COMMITMENT | EXCELLENCE | INNOVATION

ARNOLD & PORTER LLP

Issue 18, Fall 2008

Consumer Products Marketing Newsletter

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 government regulation and enforcement, competitor challenges, consumer litigation, trademark, privacy, US Food and Drug Administration (FDA), consumer product safety, and European Union (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.

In order to provide our clients and readers with more timely, easier to digest content related to the regulation of consumer marketing, advertising, and promotional activities, Arnold & Porter LLP has created the Consumer Advertising Law Blog available at http://www.consumeradvertisinglawblog.com.

We encourage you visit the blog, and our consumer advertising attorneys look forward to any feedback on how we can make this newsletter and the blog more relevant to the issues you face. To reach the editors for any reason, contact Randall Shaheen (Randal.Shaheen@aporter.com) or Amy Mudge (Amy.Mudge@aporter.com).

GOVERNMENT REGULATION AND ENFORCEMENT[1]

FTC Performance Report for 2008—Looking Behind and Looking Ahead

In November 2008, the Federal Trade Commission (FTC) released its Performance and Accountability Report for Fiscal Year 2008. The report details the FTC's current consumer protection mission and identifies potential problems and trends, as well as summaries of the FTC's performance results. The FTC exceeded all of its 2008 consumer protection targets.

Within the strategic goal of protecting consumers, the FTC's first objective is to identify fraud, deception, and unfair practices that cause the greatest consumer injury. The FTC sought to reach this goal by raising the percentage of the agency's consumer protection law enforcement actions that are responsive to consumer complaint information gathered by the FTC. In 2008, 71%, or 61 out of 81 of the agency's actions were responsive to consumer complaint information, exceeding the FTC's target of 65%. The agency shared more than 12.2 million consumer fraud, identify theft, financial, and Do Not Call Registry complaints it collected through 2008, including 3 million complaints collected in 2008 alone, with more than 1,700 national and international law enforcement organizations. The FTC also increased its focus on fraud in the mortgage market and consumer credit lending sector; we expect this focus to continue and grow with the current financial situation and the new administration.

The FTC's second objective is to stop fraud, deception, unfairness, and other unlawful practices through law enforcement. The FTC successfully prevented US$474 million of economic injury to consumers through law enforcement, exceeding their 2008 target by US$74 million and well on

TABLE OF CONTENTS

their way towards their five-year target of US$2 billion. The FTC continued to monitor the deceptive marketing of health products, including the widely publicized example of Airborne Health, Inc. Airborne reached a US$30 million settlement agreement with the FTC regarding charges that it did not have adequate evidence to support the advertising of the Airborne tablet as cold prevention and treatment. The FTC also noted the importance of publicizing its law enforcement actions in order to alert consumers to fraudulent and deceptive practices, as well as educate them while deterring similar behavior by other potential violators. We expect to see even more aggressive enforcement and higher consumer redress and/or penalties with President-elect Obama in office, particularly in areas where the FTC has encouraged self-regulation rather than focused on enforcement.

The FTC's third objective is to prevent consumer injury through education. The FTC noted the importance of education in giving consumers the tools they need to spot potentially fraudulent promotions as well as helping businesses comply with the law. The FTC tracked the number of times the print media published articles referring to FTC consumer protection activities as well as the circulation of media that publishes those articles. In 2008, the FTC exceeded its target with 3,100 articles referencing consumer protection with an average circulation of 791 million. The report noted that many major news outlets published the FTC's report on "Marketing Food to Children and Adolescents." The FTC also sought to reach the growing population of Hispanic consumers in the US by expanding its Hispanic Outreach Program, which includes a Spanish-language page on the FTC's website as well as translations of consumer publications.

1 Arnold & Porter's antitrust & trade regulation group has extensive experience in consumer protection matters before the 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.

The FTC's fourth objective is to enhance consumer welfare through research, reports, advocacy, and international cooperation and exchange. In 2008, the agency participated in 16 workshops and conferences on novel or challenging consumer protection problems or issues. To address concerns in the area of "green" marketing, the FTC held a series of three public workshops on environmental marketing claims. The workshops focused on carbon offsets and renewable energy certificates, green packaging, and the development of environmental building products, as well as consumer perceptions of those developments. The FTC also increased the number of enforcement matters with cross-border components in which it cooperated with foreign government agencies, with 46 matters in 2008, compared to 23 in 2007.

