formal refund regulations only with respect to electronic products.

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

Yes, it is usual and customary for manufacturers of prescription medical products to sponsor continuing medical education, both generally and concerning their products. Industry supported CME can encounter regulatory problems if off-label uses are included in the curriculum. In that situation, the FDA has distinguished between those activities supported by manufacturers that are independent from the substantive influence of the supporting manufacturer and those that are not. The agency decides CME issues on a case-by-case basis upon review of such factors as the sponsor's role in selection of speakers and topics, disclosure of the nature and extent of the sponsor's involvement, the extent to which the programme focuses on off-label use, the relationship between the CME provider and the sponsor, whether the provider's personnel are also involved in product promotion, the provider's prior CME activities, the number of times the same programme is held, how the CME audience is selected, the structure of the programme itself, the presence and activities of the sponsor's personnel, whether ancillary product promotion occurs, and whether any complaints are made to the FDA.

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?

Federal anti-kickback legislation makes it illegal for a company to provide, or for a physician to accept, any payment, whether in cash or in kind, to influence the prescription of items the cost of which are reimbursed by federal medical assistance programmes. Some states have analogous restrictions relative to medical assistance programmes they operate.

Beyond anti-kickback legislation, medical ethics, rather than legal prohibitions, govern the acceptance of gifts by physicians from the pharmaceutical industry and other manufacturers of prescription medical products. Many

medical societies have taken positions on such gifts, perhaps the most prominent being the American Medical Association. The ethical concerns expressed by the AMA and other societies do not distinguish between gifts accepted inside the United States and gifts accepted elsewhere. Acceptance of substantial gifts, such as lavish dinners, free trips, offers of cash and other inducements are considered unethical by the AMA and other societies. Medical ethics also preclude physicians from accepting gifts based upon the amount of a company's product they prescribe.

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?

Federal anti-kickback legislation makes it illegal for a company to provide, or for a physician to accept, any payment, whether in cash or in kind, to influence the prescription of items the cost of which are reimbursed by federal medical assistance programmes. Some states have analogous restrictions relative to medical assistance programmes they operate.

Such payments are possible, but are considered ethically suspect. The AMA's ethical guidelines provide that industry subsidies should not be accepted to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, or to compensate for the physicians' time. These guidelines also limit subsidies for hospitality, modest meals, or social events held as a part of such events. As opposed to participants, teaching faculty may accept reasonable honoraria and reimbursement for reasonable travel, lodging, and meal expenses, as may actual providers of other services, but the services they provide must be commensurate with the compensation offered. Generally, the AMA's ethical guidelines frown upon physician acceptance of direct subsidies from industry, since the giving of a subsidy directly to a physician may create a relationship that could influence the physician's choice of products. The AMA prefers that subsidies be directed to the entity sponsoring the meeting, and that the sponsor in turn use the money to reduce the overall registration fee.

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

Federal anti-kickback legislation makes it illegal for a company to provide, or for a physician to accept, any payment, whether in cash or in kind, to influence the prescription of items the cost of which are reimbursed by federal medical assistance programmes. Some states have analogous restrictions relative to medical assistance programmes they operate.

Beyond this limitation, such payments are ethically acceptable as long as the focus groups serve a genuine, legitimate and exclusive research purpose and are not used for promotional purposes. Such payments may also include compensation for time and travel expenses. Physician focus groups are ethically acceptable as long as they are of an appropriate size to accomplish the research purpose.

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

Federal anti-kickback legislation makes it illegal for a company to provide, or for a physician to accept, any payment, whether in cash or in kind, to influence the prescription of items the cost of which are reimbursed by federal medical assistance programmes. Some states have analogous restrictions relative to medical assistance programmes they operate.

The FDA has extensive regulations concerning the conduct of all clinical studies, pre- or post-marketing that are designed to generate data for submission to the agency. These rules govern the conduct of study sponsors, participating institutions, and investigating physicians. These rules permit payment of actual expenses, and allow reasonable compensation for the investigating physician's time.

Likewise, medical ethics allow for physician compensation as long as the study is serving a genuine research purpose. The ethical touchstone for evaluating the propriety of such payments is whether they are reasonable in light of the research objective, the nature of the study, and the nature of the compensation being offered.

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

Federal anti-kickback legislation makes it illegal for a company to provide, or for a physician to accept, any payment, whether in cash or in kind, to influence the prescription of items the cost of which are reimbursed by federal medical assistance programmes. Some states have analogous restrictions relative to medical assistance programmes they operate.

Payments for research are generally considered ethical as long as the physician is providing genuine services. In that case, reasonable compensation for both time and travel expenses is permissible. Token or sham advisory or consulting arrangements cannot be used to justify compensation. The ethical guidelines do not distinguish between scientific and market research.

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?

Yes. Because over-the-counter products do not require a physician's prescription and cannot be sold without having adequate directions for use on their packaging, they may be advertised to the general public without restrictions other than the general requirement that the advertising not be false or misleading.

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

Yes. Direct to consumer advertising of prescription medical

products is permitted in the United States. Direct to consumer advertisements by way of television or other mass media are permitted. All such advertisements, except for so-called “reminder” advertisements, must present a “brief summary” concerning the product’s intended use, effectiveness, side effects, warnings, precautions, and contraindications, as well as other important cautionary information or special considerations that influence the product’s use. Advertisements broadcast through television and other mass media must contain a “robust” statement of the product’s major side effects and contraindications, but the remainder of the brief statement may be made available through other means, such as an Internet website.

