Consumer Products Marketing

Issue 14 Summer 2007

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, privacy, consumer product safety, FDA, and EU. 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 editor for any reason, contact Randal.Shaheen@aporter.com or Amy.Mudge@aporter.com.

Consumer Protection

FTC Issues Report on Children's Exposure to Television Advertising

Amid concern that food advertising is contributing to the rise in children's obesity, the FTC released a report on June 1 indicating that children's exposure to paid advertising has declined since 1977. Children's exposure to total paid advertising fell 7%, and exposure to food advertising fell 9%. In addition, the report noted that there is no evidence to support the view that advertising for low-nutrition foods has increased. The report was based on Nielsen Monitor-Plus/Nielsen Media Research data from 2004.

The report also provides some insight into the possible effects of restricting food advertisements directed at children. In 2004, children saw twice as many advertisements for sedentary entertainment as for food. The report thus notes that if food advertising is restricted, advertising for video games, computer games, DVDs, and other forms of sedentary entertainment might increase.

The FTC is also conducting a study on all methods of marketing foods and beverages to children and adolescents. On July 18, 2007, the FTC and the Department of Health and Human Services will host the "Forum on Marketplace Responses to Childhood Obesity." The forum is a follow-up to a similar workshop that was held in July 2005.

A copy of the advertising report can be found on the FTC's website at: http://www.ftc.gov/os/2007/06/cabecolor.pdf.

Repeat Offender Barred for Life from Telemarketing and Selling Business Programs

We have seen the FTC more frequently requiring consumer redress as part of a settlement with its Bureau of Consumer Protection. The FTC is also getting tougher on violators of consent decrees. In *FTC v. Neiswonger*, No. 4:96CV2225SNL, 2007 WL 1050714 (E.D. Mo. Apr. 23, 2007), a federal court in the Eastern District of Missouri issued a permanent injunction barring a marketer from ever promoting or selling any type of business program. In 1997, the FTC had ordered Richard Neiswonger to stop making false representations to

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customers and to disclose material information. Neiswonger had been telling customers that they could make six-figures if they purchased his business plan. He also gave the customers a list of references without telling them that the references were being paid for sharing their experience.

In response to Neiswonger's violation of that FTC order, the court barred him, for life, from telemarketing or from selling any type of business program. The court stated that the permanent bar was needed to protect the public from Neiswonger's "get rich" business programs.

The court also noted that the permanent bar might apply to Neiswonger's business partner and their firm even though they were not subject to the 1997 FTC order. The court found that William Reed and Asset Protection Group, Inc. (APGI) acted in concert with Neiswonger and had actual notice of the 1997 order. A hearing is scheduled for July 25, 2007 to decide whether the injunction will apply to Reed and APGI.

FTC and CPSC Sign MOU with Chinese Consumer Protection and Product Safety Agencies

On June 12, 2007, the FTC and China's consumer protection agency signed a memorandum of understanding to promote consumer protection cooperation. The two agencies agreed that they would share information regarding consumer protection issues and collaborate on projects and visits between the two countries. While the agreement is not legally binding and does not alter either country's consumer protection laws, it does signal that China and the US are beginning to coordinate their consumer protection efforts. Chinese companies wanting to market their products in the US should be attuned to these changes. As recent events have shown, consumer protection issues are beginning to take on international importance.

The US Consumer Product Safety Commission (CPSC) and its Chinese counterpart signed a similar agreement in 2004. This spring, the CPSC issued a China Program Plan that reiterates the agencies' commitment to ensuring that products coming from China are safe. The CPSC recently noted that a majority of its recalls this year have been of products made in China. The China Plan also seeks to educate Chinese manufacturers and other Chinese trade groups in strategies to improve the safety of Chinese consumer product exports and increase the rate of compliance of such products with CPSC's mandatory rules and applicable voluntary industry standards. For more information on the China Plan visit: http://www.cpsc.gov/BUSINFO/intl/china.html.

Anheuser-Busch Pushed by State AGs to Limit Marketing That May Be Attractive to Kids

State attorneys general continue their aggressive policing of the marketing of products intended for adult consumers. On May 18, 2007, Anheuser-Busch (AB) announced that it will stop the production of its alcoholic energy drink, Spykes, due to concerns that the beverage is attractive to underage consumers. A week earlier, 29 state attorneys general had sent a letter to AB criticizing the company for producing the energy drink.