Finally, the FTC continued to provide consumer protection-related policy or technical input to foreign government agencies or international organizations in 2008.

The FTC Performance and Accountability Report for Fiscal Year 2008 is available at http://www.ftc.gov/opp/gpra/2008parreport.pdf. The FTC Performance Plan for Fiscal Years 2007-2008 is available at http://www.ftc.gov/opp/gpra/cbj_2008_performance_plan.pdf.

Funds Underlying Most Prepaid Cards Are FDIC-Insured

The Federal Deposit Insurance Corporation (FDIC) issued a General Counsel's Opinion (Opinion) on November 13, 2008 (http://edocket.access.gpo.gov/2008/pdf/E8-26867.pdf), clarifying that funds underlying many types of prepaid card products are considered "deposits" that are covered by FDIC insurance. The products covered by this Opinion include payroll cards, government benefit cards (such as welfare cards or child support payment cards), general spending cards, and gift cards issued by banks and thrifts with either the VISA or MasterCard logo on them. These cards have proliferated in recent years, and indeed, have become deposit account substitutes for millions of Americans. The only cards not covered are merchant-issued gift cards, such as prepaid

telephone cards, whose funds are not deposited into financial institutions for the benefit of the cardholders.

The FDIC attempted to address this issue before, and indeed had issued a previous General Counsel's Opinion in 1996 on stored value cards. However, that opinion was generally considered unnecessarily complicated and created even more confusion as to which types of cards could potentially be covered by FDIC insurance. This new Opinion clarified the issue, stating that any prepaid card product in which the funds underlying the cards are placed at an insured depository institution will be FDIC-insured. That means that most prepaid card products, other than store gift cards, potentially will be insured to the maximum allowed by law.

There are consequences to this determination to both banks and issuers of covered prepaid card products.

- First, any funds underlying these cards will be subject to FDIC insurance assessments. Depending on how banks have accounted for the funds underlying these cards previously, that may or may not be a material change.
- Second, the issuers of the prepaid cards will have to disclose that the funds underlying the cards are FDIC-insured. Indeed, the Opinion states that information concerning FDIC insurance coverage be displayed on the card itself, along with the name of the depository institution in which the funds are held.
- Third, providing separate insurance to each cardholder, as contemplated by the Opinion, requires that either the issuer or the financial institution follow certain rules, called "pass-through" insurance rules. These rules require that the funds underlying the card be placed in a custodial account for the benefit of the cardholders. Furthermore, either the bank or the seller of the card needs to maintain records that disclose the identity of each cardholder and the amount owned by each holder at any time. While this type of recordkeeping or accounting process is common for certain types of prepaid cards, such as payroll cards or government benefit cards, they are less common in gift cards, including those issued by banks. This may require some banks to institute appropriate recordkeeping processes to provide the FDIC insurance benefit to each cardholder. Of course, instituting such processes to the extent they are not already in place, may increase the costs of the products.

Regardless, this is a positive development, particularly to those who hold and use prepaid cards, such as payroll, government benefit, or general use cards for their daily cash needs. It also provides long-awaited clarity to issuers of cards on the applicability of FDIC insurance to their products.

CONSUMER LITIGATION[2]

Thorogood v. *Sears, Roebuck & Co.*

In October 2008, the Seventh Circuit reversed class certification in *Thorogood* v. *Sears, Roebuck & Co.*, 2008 WL 4709500 (7th Cir. 2008). The plaintiff bought a Kenmore-brand clothes dryer from Sears that had the words "stainless steel" imprinted on the dryer; however, the inside of the dryer was not made entirely of stainless steel. The non-stainless steel part of the drum allegedly rusted and stained the plaintiff's clothes. The plaintiff filed a class action suit on behalf of himself and other purchasers claiming that the representation that the dryer contained a stainless steel drum violated various state consumer protection statutes.

