Consumer Products Marketing

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ARNOLD & PORTER LLP

Court decisions, new and pending laws, and regulations arise every day affecting companies that produce and market consumer products. Our Consumer Products Marketing newsletter summarizes notable policy and regulatory developments, as well as court decisions, in the areas of consumer protection, Lanham Act, trademark, privacy, and consumer product safety. Our aim is to keep you informed of these issues with a concise overview of selected developments. Attorneys in all practice areas listed are available to answer any questions you may have in regard to any of these issues. To reach the editors for any reason, contact Randal.Shaheen@aporter.com.

Consumer Protection[1]

FTC Requests Comment on Limitations to Telemarketing Messages

The FTC has approved the publication of a Federal Register notice regarding two recent petitions requesting amendments to portions of the Telemarketing Sales Rule (TSR). A petition from Voice Mail Broadcasting Corporation (VMBC) asked the Commission to begin allowing pre-recorded telemarketing messages to consumers with whom the seller has an established business relationship. The FTC ultimately denied the petition after a notice of proposed rulemaking in November of 2004 yielded over 13,000 public comments opposing the amendment. The Commission cited widespread consumer opposition as one reason for the denial.

Additionally, a petition from the Direct Marketing Association (DMA) urged the FTC to modify the current method for calculating the allowable call abandonment rate under the TSR's safe haven provision. The Commission recently sought public comment on DMA's petition, as well as a new proposal to prohibit the use of pre-recorded messages in telemarketing calls that are answered by actual individuals.

The FTC amended the TSR in 2003 to allow for a provision limiting the number of telemarketing calls that can be "abandoned" without enforcement by the Commission. "Abandonment" occurs when an individual receives a call from a telemarketer, but there is no one on the line. The FTC has attempted to limit the amount of "hang-up" calls by amending the TSR to prohibit them, but also included a safe harbor provision. Under the safe harbor, a telemarketer is permitted to play a pre-recorded message when an individual answers, but only in three percent of calls.

In addition to denying VMBC's request to increase the scope of the safe harbor provision, the Commission also announced in the notice that it will begin enforcing the provisions against pre-recorded messages as cited in the TSR. The Commission had previously guaranteed that no enforcement action would

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be taken until the amendment was considered and the petition was ruled upon. Telemarketers have until January 7, 2007 to revise their calling practices and pre-recording mechanisms to conform with the original, rather than proposed, safe harbor provisions.

The Commission also proposed two new amendments related to TSR provisions. The first amendment makes it absolutely clear that the TSR prevents telemarketers from delivering pre-recorded messages when an individual answers the phone, except in very limited circumstances. Secondly, in response to DMA's petition, the Commission proposes an amendment that would change the method for calculating allowable call abandonment rates. The notice sought public comment on the proposal through November 6.

FTC Cracks Down on Deceptive Ads Targeting Hispanics

On September 27, the FTC announced the results of a Hispanic Multi-Media Surf that involved 60 partners from around the country, as well as consumer protection agencies from Colombia, Costa Rica, Mexico, Nicaragua and Panama. Participants in the Surf attempted to identify deceptive advertisements aimed at Hispanics in the areas of health, credit, and various types of business opportunities. The Surf resulted in FTC warning letters to over 165 advertisers and 77 media outlets, cautioning them that their ads may be deemed deceptive.

Participants in the Surf found that the majority of the potentially deceptive advertisements were related to health, specifically weight loss and disease cures. The Surf led the FTC to file a § 5 complaint against Natural Solution, Inc., which sells a dietary supplement that was advertised as effective in preventing and treating various forms of cancer. The supplement appeared in Spanish language infomercials around the country and, according to the FTC, used misleading statements, images, testimonials and medical endorsements. The FTC obtained a consent judgment to prevent the defendants from making such deceptive claims related to cancer treatment.

Additionally, the Surf revealed a significant number of targeted advertisements related to work-at-home offers and other business opportunities. Complaints were filed against QTX and several individuals for alleged violations of Section 5 of the FTC Act and the Telemarketing Sales Rule. The defendants advertised in local Spanish newspapers for a home business assembling small, decorative buildings. The FTC alleged that after consumers paid the company $110 to participate, the defendants failed to provide the necessary materials to build the models and ceased further communication with customers.

