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Chair's Report

Seth C. Silber, Washington, D.C.

We hope you enjoy this issue of the Chronicle—rolled out just in time for the Annual Antitrust Spring Meeting. In addition to an interesting article on pharmaceutical patent settlements and a summary of two recent Committee programs, this issue contains one of our most valuable features—an interview with a leading antitrust health care enforcer. The interview with DOJ's Josh Soven provides valuable insights on DOJ enforcement priorities and the interplay between health care enforcement at the DOJ and FTC.

As far as the Spring Meeting itself, we hope that you will be able to attend our Committee's program entitled "Health Care Mergers and Collaborations – Is Enforcement Sufficiently Protecting Consumers?" This program will be moderated by Mark Botti (Akin Gump), and feature the following panelists: Josh Soven (DOJ), Mindy Hatton (American Hospital Association), Bob Bloch (Mayer Brown), and Cory Capps (Bates White). The program will take place on Wednesday, March 25th at 3:45.

Also, for those of you attending the Spring Meeting, please stop by our Committee's table, which will be open following our program from 5:15 to 6:15 as part of Wednesday evening's "Welcome Reception." I will be there along with other Committee members. Please come by and share your ideas with us.

Later this Spring, we will also hold at least two additional programs. Next in line is a program entitled "The Latest Patent Settlement Cases, Solvay and Cephalon." It will be held on Tuesday, April 28. The program will be moderated by Karen Bokat and will feature speakers from a variety of perspectives including Meredyth Andrus (FTC), Jeff Brennan (Dechert), Linda Nussbaum (Kaplan, Fox & Kilsheimer), and Bill Rooney (Wilkie, Farr & Gallagher). More information on how to sign up for this program will be forthcoming.

As always, please feel free to contact me (202-973-8824 or ssilber@wsgr.com) if you have any ideas for future Committee programs or publications, or would otherwise like to get involved in our Committee's activities. Enjoy the Spring Meeting!

Editors' Report

Christi Braun, Washington, D.C.

Just in time for the Spring Meeting, this issue of the Chronicle includes a special feature—an interview with Josh Soven, Chief of the Department of Justice Antitrust Division's Litigation I Section. Mr. Soven shares with the Chronicle his thoughts on: differences between the Federal Trade Commission ("FTC") and the Antitrust Division; the current and future direction of the Litigation I Section; hospital mergers; health plan mergers; and CON laws.

Focusing on a topic of import to Chairman Leibowitz and the FTC, Mel Orlans and Esther Steinhauer examine past acts by the FTC, the Antitrust Division, and Congress with regard to reverse-payment patent settlements as a means of predicting the future. As representatives of the new administration begin to layout their agendas, readers may find the piece prescient.

Members of the section who focus on consumer protection should find the second article of interest. Justin Hedge summarizes the recent program co-sponsored by the Health Care & Pharmaceuticals and Consumer Protection Committees on dietary supplement enforcement and litigation.

Bringing together lawyers and economists from both the plaintiffs' and defendants' camps, the Committee's brown bag program on the Average Wholesale Price Litigation presented a rare view of these cases. The final article, by Jessica Medina, provides an insightful summary of that very interesting program.

We are always looking for authors and articles. If you have an article that you would like to publish, have a topic that you would like to see covered, or are interested in writing, please contact me at cjbraun@ober.com or my co-editor, Tracy Weir, at teweir@hhlaw.com.

In this Issue of the

Chronicle

Committees Host Seminar on Recent Developments in Dietary Supplement Regulation Enforcement & Litigation

By Justin P. Hedge, Esq.
Arnold & Porter LLP

On January 16, 2009, the Antitrust Law Section's Heath Care & Pharmaceuticals and Consumer Protection Committees co-sponsored a teleconference on recent developments facing the dietary supplement industry in the regulatory arena and in private litigation. The industry has been subject to increasing scrutiny in recent years from government agencies, as well as private plaintiffs, for its advertising practices, and the teleconference focused on some of the high-stakes emerging issues the industry faces.