In decertifying the class of consumers, the court noted the various problems associated with the class action mechanism, particularly the conflict of interest between the class and class lawyers, the enhanced risk of costly error, the sometimes enormous pressure for a defendant to settle, and the tendency of claims brought in a federal class action based on state law to undermine federalism. Based on these problems, the court suggested caution in class certification

2 Arnold & Porter attorneys have significant experience with consumer fraud and deceptive advertising class action litigation. The firm has represented a variety of companies in numerous consumer class actions, including cases involving product safety, technology issues, and banking. These actions often turn on whether the advertising or statements at issue are subject to a single understanding. Attorneys in the firm with consumer class action experience include Angel Garganta, Randy Miller, Sean Morris, Trent Norris, Eric Rubel, and Suzy Wilson.

generally, and noted that this case was a particularly weak candidate for certification. There were no common issues of law or fact, and there was no proof that the other members of the class held the plaintiff's views that when a dryer is labeled or advertised as having a stainless steel drum that this implies that the drum is 100% stainless steel or that it might prevent rust stains on clothing. The court particularly relied on the fact that Sears did not advertise the stainless steel dryers as eliminating rust stains or even providing protection against rust stains on clothes, and there was no indication that preventing rust stains was a common concern among owners of clothes dryers. General concerns about class certification, coupled with no common understanding of the significance of labeling or advertising a clothes dryer as containing a stainless steel drum, caused the court to decertify the action.

We have seen a rise in consumer class actions based on state consumer protection laws, many seeking certification of a nationwide class. Further decisions more closely scrutinizing the requirements of Rule 23 and applying them to the facts of each particular case could begin to signal a slowing of this trend.

COMPETITOR CHALLENGES[3]

District Court Defines "Opinion Puffery"

In the ongoing diaper wars, Procter & Gamble, makers of Pampers, challenged Kimberley-Clark's ad campaign for its Huggies "Natural Fit" line. *Procter & Gamble* v. *Kimberly-Clark Corp.*, 569 F. Supp. 2d 796 *E.D. Wisc. 2008). In denying its motion for a preliminary injunction, the court added to the age-old discussion as to what constitutes a claim that must be substantiated versus harmless puffing.

Huggies diapers contour between the legs, providing, according to its makers, a more natural fit. The company had done some testing to support this claim, and moved forward with an ad campaign based on this distinguishing characteristic. Its campaign, a roaring success according to company consumer testing, was called "Brick Baby," in which the announcer suggested the Huggies were designed for human babies as opposed to inanimate bricks. Procter & Gamble failed to see the humor in this and sued Kimberley-Clark under the Lanham Act, seeking to enjoin the ad campaign based on a false or misleading misrepresentation of fact—that the Huggies "fit more naturally."

Rather than focus on the testing done to support "fits more naturally," the court concluded the statement was not a claim at all but inactionable puffery for two reasons. First, the court found that "more natural fit" was inherently vague. Second, whether something fit more naturally could not be shown to be true or false by any objective measure and so the statement is mere opinion rather than a claim of fact. The court relied on the ubiquitous Papa John's "better ingredients, better pizza" puffery decision at 227 F.3d 489 (5th Cir. 2000) in reaching this result. The problem of proof is compounded in this situation as third parties are needed to opine on the fit, rather than the wearers of the diapers themselves. The court distinguished cases where the advertiser makes specific reference to consumer support—such as "tests prove…" The court distinguishes this "opinion puffery" from "exaggeration puffery" where claims will not be taken at face value by consumers, using as an example "lowest" prices of "best" products.

3 Arnold & Porter 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, Suzy Wilson, Randy Shaheen, and Roberta Horton.

PRIVACY[4]

FTC Grants Anti-Identity Theft Rule Compliance Extension, Saying Businesses Are Unaware of Their Obligations

In a highly significant move for entities subject to FTC jurisdiction, including non-profit organizations, the FTC has decided to delay for six months, until May 1, 2009, its enforcement of the "Red Flags" requirements of the anti-identity theft obligations the FTC, together with the federal banking regulators and the National Credit Union Administration (NCUA), jointly issued last year under the Fair and Accurate Transactions Act of 2003 (FACTA). In an announcement on October 22, 2008, the Commission stated that it was granting the delay because it has learned, through education and outreach on the regulations, that many entities have not understood the breadth of the Red Flags rule's application. Absent such delay, the FTC stated, those entities would not be able to meet their obligation to adopt Identity Theft Prevention Programs by the FACTA regulations' compliance date of November 1, 2008.