This is the second time this year that several states have expressed concern over AB's advertising techniques. On February 15, 2007, 23 state attorneys general sent AB a letter asking that the company work harder to keep underage consumers from viewing its new Internet site, Bud.TV. Bud.TV contains streaming beer-themed shows, sports events, and commercials 24 hours a day.

The attorneys general criticized the age verification process, as well as the fact that Bud.TV content could easily be downloaded and spread across the Internet where underage youths would have access. The recent widespread distribution of Bud.TV's new short video "Swear Jar" across the net would seem to be an example of what the attorneys general were concerned about.

New York Attorney General Attacks Adequacy of Customer Service

On May 16, 2007, New York Attorney General Andrew Cuomo filed a complaint against computer maker Dell for allegedly

[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.

failing to provide services and for allegedly engaging in a number of deceptive business practices. The attorney general's office says they received over 700 customer complaints, and according to Cuomo, "at Dell, customer service means no service at all."

The complaint alleges, among other things, that Dell: failed to provide timely onsite repair to customers who purchased service contracts promising "onsite" service; pressured customers to repair their own computers when the customers had "onsite" repair contracts; and discouraged customers from seeking technical support by subjecting them to long wait times, repeated transfers, and frequent disconnections. Because many companies promise either expressly or implicitly to deliver good customer service, at least some of the Dell allegations raise interesting questions as to when purported lousy customer service becomes a violation of the law rather than just a business issue.

The complaint also accuses Dell of luring in customers with advertising for no-interest financing, when in reality almost every customer, even those with good credit scores, were denied the financing. In what the attorney general's office described as a classic "bait and switch" scheme, Dell would instead approve customers for financing at rates that often exceeded 20%.

Lanham Act[2]

"Tastes Like Sugar, Made from Sugar" Slogan Creates Substantial Monetary Exposure for McNeil

A recent battle between makers of artificial sweeteners illustrates a new trend where Lanham Act claimants are increasingly pursuing (and getting) money damages.

Merisant, the maker of "Equal," brought a Lanham Act false advertising case against McNeil, which makes "Splenda" and claimed that its product "tastes like sugar because it's made from sugar." Merisant alleged that "made from sugar" was a false claim. Initially, Merisant argued that although sugar is used in the manufacturing process, sugar is not an "ingredient" of Splenda, and therefore Splenda does not "contain" sugar as the slogan implied. At trial, Merisant emphasized a second and more powerful claim—that the "made from sugar" slogan was used by McNeil to falsely suggest that Splenda was more "natural" than Equal, an implied claim proven by survey evidence. Merisant sought almost $200 million in damages.

The judge previously denied summary judgment, clearing the way for a jury trial. Merisant's trial strategy was to take the jury through what the judge called "Splenda-gate," a purported scheme where McNeil used the "made from sugar" claim to lure consumers into thinking that Splenda was not the artificial, synthetic, and chemically manufactured product that it is (just like Equal and the other significant competitor, Sweet 'n Low), but was a more "natural and healthy" product compared to the competition. Merisant showed the jury internal marketing and market research documents that probably would seem typical and innocent to in-house marketers and their lawyers, but looked manipulative and sinister to a lay jury.

One of McNeil's key defenses was that Merisant knew about the "made from sugar" slogan, but waited four years to bring suit, during which time McNeil spent millions to develop the slogan. McNeil's legal theory was the equitable doctrine of "laches" *i.e.*, that Merisant unreasonably delayed in suing, and that the delay prejudiced McNeil, which had invested in the slogan. The court found that fact issues on the laches defense precluded summary judgment, and Merisant used McNeil's presentation of the defense to the jury to its advantage, telling the jury that "they want you to let them continue deceiving customers because we didn't catch them soon enough."

Things went badly at trial for McNeil, and the parties settled during jury deliberations after the jury requested damages-related exhibits to aid their deliberations. According to press reports, jurors interviewed after trial said that they were prepared to hit McNeil with a substantial money damages

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.

award. The parties continue to battle, with Merisant alleging that McNeil has failed to abide by the settlement agreement.

For a reprint of a recent article describing the change in Lanham Act law clearing the way for more money damages claims, please email Randall.Miller@aporter.com.