Finally, the Surf also discovered possible fraud related to advertisements offering credit and mortgages to Spanish-speaking consumers. An FTC complaint against Mortgages Para Hispanos.com led to a $10,000 payment for consumer redress; a bar on misrepresenting the terms, costs or conditions of mortgage loans; a requirement that brochures explaining mortgage loans be published in Spanish; and a $240,000 judgment that was suspended based on the company's inability to pay.

These cases were part of the FTC's Hispanic Initiative that began several years ago and was most recently discussed during the New York City Hispanic Fraud Prevention Forum. The commission vote authorizing staff to proceed with each case of alleged Section 5 violations was 5-0.

Hot Topics in Food Advertising

Fast food advertising continues to be a hot topic in advertising law. Below is a brief list of some recent developments:

- Consumer advocacy groups such as the Center for Science in the Public Interest ("CSPI") are continuing their campaign against quick service restaurants. CSPI alleges that these companies should conspicuously disclose the nutritional content of food products and post health warnings at the point of sale. CSPI recently has turned to litigation after it failed to obtain the regulations requiring such point-of-sale disclosure from the Food and Drug Administration, filing a case in the District of Columbia against KFC this summer and threatening to file suit against other restaurants.

[1] Arnold & Porter's Antitrust & Trade Regulation Group has extensive experience in consumer protection matters before the Federal Trade Commission (FTC), state Attorneys General, and the National Advertising Division. Members of our group include Bob Pitofsky, former FTC Chairman and Director of the Bureau of Consumer Protection; Mike Sohn, former FTC General Counsel; Bill Baer, former FTC Bureau of Competition Director; Debbie Feinstein, former Assistant to the FTC Bureau of Competition Director and Attorney Advisor; Randy Shaheen and Amy Mudge who collectively have practiced in this area for over 25 years. In our EU offices, Tim Frazer and Susan Hinchliffe have advised clients on numerous non-US consumer protection matters.

- In a September 16 Order in *Pelman v. McDonald's*, 2006 WL 2663214 (S.D.N.Y.), Judge Sweet denied McDonald's most recent motion to strike and/or dismiss the Complaint. In *Pelman*, consumers alleged that McDonald's failed to warn consumers about the dangers of sustained consumption of McDonald's food.

- The Children's Advertising Review Unit ("CARU"), of the Better Business Bureau, works with advertisers to ensure appropriate messages are relayed to young audiences. CARU is expected to release new guidance in the area of food advertising to children within the next six months.

- Senator Harkin (D-Iowa) has continued to express concern about a perceived link between food advertising and childhood obesity. He has attracted allies who are considering advertising legislation, and his efforts may increase if there is a change in leadership in Congress after the fall elections.

- As an outgrowth of concern on Capitol Hill about the alleged link between food advertising and the childhood obesity issue, on October 18, 2006 the FTC approved issuance of a notice requesting comments on a proposal to collect information from food and beverage companies and quick-service restaurants on marketing targeting children and adolescents. The notice may be found at http://www.ftc.gov/os/2006/10/P064504foodindmarketingchildrenFRN.pdf.

- On October 30, the fast-food chain KFC announced that it was phasing out trans fats in cooking its fried chicken and other menu items. The announcement came just before a New York City Board of Health public hearing on a plan to make New York the first US city to ban the use of trans fats by restaurants. According to the FDA, trans fats are so heavily used in cooking that the average American consumes 4.7 pounds of it every year. The hamburger chain Wendy's International, Inc. has already switched to zero trans fat oil. McDonald's announced that it intended to follow suit, but has yet to follow through.

Lanham Act Deceptive Advertising[2]

Lanham Act Plaintiffs: Don't Skip the Survey!

False advertising plaintiffs frequently do not want to endure the time and expense of conducting a proper consumer survey to support their claims. In virtually every instance, this view is short-sighted and will result in the defeat of implied falsehood claims. A recent Pennsylvania case provides an example of something even worse than failing to conduct a proper survey. In *Diamond Triumph Auto Glass, Inc. v. Safeway Glass Corp.*, 441 F. Supp. 2d 695 (M.D. Pa. 2006), the claimant's expert conducted no survey at all. Instead, she offered her "expert" opinion about how consumers would "likely" react based on her subjective opinion and review of depositions. The court had no difficulty awarding summary judgment to the opposing party. The court concluded that claimant was obligated to "demonstrate"—through scientifically designed survey data—"how consumers actually do react, not how they could react" in the subjective mind of the expert.