The FTC's announcement strongly signals that the applicable scope of the Red Flags rule is broader than many businesses may have understood. Specifically, because the Red Flags rule applies to "financial institutions" and "creditors," it appears that many entities other than banks, savings and loan associations, credit unions, and credit card lenders have failed to recognize the broad scope of those terms as defined for purposes of the rule.

Under the FACTA, a "financial institution" includes "any… person that directly or indirectly holds a transaction account …belonging to a consumer…." A "transaction account… belonging to a consumer" is just about any account holding a consumer's funds subject to withdrawal or transfer by the consumer. In addition to deposit accounts held by banks, savings associations, and credit unions, "transaction accounts" would include, for example, health insurance accounts such as Health Savings Accounts and Flexible Spending Accounts. The holder of any such account is thus a "financial institution" for purposes of the Red Flags rule.

A "creditor" includes "any person or entity who regularly extends, renews, or continues credit" and "credit" means "the right granted by a creditor to a debtor to *defer payment of debt* or to incur debts and defer its payment or to purchase property or services and defer payment therefore." Under this definition, credit can be extended even in cases where there is no finance charge and even if a customer does not actually defer payment, so long as he or she had the right to defer. The key factor is whether *goods or services have been provided without obtaining advance or simultaneous payment*. If they have, the provider of those goods or services is a "creditor" for purposes of the regulations.

The obligation under the Red Flags rule to establish and implement an Identity Theft Prevention Program should not be underestimated. It requires a major analysis of existing procedures and the development of written policies and procedures to:

- Identify relevant red flags for the covered accounts and incorporate those red flags into the Program;
- Detect red flags that have been incorporated into the Program;
- Respond appropriately to any red flags that are detected; and
- Ensure the Program (including the red flags determined to be relevant) is updated periodically to reflect changes in risks to customers and to the safety and soundness of the financial institution or creditor from identity theft.

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 Central Intelligence Agency (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 Federal Communications Commission (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 Richard Dickinson in our London office.

Organizations that have not yet determined whether or not they are covered by the FACTA identity theft regulations should immediately analyze their activities to reach such a determination. Those that are covered should move promptly to adopt the policies and procedures required to comply. Input from legal counsel should guide both the analysis of the applicability of the rules and the design and evaluation of particular compliance measures. The FTC takes identity theft very seriously, and its authority to impose penalties under the regulations may well be exercised vigorously once the enforcement date is reached.

TRADEMARK[5]

PRO-IP Act Aims to Help in the Fight Against Counterfeiting and Piracy

On October 13, 2008, President Bush signed into law the Prioritizing Resources and Organization for Intellectual Property Act (PRO-IP Act) of 2008, S. 3329. Acknowledging the harm caused by trademark and copyright counterfeiting and infringement to the US economy, the PRO-IP Act amends the Lanham Act, the Copyright Act, and IP-related criminal provisions of Title 18 of the US Code to expand the scope of liability and remedies resulting from piracy and counterfeiting. The PRO-IP Act also provides for increased funding and support for enforcement at the federal, state, and local level, and creates a cabinet-level Intellectual Property Enforcement Coordinator (IPEC) within the executive branch.

The PRO-IP Act contains several provisions that are of particular help to brand owners. One of the more significant sections pertains to the amount of statutory damages available in counterfeiting cases: the range available has been raised in cases of non-willful infringement to US$1,000 to US$200,000 (from US$500 to US$100,000), and in cases of willful infringement, the maximum has been raised to US$2 million (from US$1 million) per counterfeit mark per type of goods or services sold. With respect to actual damages, the treble damages provision has been expanded to encompass those who intentionally provide the goods and services necessary for use of a counterfeit mark in commerce. This provision in effect targets not only those who manufacture and sell counterfeit goods, but those who, for example, knowingly supply counterfeit materials and labels used to make counterfeit goods.