Privacy[3]

Privacy Concerns Surround Google's Acquisition of DoubleClick

Google's proposed acquisition of Internet advertising firm DoubleClick has sparked heated debate about how companies retain and use consumer data collected online. On April 20, 2007, the Electronic Privacy Center (EPIC), the Center for Digital Democracy, and the US Public Interest Research Group, filed a complaint with the FTC asking the agency to investigate personal privacy issues allegedly raised by Google's acquisition of DoubleClick.

The complaint, which is supported by the New York State Consumer Protection Board, alleges that the acquisition will put Google in a unique and potentially threatening position. Google is the largest Internet search engine in the United States, and DoubleClick is a leading provider of Internet-based advertising. By combining with DoubleClick, the complaint claims, Google would gain access to more information about the Internet activities of consumers than any other company in the world. Although the complaint does not specify precisely the types of harm that might result from such access, it alleges that consumers are at risk because Google does not clearly inform customers about how it uses and collects data—which, the complaint alleges, constitutes an unfair trade practice in violation of Section 5 of the Federal Trade Commission Act.

The complaint comes at a time when Google is also dealing with privacy concerns in Europe. In May of this year, EU data protection authorities demanded that Google explain its data collection and retention polices, as well as how the company was complying with EU data protection rules generally. On June 10, 2007, Google announced that it would anonymize user data after eighteen months, thereby addressing at least one aspect of the EU's concerns. Additional concessions, however, may be required or volunteered.

Although the current privacy concerns focus principally on Google, DoubleClick has been the subject of similar concerns in the past. In 2000, EPIC filed a complaint against DoubleClick for unlawfully tracking the online activities of Internet customers. In response to the complaint, the FTC launched an investigation. No charges were filed, but the FTC announced that DoubleClick had agreed to disclose its tracking techniques in a privacy policy accessible to the public.

It is likely that the consumer groups are looking for similar concessions from Google—at the very least, for Google to disclose its privacy practices more clearly. Any such policy has significant legal implications, for the FTC has challenged noncompliance with a posted privacy policy as a violation of Section 5 of the FTC Act.

While the Google/DoubleClick merger is a unique situation because of the nature of the two companies' Internet presence, the privacy concerns raised in connection with the deal should alert all companies to the increasing scrutiny being focused on online data privacy. Any company with a website that tracks or collects consumer information should carefully consider the disclosures in its privacy policy regarding its use of and right to disclose such information.

Ambiguity in Fair and Accurate Credit Transaction Act Spurs Hundreds of Lawsuits

Since December 2006, more than 100 lawsuits have been filed nationwide against retailers for violating the Fair and Accurate Credit Transaction Act (FACTA). FACTA, which was enacted in 2003 as amendments to the Fair Credit Reporting Act (FCRA), is designed in part to prevent identify theft by requiring more stringent protection for personal financial information. The FACTA provision at issue in the recently filed lawsuits

[3] 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.

requires retailers to limit the amount of information printed on customers' credit and debit card receipts.

The pertinent FACTA provision states that "no person that accepts debit or credit cards for the transaction of business shall print more than the last five digits of the card number or the expiration date upon any receipt provided to the cardholder." This provision, which became effective in December 2006, is arguably unclear as to whether a retailer can print *either* the last five digits of the card number *or* the expiration date, or whether a retailer is forbidden from printing *both* more than five digits of the card number *and* the expiration date.

Many retailers thought that they had a choice: print either the last five digits of the card number or the expiration date. But according to a recent FTC publication, they were wrong. The FTC publication states: "You may include no more than the last five digits of the card number, and you must delete the card's expiration date." Thus, the FACTA obligation is now clear.

The FTC's guidance came too late, however, to prevent plaintiffs' attorneys from filing hundreds of class action lawsuits against retailers who, between December 1, 2006 and the recent release of guidance, apparently were uncertain of their responsibilities under the FACTA provision. Even retailers whose prior failure to comply with both requirements did not cause any actual consumer harm are nevertheless subject to claims for vast statutory damages for allegedly "willfully" violating the FACTA.