Closed-Ended Questions in Internet Survey Excluded

Astra-Zeneca v. Tap Pharmaceutical, 2006 WL 2338144 (D. Del. June 23, 2006) involved an alleged deceptive superiority claim for an acid reflux treatment. The court excluded TAP's survey responses to closed-ended questions when the open-ended questions suggested that only 11 percent of survey respondents may have been misled. The decision exemplifies a trend where courts are increasingly hostile toward leading closed-ended questions to support implied falsehood claims.

Standing: Not Just for Competitors?

It is a truism that the Lanham Act provides a cause of action for competitors—it is not a consumer protection statute and neither consumers nor other non-competitors purporting to vindicate consumer rights have standing to sue. A recent Oregon case, however, denied a summary judgment motion based on standing in a case where "each party offers different services to different customers." The court held that disputed facts prevented it from resolving the issue on summary

2 Arnold & Porter LLP attorneys have significant experience with Lanham Act deceptive advertising counseling and representing both plaintiffs and defendants in deceptive advertising litigation. The firm has represented companies and advertising agencies in diverse product areas (including some seminal cases in the pharmaceutical sector) and has handled both literal-falsehood cases and implied-falsehood cases, which require scientifically designed surveys. Attorneys in the firm with Lanham Act experience include Randy Miller, Chuck Ossola, Helene Madonick, Suzy Wilson, Randy Shaheen, and Roberta Horton.

judgment. The court went on to state that it could not exclude the possibility that the plaintiff could have standing "as a private attorney general seeking to vindicate the rights" of consumers. *Collegenet, Inc. v. XAP Corp.*, 442 F. Supp. 2d 1070 (D. Ore. July 17, 2006). This case clearly offers a minority view. Most Lanham Act litigants can expect that the issue of standing will be resolved by the time of summary judgment. Additionally, parties who are unable to demonstrate a competitive interest can anticipate losing their claim.

Trademark[3]

Fraud Cases Send Warning to Trademark Owners

Businesses should use caution in making statements before the United States Patent and Trademark Office ("PTO") following several Trademark Trial and Appeal Board (TTAB) decisions finding fraud in procuring a trademark registration. The three-year-old TTAB decision in *Medinol Ltd. v. Neuro Vasx, Inc.*, 67 U.S.P.Q.2d 1205 (TTAB 2003), gained attention recently when the full ramifications of the TTAB's strict holding became clear. In *Medinol*, the TTAB voided a US registration when the statement of use filed by the applicant identified goods that were included in the original application, but not actually in use when the statement of use was filed. The TTAB held that the applicant had committed fraud in procuring its federal registration by specifying products on which the trademark was not actually in use. The TTAB made a similar finding in *Standard Knitting Ltd. v. Toyota Jidosha Kabushiki Kaisha*, Opposition No. 91116242 (TTAB 2006), when it cancelled registrations on the basis of fraud in procurement because the marks were not in use on many items identified in the registration on the date the statements of use were filed.

Unlike patent applicants, trademark applicants have few clear guidelines regarding the scope of disclosures to the PTO. Several other TTAB decisions applying the new *Medinol* rule have been designated uncitable, leaving trademark owners and practitioners with limited guidance. Fraud in the procurement of a trademark registration has historically been a disfavored defense and difficult to prove. However, the Board's recent actions in the *Medinol* and *Standard Knitting* cases demonstrate an intent to hold trademark applicants and registrants to a strict standard when making verified statements to the PTO about the use of their trademark. Applicants now risk cancellation of entire registrations if they make inaccurate statements about the scope of use of a trademark during the prosecution of an application or maintenance and renewal of a registration.

The Board has sent a clear message that misstatements regarding use of a mark may constitute fraud, but questions remain about the full scope of disclosures necessary after the *Medinol* decision. Will applicants be able to use class headings in identifying goods or services? Will the holdings in these cases be used to evaluate whether an applicant had a *bona fide* intent to use a mark for each good or service identified in an intent-to-use application? For now, trademark owners must carefully review statements made in applications and renewal filings before the PTO.