Criminal provisions pertaining to trademark infringement have also been expanded. Section 42 of the Lanham Act, which forbids the importation of goods bearing infringing marks or names, now also prohibits transshipment or exportation of goods and services. Forfeiture provisions applicable in IP cases have been expanded to provide for the destruction of seized items, including property used in the commission or facilitation of infringement, and for the payment of restitution by a convicted infringer to the victim of the infringer's criminal acts.

Finally, the PRO-IP Act increases government funding and coordination of IP enforcement efforts through additional resources, grant programs, and the creation of the IPEC position. The Act provides that the US Department of Justice may provide grants totaling up to US$25 million annually to state and local law enforcement entities for the training, prevention, enforcement and prosecution of IP theft, and infringement crimes. The Act also gives additional funding to increase the number of Federal Bureau of Investigations (FBI) agents assigned to investigate IP crimes and the amount of US attorneys available to assist in prosecution of IP crimes. With respect to coordination of IP enforcement, one of the duties of the IPEC is to chair an IP enforcement advisory committee, which will be tasked with preparing a Joint Strategic Plan against counterfeiting and infringement of copyright, patent, trademark, trade secret, and other IP rights.

5 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: Roberta Horton, and Anna Manville; in our NY office Jim Swire and Lou Ederer; in our LA office: Suzy Wilson, Ron Johnston, and Jim Blackburn; and in our London office: Ian Kirby, Paula Levitan, and Clive Thorne.

EU[6]

Proposed European Directive on Consumer Rights

On October 8, 2008, the European Commission adopted the proposal for a Directive on Consumer Rights which will offer increased and uniform protection to consumers when they make a purchase in a shop or from an online retailer based in the EU.

Why is the new Directive needed? European consumers have certain rights when they buy from any retailer, including the right to return faulty goods for repair or exchange and a "cooling off" period during which orders placed online or with a "door-to-door" salesman can be cancelled. These rights are derived from EU legislation; however, rules currently vary from one Member State to another because national legislators have discretion to adapt the legislation during national implementation.

The proposed Directive will replace four existing EU Directives: sale of consumer goods and guarantees (99/44/EC); unfair contract terms (93/13/EC); distance selling (97/7/EC); and doorstep selling (85/557/EC) and will also reflect the development of new methods of purchasing including mobile commerce (m-commerce) and via online auctions.

What is proposed? The Directive will create common rules for all EU consumers, and Member States will no longer be able to impose additional requirements. The draft Directive introduces the following key provisions:

- Before the conclusion of the contract, the trader is required to give consumers key information (for example, there should not be any hidden or extra costs on top of the stated price).
- When the consumer buys online or during a visit of a trader to his home, he has a 14-day cooling off period during which he may cancel the order, return the goods and get his money back.
- The consumer is protected against the risk of loss and damage to transported goods until he actually receives them.
- Consumers have the right to have defective goods replaced or repaired within two years from the date of purchase. If this is not possible, the consumer should have a refund.

How will consumers benefit? Consumers will benefit from the proposal because, once adopted, the new Directive will offer the same protection when consumers buy online from a website based in any EU Member State or from a trader who visits them in their home. The measure should enhance consumer confidence in cross-border shopping and give consumers access to a better choice of products across the EU.

How will companies benefit? Currently, businesses wishing to sell in all 27 Member States need legal advice on the national rules in each country, and the cost can be prohibitive for small companies. The proposed Directive will make it easier and less costly for traders to sell cross border.

What happens next? The draft Directive will be submitted to the European Parliament and the Council of Ministers for comment before it is finally adopted. It is difficult to forecast how long this process will take. Following adoption, there will be a transition period of two years for Member States to adapt their national laws.

The text of the draft Directive is available at: http://ec.europa.eu/consumers/rights/docs/COMM_PDF_COM_2008_0614_F_EN_PROPOSITION_DE_DIRECTIVE.pdf.