The adjudication of these lawsuits will be influenced by the US Supreme Court's recent decision in *Safeco Insurance Company of America v. Burr*, in which the Court held that a "willful" violation of the FCRA exists when a person acts with "reckless disregard" for the law. 127 S. Ct. 2201 (2007). Under this standard, the retailers may be liable even if they did not violate the law knowingly, but were "grossly negligent" by acting "recklessly" with respect to it. The Supreme Court held that a company does not act in "reckless disregard" of the FCRA if its action was consistent with a "reasonable reading of the statute's terms." Thus, a key question in the retailer suits will be whether the ambiguity in the statute's text was sufficient to justify the retailers' assumption that the FACTA provision allowed them to print *either* the expiration date *or* the last five digits of the card number.

Even without the Supreme Court's guidance in *Safeco*, at least one court found grounds for denying class certification in one of the pending cases against retailers, which effectively may end that suit and have potential ramifications for others. In *Spikings v. Cost Plus, Inc.*, No. CV 06-8125-JFW (C.D. Cal. May 23, 2007), the court held that class certification would be "inappropriate" where the plaintiffs were not harmed and the penalties imposed under the statute (as much as $3.4 billion) would be disastrous to the retailer. The court also seemed to question the motives of plaintiffs' counsel when it noted that the "potential for abuse is an additional reason" for not certifying a class action. It remains to be seen whether other courts will take a similar "reality-based" approach in the other pending cases.

CPSC[4]

President Bush's Nominee to Head CPSC Withdraws

On May 23, Michael E. Baroody withdrew his nomination to be chairman of the CPSC. Baroody, an executive vice president of the National Association of Manufacturers, had come under fire from consumer advocacy groups for what they argued were close connections to manufacturers. The opposition against him increased in the weeks leading up to the confirmation hearing, when reports circulated that the National Association of Manufactures was giving Baroody a $150,000 severance package. Baroody's Senate confirmation hearing was set for May 25, but the White House said that some members of the Senate had rushed to judge him and that it became evident he would not be confirmed. The White House has not announced a timetable for selecting a new nominee.

Without a chairman, the CPSC lacks a voting quorum. Former Chairman Hal Stratton resigned in July 2006, leaving the three-member agency with just two commissioners. The agency's authorizing statute allows for a two-commissioner quorum for up to six months, but that period expired on January 15,

[4] 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.

2007. Without a quorum, the CPSC cannot take official action on important issues such as rulemaking proceedings, setting civil penalties, and initiating litigation.

Shortly before the quorum expired, on December 11, 2006, the CPSC granted a petition from the Sierra Club to begin rulemaking proceedings regarding the amount of lead in children's jewelry. But until a new chairman is confirmed, the agency will be unable to advance this or other rulemakings or otherwise attend to its regulatory agenda. That agenda includes such issues as addressing the safety hazards of all-terrain vehicles and infant pillows and issuing an interpretive rule that explains the factors that will be considered by the staff in evaluating the appropriateness of civil penalties.

Senator Mark Pryor (D-AR), the chairman of the Consumer Affairs Subcommittee of the Senate Commerce Committee, has introduced an amendment in an unrelated bill that would extend the two-person quorum for an additional six months. The bill (S.4) passed the Senate on March 20, 2007, but it is stuck in conference negotiations with the House. The six-month period would begin on the enactment date of the bill.

The day-to-day functions of the agency are continuing. On January 12, 2007, the remaining two commissioners voted to delegate some of their authority to the staff, including the ability to conduct voluntary recalls. In the past few weeks, the CPSC has issued several voluntary recalls on various products, including children's jewelry, a ceramic cooktop, cribs that contain incorrect assembly instructions, and children's clothing.

FDA[5]

FDA Requests Information on Nanoscale Zinc Oxide and Titanium Dioxide in Sunscreens

On February 22, 2007, the FDA published a notice requesting information on insect repellent products that contain over-the-counter sunscreen ingredients. Included in the request was a call for information concerning the safety of nanoscale zinc oxide and titanium dioxide. This request presents a potentially significant development in FDA's consideration of the safety of nanomaterials used in cosmetics and personal care products.

Nanotechnology generally refers to the process of reducing particles to sizes as small as a nanometer (one-hundred-thousandth the width of a human hair). Nanoscale particles sometimes have different characteristics than their larger-scale counterparts. For example, zinc oxide used in sunscreens normally appears as a white, opaque substance. When the zinc oxide is reduced to nanoscale, however, the ingredient becomes transparent. Because transparent zinc oxide is more asthetically acceptable to consumers, it might lead to increased use of sunscreens, decreasing consumers' exposure to the harmful effects of the sun.