New Trademark Dilution Revision Act Clarifies Some Issues While Raising Others

On October 6, President Bush signed the Trademark Dilution Revision Act into law. The main purpose of the Act is to overturn the 2003 Supreme Court decision of *Moseley v. V Secret* Catalogue, 537 U.S. 418 (2003). The *Moseley* case involved a small "adult" business located in a strip mall near Louisville, Kentucky called "Victor's Little Secret." The large lingerie retailer "Victoria's Secret" sued for trademark dilution. Dilution has previously been defined as "the lessening of the capacity of a famous mark to identify and distinguish goods and services." 15 U.S.C. § 1127 (2000).

The Supreme Court held that a plaintiff in a trademark dilution case must prove actual dilution, not merely a likelihood of dilution. The central criticism of the *Moseley* case revolved around the idea that by the time a plaintiff was able to show actual dilution, the damage to the mark and its reputation were already done. Critics claimed that the *Moseley* case set the standard of proof for dilution cases so high that it was practically unreachable for plaintiffs.

The new dilution law clarifies the requirements that plaintiffs must meet to maintain a valid cause of action for trademark dilution. Under the Act, the mere likelihood that a defendant's

[3] Arnold & Porter has extensive experience in all areas of trademark and domain name law, including emerging issues in the areas of federal dilution law and nominative fair use over the Internet. Members of the group include, in our DC offices: Chuck Ossola, Roberta Horton, and Anna Manville; and in our LA office: Suzy Wilson, Ron Johnston, and Jim Blackburn.

mark will cause dilution to the plaintiff's mark is enough for the case to proceed. This significant change in the law will no doubt re-energize the academic debate surrounding the recognition of the principle of trademark dilution in general.

A few of the highlights of the new legislation include:

1. The Act limits dilution claims to two categories: dilution by blurring or dilution by tarnishing. Some courts had previously hinted that there could be other bases for dilution other than blurring or dilution. The Act eliminates the potential for any other basis for dilution.

2. The Act forecloses the "niche fame" theory through its requirement that a famous mark be "widely recognized by the general consuming public of the United States." Based on this definition of "famous mark," a small number of marks will likely qualify for protection.

3. The Act includes a clarification of the fair use defenses, including protection for comparative advertising, parody, criticism, and "any noncommercial use of the mark."

The Act also addresses the burden of proof for trade dress dilution where the plaintiff's trade dress is not registered on the principal register. The Act requires the plaintiff to prove that the claimed trade dress is not functional and is famous on its own.

The new Act is meant to resolve several lingering issues that arose in courts throughout years of trademark dilution litigation. But even the Act's "clarifications" are subject to interpretation by the courts. For example, the Act lists several nonexclusive factors courts may consider when determining if a mark is "famous" and to determine if "blurring" has occurred. The courts will have to determine how these factors should be applied on a case-by-case basis. Furthermore, it appears that the new standards regarding when damages will be recoverable are unclear and may raise the prospects of large damages claims by the owners of famous marks where another company has clearly intended to trade on the association of the famous mark. The effects of the new legislation are largely unknown, but will no doubt raise interesting issues with regard to trademark dilution in the near future.

Privacy[4]

Phone Pretexting Under Attack by the FTC and Congress

The recent corporate spying scandal at Hewlett-Packard has placed "pretexting"—using false pretenses to obtain information about an individual or entity—in the public spotlight. The company's reported tactics for obtaining phone records of board members and journalists have raised new and serious concerns about the various ways in which personal information may be obtained and used without prior authorization. Although most agree that pretexting is morally and ethically wrong, there currently are no laws explicitly declaring the practice to be unlawful.

The Federal Trade Commission, however, is not waiting for enactment of such laws to challenge pretexting. Using its authority under Section 5 of the Federal Trade Commission Act to take enforcement action against unfair and deceptive trade practices, as well as its authority under the Gramm-Leach-Bliley Act to proceed against financial institutions that improperly handle nonpublic personal information, the Commission has initiated at least five pretexting actions in federal court. On October 5, the Commission announced the first settlement of one of these cases, *FTC v. Integrity Security & Investigation Servs. Inc.*, E.D. Va., No. 2:06-CV-241-RGD-JED (*consent order approved* 10/3/06). In that case, the Virginia-based company Integrity Security and Investigation Services (ISIS) was alleged to have used fraud to obtain personal telephone and credit information, which it then sold to other entities. Under the settlement agreement, ISIS is banned from obtaining or selling any confidential consumer records and must return the $2700 in profits it made by selling the information.