Amy Mudge, Counsel in Arnold & Porter LLP's Antitrust/Consumer Protection practice group, and a Vice-chair of the Health Care & Pharmaceuticals Committee, moderated the panel. She began by introducing the panelists and provided a brief overview of the Dietary Supplement Health & Education Act of 1994 ("DSHEA"),[1] which is the primary federal legislation that governs the marketing of dietary supplements. Among other things, DSHEA restricts the representations that dietary supplement manufacturers can make in marketing and labeling their products. For example, to make claims that their products cure a disease, manufacturers must go through the Food and Drug Administration's ("FDA") new drug approval process. Acceptable claims are limited to statements of nutritional support (i.e., structure-function claims), and marketers must have scientific substantiation for any such claims. By a longstanding Working Agreement between the Federal Trade Commission ("FTC") and FDA,[2] the FTC has enforcement oversight for the advertising and marketing of dietary supplements pursuant to Section 5 the FTC Act,[3] while FDA enforces DSHEA's provisions as they relate to product labeling. FDA also provides scientific support for investigations into the substantiation of dietary supplement claims. The states' attorneys general and consumers can challenge dietary supplement claims under state consumer protection laws, and competitors can challenge claims in court under the Lanham Act[4] or through the self-regulatory process at the National Advertising Division of the Council of Better Business Bureaus ("NAD").

Michael McGuffin

President, American Herbal Products Association

Michael McGuffin, President of the American Herbal Products Association ("AHPA"), started the presentation by providing an overview of the dietary supplement industry. AHPA is one of two leading trade associations in the dietary supplement industry. McGuffin stated that according to the *Nutrition Business Journal,* the dietary supplement industry as a whole has seen 55 percent growth over the last decade, with an average of three to five percent growth each year. Products in the industry include vitamins and minerals, as well as herbal substances. These products can either be sold alone or together in a single, combined-dose form. About 65 percent of U.S. industry sales are made through retail outlets, 20 percent through direct sales, and the balance through service professionals (e.g., acupuncturists) and internet and mail orders.

Dietary supplement companies usually operate in one or several of the multiple levels of the supply chain which includes: 1) supplying ingredients, 2) manufacturing finished products, and 3) marketing finished products. According to FDA study results released in 2007,[5] there are some 1,460 companies in the dietary supplement industry. Over half of the industry is made up of small companies who employ fewer than 20 people and generate less than one million dollars in median revenue annually.

McGuffin discussed the general regulatory framework for the dietary supplement industry. Pursuant to the Bioterrorism Law of 2002,[6] dietary supplement manufacturers have to register their facilities with the federal government. The ingredients used must conform to certain standards. Products can only be oral, not topical, and are only allowed to be in a form that is digestible, which FDA has interpreted to exclude nasal sprays, lozenges, and gum. Before marketing with structure or function statements, a manufacturer must have scientific substantiation for such claims. In June 2007, FDA published a rule on good manufacturing practices for dietary supplements to be implemented over a three-year period, beginning with larger companies first.[7] Additionally, as of December 2007,[8] dietary supplement companies have an obligation to submit serious adverse events reports to FDA, a requirement modeled after one imposed on the pharmaceutical industry.

Finally, McGuffin provided a summary of recent enforcement actions brought against dietary supplement companies. In December 2008 and January 2009, FDA issued warning letters regarding 69 weight loss products, which may be tainted by undisclosed active ingredients contained in the products.[9] FDA has indicated it is seeking recalls and may

1 Pub. L. No. 103-417 (1994).

2 3 Trade Reg. Rep. (CCH) ¶ 9,859.01 (1971).

3 15 U.S.C. § 45 (a).

4 15 U.S.C. § 1125.

5 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34,752, 34,920-21 (June 25, 2007) (to be codified at 21 C.F.R. pt. 111).