The same unique properties that make nanomaterials beneficial have also led to questions about their safety. In May 2006, a group of public interest organizations led by the International Center for Technology Assessment (ICTA) petitioned FDA to amend its over-the-counter drug sunscreen monograph to regulate nanoparticles—including, specifically, nanoparticles of zinc oxide and titanium dioxide—as separate ingredients from their larger counterparts and to declare them "new drugs" requiring affirmative FDA approval prior to marketing. The ICTA petition claims that nanoparticles of these and other ingredients are capable of penetrating the skin and circulating throughout the body, leading to unknown potential for harm.

In promulgating the sunscreen monograph in 1999, FDA considered whether "micronized" forms of zinc oxide and titanium dioxide raised different questions of safety or effectiveness and chose not to treat them differently than their larger counterparts. FDA's call for a new round of comments on what is essentially the same question suggests that the agency is reconsidering its earlier conclusion. The odd shoehorning of this call for comments within a notice on insect repellents used in sunscreens suggests that it may have been done in response to the ICTA petition.

[5] 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).

In what also may have been a response to the ICTA petition, FDA created a Nanotechnology Task Force in August 2006. The Task Force held its first public meeting on October 10, 2006, and its initial report is expected in July. The Task Force report may provide further insight into the agency's thinking on the use of nanotechnology in cosmetics and personal care products.

To read more about legal issues relating to nanotechnology, please visit the Arnold & Porter website at: http://www.arnoldporter.com/practice.cfm?practice_id=128.

Legislation on Direct-to-Consumer Prescription Drug Advertising

In recent years, various Members of Congress and advocacy groups have criticized FDA for weak enforcement relating to direct-to-consumer (DTC) advertising, and DTC concerns have become a significant focus of the ongoing debate over FDA funding and drug safety legislation. While industry has cited the voluntary Pharmaceutical Research and Manufacturers of America (PhRMA) *Guiding Principles on Direct-to-Consumer Advertisements* as obviating the need for DTC-related legislative action, recent events, such as warning letters and consumer group complaints about advertising, have kept the concerns at a high level.

On May 9, 2007, the Senate passed S. 1082, the "Food and Drug Administration Revitalization Act" (FDARA), by a vote of 93-1. The bill includes provisions that would create new FDA authorities—as well as a new review process—relating to DTC advertising. The House is expected to consider counterpart legislation shortly, with conference on and passage of FDARA likely prior to the August recess. The legislation could change substantially before enactment.

A. PDUFA Reauthorization and Voluntary DTC Broadcast Advertising Reviews

On January 16, 2007, the FDA published in the *Federal Register* proposed draft recommendations to Congress for the fourth reauthorization of the Prescription Drug User Fee Act (PDUFA) program. These recommendations are based on statutorily required negotiations between FDA and industry. Among other proposals, FDA recommended creation of a separate new user-fee program to collect fees from companies that voluntarily seek FDA advisory reviews of their DTC television advertisements. The recommendation was included in the FDA PDUFA package transmitted to Congress.

The FDARA legislative text incorporates FDA's PDUFA recommendations. Under Section 736A of S. 1082, the Secretary is authorized to collect user fees for the new program beginning in FY2008 (October 1, 2007). The program sunsets in FY2012. The user-fee program will focus only on new advertisements; user fees will not be used to fund reviews of existing advertisements. The annual revenue target for the program is $6.25 million, which will be adjusted for inflation and workload (if needed) each year. No fees will be assessed if the sponsor is required to submit the advertisement to FDA for pre-review as part of a proposed Risk Evaluation and Mitigation Strategy (REMS) program described in S. 1082 (discussed below). The program will be terminated if available funds are less than $11.25 million in FY2008. In subsequent fiscal years, the program will be terminated if funds are less than $9 million.

The funding mechanism has two parts—an annual fee for advisory reviews and an operating reserve fee.

- *Advisory Review Fee* – The fee amount will depend on the total number of submissions each year. PhRMA has estimated that the fees will likely range from $40,000 to $60,000 per submission. To calculate the fee, FDA will issue a *Federal Register* notice 120 days before the start of each fiscal year, asking manufacturers to identify the number of advertisements that they plan to submit for advisory review during that fiscal year. The response will be considered a commitment to pay the fees, and FDA will then calculate the fee based on the number of submissions. FDA must announce the fees in the *Federal Register* 60 days before the fiscal year begins. The fee per submission may not exceed $83,000 in FY2008 and in subsequent years may not be more than 50% more than the previous year. Fees will not be refunded under any circumstances. If companies submit more advertisements than they initially reported, they will be assessed a 50% fee penalty. Only one uncompleted review can be "carried over" annually.