FTC officials have informed Congress that the Commission supports the passage of a federal telephone record pretexting

[4] Arnold & Porter's Privacy Team provides legal and strategic counsel to help clients meet their privacy obligations in a demanding, evolving, and competitive marketplace. Our attorneys have held significant senior government positions, including Jeff Smith, former General Counsel of the CIA; Bob Pitofsky, former Chairman of the FTC; Ron Lee, former General Counsel of the National Security Agency; Rick Firestone, Chief of the Common Carrier Bureau of the FCC; and Brian McCormally, former director of the Enforcement and Compliance Division of the Office of Comptroller of Currency. Others with extensive experience in this area include Nancy Perkins and Scott Feira in our DC office; Gregory Fant in our LA office; and Sarah Kirk in our London office.

law. In testimony before the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations, on September 29, Betsy Broder, Assistant Director of the FTC's Division of Privacy and Identity Protection, stated that the Commission would welcome a law giving the FTC the authority to assess civil penalties against defendants accused of phone pretexting. The agency currently lacks such authority and can only seek injunctive and restitutionary relief under Section 5, as it did in the ISIS case. Broder also said the Commission believes such a law would bolster the ability of the FTC to continue cracking down on defendants alleged to have obtained records through pretextual means.

Lawmakers from both parties appeared to be in agreement that outlawing the fraudulent acquisition of phone records ought to be a priority earlier this year. After an increase in media coverage regarding pretexting, four bills made it out of committee in March. Eventually, all four bills stalled, amidst concerns over the use of pretexting for gathering intelligence.

A bill approved by the House Commerce Committee in March (HR 4943) would have made it illegal to sell any phone records that were obtained in a fraudulent manner and would have allowed the FTC to impose civil penalties for pretexting. The measure was slated for floor action in May, but was pulled from the calendar due to competing priority legislation. In April, the House unanimously passed a similar bill (HR 4709) that creates criminal penalties for obtaining or disclosing personal phone records through fraud.

In the Senate, two bills were pending earlier this fall related to phone pretexting, however neither passed before the end of the session. Whether Congress will be in a position to pass anti-pretexting legislation in the lame duck session is unclear. But if it does not, the widespread media coverage of pretexting as a major problem will likely put pressure on Congress to move on such legislation next year. In the meantime, the FTC can be expected to continue to take an aggressive stance on the issue. Accordingly, companies and individuals should be on notice that the Commission will not hesitate to file charges of unlawful pretexting where fraudulent or unfair trade practices, or violations of personal privacy, can be proven to have occurred.

Consumer Product Safety Commission[5]

CPSC, Dell and Sony Recall Millions of Laptop Lithium-Ion Batteries

On August 15, 2006, CPSC, Dell, Inc. and Sony Energy Devices Corp. announced a recall of 4.1 million laptop computer lithium-ion batteries. The batteries reportedly were susceptible to an internal short that could lead to overheating and venting. The Dell/Sony recall alone was larger than *all* prior CPSC-led lithium-ion battery recalls.

This recall was quickly followed by an announcement on August 24 from Apple Computer, Sony Energy Devices Corp. and CPSC of a similar recall, this one involving 1.8 million laptop computer batteries. CPSC announced additional recalls of notebook computer batteries made by Sony in September and October.

CPSC has announced 42 battery recalls in its history (including recent recalls), and, although battery descriptions in its official pronouncements are not always very clear, it appears that approximately 26 of these have involved lithium-ion cells. Yet it was not until the Dell recall was announced that the popular press focused with detailed coverage on the benefits and risks associated with lithium-ion technology. The Dell recall was followed, for example, by lengthy articles in the *New York Times*, the *Wall Street Journal* and the *Washington Post* in which the technology was described, along with descriptions of its occasional risks.

These recalls came on the heels of a publicized hearing by the National Transportation Safety Board on July 12–13, 2006, in which CPSC and other federal agencies (and private parties) provided testimony about lithium-ion technology. The hearing concerned the investigation of a fire on a UPS cargo plane at the Philadelphia airport on February 7, 2006. Investigators are considering whether a load of lithium-ion batteries caused or exacerbated that incident.