In direct to consumer print advertising, it is commonplace for manufacturers to comply with the brief summary requirement by presenting verbatim the entire risk-related sections of the product’s FDA-approved professional labelling.

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?

As discussed above, direct to consumer advertising of prescription drugs is permitted in the United States. Disease awareness advertising is also permitted in the United States, however.

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

Yes. There are no legal restrictions on the distribution of press releases concerning prescription medical products, and such releases are routinely sent to newspapers and other non-scientific publications. Press releases involving off-label uses have on occasion been viewed as improper promotional activity, but such problems arise independently of whether they are directed to scientific or non-scientific publications.

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

None, except the general prohibition against promotion of off-label uses.

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

Manufacturers of prescription medical products routinely provide charitable funding for patient support groups interested in the conditions that their products treat. In the United States, there are no legal restrictions upon such support that are unique to prescription medical products. To the extent there are legal reporting requirements applicable to patient support groups, they are a function of the law generally applicable to charitable organisations.

7 The Internet

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

Interestingly, the FDA has yet to issue any formal regulations or even informal guidance concerning the advertising and promotion of regulated products on the Internet. Indeed, it has not even stated definitively whether Internet promotions are “labelling,” “advertising,” or both. Generally the FDA has attempted to apply its general standards relating to these activities to the content of manufacturer websites. The agency has conducted periodic sweeps of Internet websites to identify arguably illegal content, but enforcement to date has been limited to specific Internet promotions or to the marketing of unapproved products. This action, together with competitors complaining about one another, has been reasonably effective in ensuring that the website content of major American manufacturers is restricted to labelled uses (and bars hyperlinks to foreign sites discussing off-label uses) and does not contain unsubstantiated claims regarding product safety and effectiveness. The internet being a transnational system, however, the FDA has been ineffective in preventing websites operated from outside the United States from engaging in promotional, advertising, and product distribution activities that would be illegal if conducted by American firms operating in traditional fashion.

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?

There are no legal requirements concerning website security in the United States.

8 General - Medical Devices

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

Medical devices, like drugs, are regulated by the FDA. A special statute, the Medical Device Amendments, 21 U.S.C. §§360-360m, governs these products. The FDA regulates promotion and advertising of medical devices in similar fashion to its regulation of prescription drugs and biologics.

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

Neither the anti-kickback laws nor the medical ethics guidelines discussed above in connection with prescription drugs distinguishes between drugs and medical devices. In practical terms, many medical devices require hands-on training in their use, thus the ethical guidelines concerning the appropriateness of reimbursement for this type of training, and accompanying hospitality, may be easier to satisfy for medical devices as opposed to drugs.

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?

On January 24, 1996, the FDA issued the most thoroughgoing revision to its drug labelling regulations in several decades. A number of these labelling changes will affect how these products can be advertised. These regulations also purport to expand the scope of federal preemption of state-law claims governing advertising. The new labelling requirements mandate the inclusion of a "highlights" summary of important prescribing information, and the FDA may decide to allow this summary, or some variant of it, to serve as the brief summary of pertinent information that must be provided in conjunction with direct to consumer advertising.



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

Possibly. The FDA is engaged in an ongoing prescription drug advertising initiative. As a consequence of this initiative, there could be proposals for changes to the agency's direct-to-consumer advertising or Internet regulations in the upcoming year. The FDA, however, is not under any firm deadlines as to this initiative. The position taken by the FDA concerning preemption, mentioned above, is highly controversial. Much litigation over whether courts should follow the FDA will undoubtedly occur. Legislative or administrative challenges to the FDA's position are also possible.



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Mr. Beck is of counsel to Dechert LLP. He graduated from the University of Pennsylvania Law School in 1982. He is a member of Dechert's Mass Torts group, specialising in drug and medical device product liability litigation. Mr. Beck has defended pharmaceutical and medical device companies in many national product liability litigations.

Mr. Beck is the lead author of the "Drug and Medical Device Product Liability Handbook (Law Journal Press 2004). He belongs to the American Law Institute, the Product Liability Advisory Council, and the Food & Drug Law Institute. He edits the newsletter of the Mass Torts Committee of the Litigation Section of the American Bar Association. His 1998 law review article, "FDA, Off-Label Use and Informed Consent: Debunking Myths and Misconceptions," in the Food & Drug Law Journal, has been cited by numerous appellate courts, including the United States Supreme Court, concerning off-label use of prescription medical products.

Dechert LLP

With more than 900 lawyers in 18 cities around the world, Dechert is an international law firm with top-ranked, world-class practices in corporate and securities, complex mass tort litigation, finance and real estate, and financial services and asset management. Dechert occupies top spots in numerous national and international rankings, is noted for client service, and has undergone steady advances in stature, size, and profitability.

Dechert is particularly noted for its excellence in pharmaceutical product liability litigation. Dechert's recent win of the first defence verdict in a Vioxx case was one of the top ten US defence verdicts of 2005. In 2006 Dechert won a ground-breaking legal ruling expanding the scope of federal preemption by FDA regulation in a Paxil case. In recent years, Dechert has represented pharmaceutical defendants in numerous other complex litigations involving FDA-regulated products, including Diet Drugs, Baycol, Latex Gloves, Ephedra, Neurontin, and Tylenol.