- *Operating Reserve Fee* – The operating reserve fee must be paid only in the first year that the sponsor participates in the program. The reserve fund fee is equal to the number

of reviews anticipated by the sponsor multiplied by the advisory review fee. At the end of the program, reserve fund fees will be refunded on a *pro rata* basis to each applicant that paid a reserve fee. FDA has stated that the operating reserve fees are necessary to ensure year-to-year stability in resources, including review staff.

The fees will fund 27 new full-time equivalent employees (FTEs) for FDA pre-market advisory review. Eight FTEs currently review advertisements. If excess resources result, FDA may use the funds for advisory review of other media, such as print advertisements, but not for activities such as enforcement. The proposed performance goals transmitted to Congress with the PDUFA IV recommendations establish staggered metrics for the program's performance. In FY2008, 50% of 150 original review submissions will be reviewed within 45 days, and by FY2012, 90% will be reviewed within 45 days. For resubmissions, FDA will review 50% of 75 resubmissions within 30 days in FY2008 and 90% of resubmissions in FY2012.

B. DTC and Risk Evaluation and Mitigation Strategies (REMS)

S. 1082 would also address DTC as part of the institution of a new Risk Evaluation and Mitigation Strategy (REMS) framework for addressing drug safety concerns. S.1082 states at Section 505(o)(7)(A)(ii)(I)(aa) that "the Secretary may require that an applicant for a drug submit a proposed [REMS] for a drug if the Secretary [or the responsible FDA office] determines that, based on a signal of serious risk with the drug, a [REMS] is necessary to assess such a signal or mitigate such a risk." "Signal of serious risk" is defined as "information related to a serious adverse drug experience derived from (1) a clinical trial; (2) adverse event reports under subsection (k)(3); (3) routine active surveillance under subsection (k)(3); (4) a postapproval study…or; (5) peer-reviewed biomedical literature."

Under S. 1082, there are four circumstances that may lead a sponsor to submit a REMS for an approved drug:

- Sponsors may voluntarily submit a REMS at any time.
- The Secretary (acting through the office responsible for reviewing the drug or overseeing postmarket safety) determines that information or data included in a supplemental application requires a sponsor to undertake a REMS element such as post-approval studies, dissemination of Medication Guides, pre-review of or limits on DTC advertising, or restricted distribution and use.
- The Secretary (or responsible office) may order a REMS proposal within a specified timeframe (not less than 45 days) if new safety information indicates that the labeling should be changed or REMS elements described above (except restricted distribution and use) are needed.
- The Secretary (or responsible office) may order that a REMS proposal be submitted within 90 days if new safety information indicates that a drug should have use or distribution restrictions.

S. 1082 would include potential restrictions on DTC advertising as part of the REMS program. Among other requirements, under a REMS, FDA may require sponsors to:

- submit advertisements for pre-review (separate from the user-fee program) not later than 45 days before dissemination of an advertisement;
- disclose serious risks listed in the labeling or describe protocols for safe use (as described in the labeling) in the advertising.

Another provision requires that the "major statement" included in every DTC broadcast ad must be stated in a "clear, conspicuous (neutral) manner." FDA would be required to promulgate regulations to establish standards to determine "neutral manner." The legislation passed by the Senate also establishes civil penalties for dissemination of DTC advertisements that are false and misleading. No penalty shall apply, however, if the applicant submitted the advertisement to the Secretary and incorporated any comments received.

Initial versions of S. 1082 included FDA authority to require a moratorium of up to two years on DTC advertising of a drug under a REMS. During floor consideration of S. 1082, an amendment eliminated the two-year moratorium. Although the current House bill excludes an initially proposed three-year moratorium and instead includes increased civil penalties, there will undoubtedly be attempts to resurrect the moratorium authority as the legislation moves toward enactment.