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 healthcare. The offices' clients include multinationals and European concerns ranging from start-ups to Fortune 500 firms. In our EU offices, Tim Frazer, Susan Hinchliffe, and Paula Levitan have advised clients on numerous non-US consumer protection matters.

CONSUMER PRODUCT SAFETY COMMISSION (CPSC)[7]

A New Era at the CPSC

Last year's torrent of highly publicized consumer product recalls has produced a flood of new regulation to continue throughout next year. In response to the widespread public apprehension about faulty cribs and lead-painted toys that made 2007 the "Year of the Recall," Congress enacted, in August 2008, the Consumer Product Safety Improvement Act. Congress strengthened product safety standards, enhanced the authority and budget of the CPSC, and required CPSC to implement a series of new rules at a breakneck pace. CPSC has swung into action.

Certificates of Compliance

On November 18, 2008, CPSC published a final rule affecting every company that makes or imports a consumer product in the United States (73 Fed. Reg. 68328). The Consumer Product Safety Improvement Act mandated that for any product manufactured on or after November 12, 2008 manufacturers, including importers and private labelers, must certify that their products comply with all applicable safety rules and related regulations by issuing a certificate that accompanies the product. CPSC reported that it has received "thousands of inquiries" because of the "confusion" created by the law's "extremely short deadline" and its "vast expansion" of reporting requirements (73 Fed. Reg. 68328). Therefore, to streamline the process, CPSC determined in part that:

(1). for imports, only the importer must certify compliance, and for domestically manufactured products, only the manufacturer must certify compliance;

(2). for imports, certificates must be available to CPSC as soon as the product or shipment is "available for inspection" in the United States; for domestically manufactured products, certificates must be available before the product or shipment is "introduced into domestic commerce"; and

(3). the required certificate may be provided by electronic means.

CPSC stated that it expects in the future to "consider whether this rule needs to be revised based on actual experience" (73 Fed. Reg. 68328). (For further details and specific applications of this rule, please consult the rule itself or your legal counsel.)

Labeling Requirements for Toy and Game Advertisements

On November 17, 2008, CPSC published a final rule for advertisements of toys and games (73 Fed. Reg. 67730). The Federal Hazardous Substances Act (the Act) requires that packaging for toys and games intended for children from three to six years old that contain small balls, marbles, or small parts be labeled with a choking-hazard warning. The Consumer Product Safety Improvement Act extended that requirement, mandating that any advertisement that provides a direct means to purchase such a toy or game must also bear the required warning. The CPSC's rule, effective February 10, 2009:

(1). provides detailed requirements for the size and placement of the cautionary labeling and the use of abbreviated warnings;

(2). exempts catalogues circulated solely between businesses, except where a business might be expected to be purchasing the product for the use by children rather than for resale;

(3). provides a 180-day grace period (until August 9, 2009) for distribution of catalogues and other printed materials printed prior to the February 10, 2009 effective date.

7 Arnold & Porter has several attorneys with broad experience on matters involving the US Consumer Product Safety Commission, including two former General Counsels of the agency—Eric Rubel and Jeff Bromme—and Blake Biles, formerly with the US 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.

CPSC also reiterated that Internet advertisements must comply with the Act's labeling requirements no later than December 12, 2008. (For further details and specific applications of this rule, please consult the rule itself or your legal counsel.)

Upcoming Rulemakings

The two final rules discussed above are only a sample of the range of issues that CPSC is currently addressing, which includes lead and phthalate standards, and accreditation requirements for third-party testers of everything from cribs to children's jewelry. CPSC's flurry of activity, including additional rulemakings, will continue through next year and beyond. For just one example, CPSC is currently inviting comment on a rule to be issued no later than August 14, 2009, interpreting how CPSC will weigh various factors in imposing its enhanced civil penalty authority. With such penalties applying to a broadened array of violations, and with the dramatic increase in the maximum penalty from US$1.825 million to US$15 million, many will be watching this rulemaking with interest.

FDA[8]

FDA Issues Warning Letters to Bayer HealthCare for Marketing OTC Drug with Dietary Supplement

Can makers of over-the-counter (OTC) drugs add dietary supplements to their products without the approval of the FDA? Some have advocated that they should be able to combine previously approved OTC drugs with ingredients that are accepted for dietary supplement marketing, and use the claims made by the dietary supplement makers, in order to compete with the dietary supplements. The FDA has now taken a strong position to the contrary.