[5] Arnold & Porter has several attorneys with broad experience on matters involving the U.S. Consumer Product Safety Commission, including two former General Counsels of the agency—Eric Rubel and Jeff Bromme—and Blake Biles, formerly with the Environmental Protection Agency. We take a proactive approach to product safety issues, helping clients establish and audit internal controls. We represent clients in CPSC enforcement actions, as well as in private litigation that can result from CPSC matters.

Lithium-ion batteries are ubiquitous. A large number of consumer products companies use this technology in a wide range of applications, including cellular telephones, PDAs, computers and other electronic equipment. The batteries are attractive because, among other reasons, they provide large amounts of power in a small, light package and are superior in this regard to competing technologies. The cells are primarily made in Japan, Korea and China.

Despite the growing focus on this technology, CPSC seems to have done very little original research in the field, and its staff with expertise in battery matters is small, probably not more than two or three individuals with core expertise. Last year, the CPSC announced that it had commissioned a study of the technology from the Naval Surface Warfare Center, but little has been heard of the results of that study. In the meantime, the agency is largely dependent upon industry-based voluntary standards organizations to police and develop the technology and upon companies to voluntarily report battery defects pursuant to Section 15 of the Consumer Product Safety Act.

FDA[6]

Tenth Circuit Provides FDA Potentially Powerful Mechanism for Policing Dietary Supplements

In August, the Tenth Circuit ruled that FDA has a potent new means with which to regulate potentially dangerous dietary supplements. In *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033 (10th Cir. 2006), the court upheld FDA's ban on the sale of all ephedrine-containing dietary supplements (EDS) in the United States. These products were being sold to aid in dietary weight loss. The ban was based on FDA findings that EDS posed serious health risks, including heart attack, stroke, seizures and even death, that were not reasonable in light of the limited benefits of EDS. The court upheld the agency's use of a risk-benefit analysis as well as the scientific evidence amassed by FDA to support its findings.

Regulation of dietary supplements is governed by the Dietary Supplement and Health Act (DSHEA). It authorizes FDA to remove "adulterated" supplements from the market. Under DSHEA, a supplement is considered "adulterated" if it contains any ingredient that "presents a significant or unreasonable risk of illness or injury." The agency concluded that the risks that EDS presented were "unreasonable" in light of the marginal contribution to weight loss and ordered EDS off the market. An EDS manufacturer sought to overturn FDA's order through judicial review under the Administrative Procedure Act. The United States District Court for Utah rejected FDA's analysis, saying that "unreasonable risk" under DSHEA did not anticipate a risk-benefit analysis. The Tenth Circuit reversed, allowing the ban to be implemented.

FDA began investigating EDS in the 1990s after receiving reports of serious side effects associated with using EDS products. The agency gathered data from a number of sources on the possible health effects of EDS, including a report commissioned by the National Institutes of Health and research compiled by a professor of pharmacology. After years of investigation, FDA first proposed (in June 1997) and, after several re-proposals, finally adopted (in February 2004) a regulation banning EDS at all dosage strengths based on the risk-benefit analysis described above.

The Tenth Circuit's decision opens the door to a host of questions regarding FDA's power in policing dietary supplements. For example, a number of dietary supplement ingredients have been tested in controlled studies and found no different in their effect than placebos. Does this mean that they have no benefits? In fact, most of these studies evaluated possible benefits of supplements in the prevention or treatment of a specific disease or condition (e.g., pain in osteoarthritis, depression). Dietary supplements, however, are not permitted to claim that they prevent or treat a disease, only that they "affect the structure or function of the body." Thus, these studies might not be pertinent, which begs the question: What research is scientifically valid to measure the "benefit" the product claims to bestow in "affecting the structure or function" of an individual?

A second issue concerns the level of risk that should trigger FDA action. Could FDA ban a supplement if it has any risks

[6] Arnold & Porter's Food, Drug and Medical Devices Group has represented a variety of companies in responding to inquiries from FDA and other agencies about advertising claims and other marketing activities, as well as worked on complaints to FDA and others regarding apparently violative conduct by competitors. Members of the group in our DC office include Bill Vodra, Arthur Levine, and Don Beers, each of whom previously were prominent lawyers at FDA; Dara Corrigan, former Acting Inspector General at HHS; Dan Kracov; Helene Madonick; Greg Levine; and Kathy Means (a Senior Health Care Policy Advisor).

at all, merely because it has no demonstrable health benefit? Should FDA act only if the risks are significant?