C. Prospects and Likely Impact

It is generally acknowledged that PDUFA is "must pass" legislation because user-fee funding remains essential to the funding of the FDA drug review process and PDUFA will sunset by October 1, 2007 if not reauthorized. Thus, it is highly likely that PDUFA will serve as a vehicle for passage of drug safety legislation. The legislation will likely include some safety-based authorities with respect to DTC advertising, as well as the negotiated, voluntary broadcast DTC review system.

With respect to broadcast DTC advertising, the voluntary review system may become the standard approach to FDA review of such advertising, with many manufacturers seeking what is essentially an enforcement "safe harbor." Although the FDA review should be relatively speedy given the number of FTEs devoted to such reviews, the scrutiny will come at a steep price.

To the extent products present safety issues that bring them within what will likely be a REMS-based drug safety construct, DTC advertising could be subject to both additional safety-related disclosures and restrictions. Often these will be "voluntary" restrictions that companies will agree to in the course of REMS negotiations. The consequences of DTC enforcement could also be more significant in the future, in that drug safety legislation will likely include civil monetary penalty provisions, although FDA has limited resources to pursue such civil penalty processes.

In general, the current administration has been a high-water mark of tolerance for DTC advertising and related commercial speech concerns. The passage of this legislation will likely mean the beginning of an era of increased DTC scrutiny and enforcement.

EU[6]

UK Office of Fair Trading ("OFT") Publishes New Findings on Internet Shopping

The OFT recently published the results of an exploratory investigation under Section 5 of the Enterprise Act 2002 into the current state of online shopping. The report noted that many businesses are unaware of their obligations under the Distance Selling Regulations (DSRs) and 2002 Electronic Commerce Directive that are designed to protect online shoppers from fraud, security threats, and privacy threats.

The detailed report assesses the increased number of security risks in the purchase of products online. With the recent rapid growth of online shopping and public concerns regarding online security, the report assures consumers that the OFT is working with online organizations to curb such threats and encourages the industry to self-assess and ensure that it is complying with applicable legislation. The report notes, however, that some UK legislation is in need of modernization to be commensurate with comparative European laws. Some modernization has already been achieved through the recent implementation of the Consumer Protection Co-Operation Regulations and Consumer Protection from Unfair Trading Regulations 2007 (CPR), in addition to the launch of a national Local Better Regulation Office.

Among the proposals put forward by the OFT, to be developed over the next six months, are new initiatives to implement forward-looking strategies for online shopping. These initiatives will include tighter working associations with Trading Standards Services, consumer groups, businesses, and other public bodies in order to determine how to improve future enforcement of online consumers' rights as well as developing a strategy to raise awareness of these rights. Other proposals include programs to ensure that businesses have access to succinct information and advice about selling online (for example identifying the location of a trader and resolving problems from cross-border purchases online), advice to shoppers on how to protect themselves from security and privacy threats, and initiatives to improve compliance and enforcement to make the Internet a safer harbor for buying and selling.

The OFT points out several recent developments relating to the prevention of fraud and security online, for example through the

[6] 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.

enactment of the Fraud Act 2006. Other recent developments include: (1) a review of the EU Consumer Acquis, with the intention of harmonizing and modernizing consumer protection laws; (2) the planned introduction in April 2008 of EU principle-based regulation for business-to-consumer transactions (which will repeal existing UK business-to-consumer legislation); (3) a second review of the Electronic Commerce Directive; (4) the introduction of a European Small Claims Procedure (to be finalized later this month), which will make it easier to resolve cross-border cases; and (5) the introduction of a Directive on Payment Services that will establish a legal framework to simplify and improve the security of online cross-border payments.

The full market study is available at http://www.oft.gov.uk/advice_and_resources/resource_base/market-studies/internet.

License to Sell? The New Rules on Product Placement

New rules proposed in the draft Audiovisual Media Services Directive will provide for the use of product placement throughout the EU. The proposed legislation, which will replace the Television without Frontiers Directive, will permit product placement subject to the following restrictions: (1) the content and scheduling of programs must not be influenced by the product placement in a way that affects the responsibility and editorial independence of the media service provider; (2) the purchase or rental of goods or services must not be directly encouraged by the program; (3) undue prominence must not be given to the product in question; and (4) viewers must be clearly informed of the existence of product placement (e.g., before and after the program and after commercial breaks).

More detail can be found in our recent advisory available at http://www.arnoldporter.com/pubs/files/A&PCA-LicencetoSell-TheNewRulesOnProductPlacement_062107.pdf.