On October 28, 2008, the FDA issued letters to Bayer HealthCare warning the company that two of its combination drug-dietary supplement products, Bayer Women's Aspirin plus Calcium and Bayer Aspirin with Heart Advantage, are unapproved new drugs that require an approved new drug application in order to be legally marketed, and cannot be marketed for OTC use. The FDA also concluded that the products are misbranded because their labeling lacks adequate directions for use by consumers. The FDA gave Bayer until November 18, 2008 to respond to the warning letters.

In a statement given by a spokesman for the company, Bayer defended its marketing practices, asserting that Bayer "stand[s] behind both products and all marketing claims made in their support." Furthermore, the spokesman stated that "all of [Bayer's] communication on product benefits prominently features information for consumers to check with their physicians to determine whether the product is right for them, and, in the case of Bayer Aspirin with Heart Advantage, highlights the fact that the product is not a replacement for cholesterol-lowering medication."

The FDA's recent warning letters reaffirm the position taken by the FDA in two previously issued warning letters sent to B.F. Ascher & Co., Inc. regarding Melagesic PM, and to Omni Nutraceuticals, Inc. regarding Inholtra Joint Pain products. In those letters, the FDA stated its position that combination drug-dietary supplement products require agency approval to be legally marketed in the United States.

The FDA warning letters to Bayer came two weeks after the US House of Representatives Committee on Energy and Commerce sent a letter to Bayer questioning the safety and effectiveness of the products. The letter noted that the company had ignored the FDA's prior recommendations to refrain from marketing combination drug-dietary supplement products. The House Committee also sent a letter to the FDA asking if it had changed its position on the marketing of such products.

8 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, Don Beers, and Vernessa Pollard, each of whom previously were prominent lawyers at FDA, and Dan Kracov.

The two Bayer products contain aspirin and either phytosterols or calcium and are labeled as being both a drug and a dietary supplement for use in reducing the risk of heart disease. Bayer Women's is also labeled for use in fighting osteoporosis. Neither product has received approval from the FDA for either use. The FDA asserts that when a product is marketed as a combination of a drug and a dietary supplement, it will be regulated by the FDA as a drug.

In its warning letter, the FDA said that "statements and representations" on the packages suggest that daily use may prevent heart attacks and high cholesterol, which amounts to claims that the products can be used to treat cardiovascular disease and hypercholesterolemia. According to the FDA, the uses for which these products are being marketed require the diagnosis and supervision of a healthcare professional; therefore, these products cannot be labeled for use by consumers and sold as OTC products. In both its letters, the FDA said that notwithstanding Bayer's "attempt to market th[ese] product[s] as…combination drug-dietary supplement[s], the presence of aspirin…with its intended uses as an analgesic and to mitigate, treat, and prevent cardiovascular diseases, renders the entire product a drug." As such, in order to be marketed, the products require approval by the FDA as new drugs.

The FDA also expressed concern that misuse or overuse of these products could put consumers at risk of internal bleeding and other adverse events, although it acknowledged that it had not received any reports of adverse reactions to either of the two products.

In its letters to Bayer, the FDA warned that it would "take enforcement action against manufacturers found to be violating the law or attempting to circumvent the drug approval process." It also warned that failure to immediately correct the violations could result in "legal action without further notice, including, without limitation, seizure and injunction."

These recent warning letters indicate that any claims that combination drug-dietary supplement products can treat health conditions render the products drugs that require new drug approval before they can be marketed. However, simply omitting such claims would not necessarily immunize these products from scrutiny, as the FDA considers it impossible to properly label these products for OTC use. Furthermore, the FDA's warning letters to Bayer indicate that all combination drug-dietary supplements will need new drug approval, and that the FDA will impose severe penalties on companies who continue marketing combination products without seeking such approval.

A press release issued by the FDA, as well as the warning letters themselves, can be found at: http://www.fda.gov/bbs/topics/NEWS/2008/NEW01907.html.