Even with this regulatory authority, FDA faces practical obstacles to exercising it. The appellate opinion relied on government and academic research on EDS to determine whether risks existed. That court was clear in its decision that the burden of proving risks associated with supplements lies squarely on the agency. FDA, however, might not be able to support similar research on many other supplement ingredients. Moreover, the time commitment for the EDS action was substantial; over nine years elapsed between the first formal proposal to ban EDS to the affirmation of the Tenth Circuit. Will FDA be willing to invest so much time in other, less risky dietary supplements?

Thus, the Tenth Circuit's decision undoubtedly left many administrative issues unanswered with regard to dietary supplement regulation under DSHEA.

FDA Approves Dispensing of Plan B Contraceptive Behind the Counter

On August 24, the FDA announced its decision allowing the emergency contraceptive, Plan B, to be available without a prescription for women 18 and older and men purchasing for their female partners. Women 17 and younger will still require a physician's prescription to obtain the drug from pharmacists. Barr Pharmaceuticals Inc. agreed to a voluntary accord proposed by the FDA to have the medication available only behind the pharmacy counter to ensure the age restrictions are followed. Barr applied for over-the-counter dispensing of the drug in 2003. The compromise by the FDA is viewed as at least a partial victory for both women's health and medical groups who vigorously supported the application.

The imposition of behind-the-counter dispensing of medication has added fuel to the debate as to whether the FDA should distinctly recognize a third class of drugs. Currently, the FDA maintains two classes of medications. Prescription drugs normally require a visit to a physician and must be dispensed by a licensed pharmacist. Conversely, over-the-counter drugs are freely dispensable to consumers without a pharmacist's consultation. Groups such as the American Pharmacists Association argue that the two classes are no longer adequate to classify the emergence of drugs that fall somewhere in between, such as Plan B. While consumers would not be required to present a prescription for behind-the-counter drugs, they must consult with a pharmacist before acquiring the medication.

Whereas many groups support the recognition of behind-the-counter medications, American drug companies have voiced concern regarding the effect such restrictions will have on sales. Requiring consumers to speak with pharmacists about potentially embarrassing products may hinder the sale and use of those drugs. The Consumer Healthcare Products Association has lobbied for the existing two-tired system to remain, stating that consumers should have the option of speaking with a pharmacist, but should never be required to do so unless the drug distinctly requires a prescription.

There are currently several drugs that remain dispensable only behind the counter, including smoking cessation aids and pseudophedrine. Plan B will soon join these medications in an intermediate position between the doctor's office and the supermarket shelves.

EU[7]

New Food Additive Legislation Synchronizes Current Laws

On 28 July 2006, the Commission proposed a new package of legislation on food additives, flavourings and enzymes. This would produce harmonised EU legislation for the first time and upgrade current rules on flavourings and additives to take into account scientific developments. The Commission's proposals also include establishing a centralised authorisation procedure for food additives, food enzymes and food flavourings that is based on risk assessments carried out by the European Food Safety Authority (EFSA).

Under the proposals, food additive legislation would be simplified to produce a single instrument dealing with principles, procedures and approvals. This aims to combine current legislation, including that on sweeteners, colors and other products. This would

[7] The practice areas of our London and Brussels offices, Arnold & Porter (UK) LLP, and Arnold & Porter (Brussels) LLP, include competition and EU law, litigation, telecommunications, information technology, intellectual property, corporate, biotechnology, pharmaceutical regulatory, product liability, and health care. The offices' clients include multinationals and European concerns ranging from start-ups to *Fortune 500* firms.

include a safety evaluation based on the scientific opinions of the EFSA for new products and the establishment of a re-evaluation panel for existing products. Genetically modified derived material would also require a separate approval.

An assessment of the existing Directive 89/107/EEC has led to the development of a specific proposal for food enzymes. The current framework only covers enzymes used as food additives and only two enzymes are authorised under this Directive. The remaining enzymes are not regulated at all or are regulated as processing aids under diverse legislation across the Member States. Harmonised rules across the Community are proposed to promote fair trading of the market in food enzymes and ensure protection of human health and consumers' interest.

New scientific and technological developments in the area of flavourings are also taken into account by the new proposals. These will replace the existing Directive 88/388/EEC on flavourings and update rules for use of flavourings, labeling and maximum levels to be allowed in products.