6 Pub. L. No. 107-188 (2002).

7 Current Good Manufacturing Practice, *supra* note 5.

8 Dietary Supplement & Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462 (2006) (effective December 2007).

9 Press Release, Food & Drug Admin., FDA Expands Warning to Consumers about Tainted Weight Loss Pills (Dec. 22, 2008, rev. Jan. 8, 2009), *available at* http://www.fda.gov/bbs/topics/NEWS/2008/NEW01933.html.

also institute seizures, injunctions, or criminal charges. Over the last several years, FDA has banned a number of other dietary ingredients, including ephedrine alkaloids (April 2004), androstenedione (March 2004), Comfrey (July 2001), aristolochic acid (July 2000), and Pharmanex's Cholestin brand of red yeast rice (1998). The FTC has been active as well, obtaining a December 2008 settlement for $150,000 with two weight loss marketers, Ultralife Fitness, Inc. and Tru Genix, LLC, to resolve alleged unsubstantiated claims and other deceptive and unfair marketing allegations.[10]

Mark Levine

Senior Attorney, National Advertising Division

Mark Levine, a Senior Attorney with NAD, spoke next about NAD's efforts to help the dietary supplement industry self-regulate with regard to marketing issues. NAD membership is made up of numerous national advertising trade associations and provides a dispute resolution forum for claims against a competitor's marketing practices. NAD covers more than just dietary supplements, but since forming an initiative with the Council for Responsible Nutrition in 2007, its coverage of the industry has greatly increased. NAD boasts resolution of more than 50 dietary supplement cases since the inception of the cooperative initiative with nearly 100% industry participation and compliance. As Levine explained, challenges made under NAD's dispute resolution system are designed to promote a level playing field among competitors through self-policing. However, individual consumers, other trade associations, and advocacy groups can also initiate complaints; the process is not limited to competitors. NAD also monitors the dietary supplement industry and initiates actions on its own.

Levine discussed the procedure that is followed in a NAD challenge. Once a complaint has been made, the advertiser has an opportunity to provide its substantiation for any challenged claims. Then, NAD evaluates the provided science behind the claim. NAD also forwards this supporting documentation to the complaining party to afford it an opportunity to respond and comment on the merits of the documentation. An advertiser is allowed to submit a reply to any comment from the complaining party. Finally, NAD will meet with the parties, and sometimes even bring in outside experts to supplement its in-house scientific expertise.

Levine stressed that all NAD proceedings are confidential until a final decision is published, although an advertiser is allowed to keep certain facts confidential, even from the complaining party. Published decisions are only available by subscription to the NAD database. After reviewing the NAD decision, advertisers are able to submit their own statement, which is published alongside the decision. Per NAD protocol, any refusal to comply with NAD procedure could result in referral of the matter to the FTC, FDA, or other appropriate government agency. If an advertiser disagrees with the final NAD decision, it can appeal to the National Advertising Review Board ("NARB"). Advertisers have an absolute right to appeal, whereas complaining parties can appeal only if the NARB chairman approves the appeal request.

The most frequent current issues in NAD dietary supplement cases are: (1) determining whether a product is making an ingredient claim or a product claim; (2) improper extrapolation of ingredient test results; and (3) in the case of multiple ingredients and multiple claims, determining which ingredient supports each claim. Levine went on to discuss some recent NAD decisions. In a case about "Cognivin," NAD scrutinized claims that the product would "improve focus and concentration," reduce age-related cognitive decline, improve memory retention, reduce stress and anxiety and provide "sustained energy," with elevated mood.[11] NAD found that the company had not provided a scientific study on these effects; rather, it was basing its claims only on ingredients. NAD also found that the claims were too broad and required packaging changes.

In another case, 5-hour energy.com was marketing a five-hour energy drink that made various claims relating to daily energy, focus, and mood.[12] NAD found that the claims were overly broad and required the company to disclose more clearly that the product contained significant amounts of caffeine.

An investigation of Ameal BP, a product marketed for blood pressure maintenance, found that its representation of 14 clinical studies was not entirely accurate, because only three were deemed relevant and reliable.[13] The NAD panel required that there be more clear disclosures about the fact that the product was not a prescription medication and that a doctor should be consulted prior to taking the supplement.

An FRS healthy energy product faced scrutiny for its endorsement from Lance Armstrong stating that he "need[s] a healthy source of energy with all [he] has going on, [which he needs to] make it happen with FRS."[14] NAD found the representations that the product was "healthy" were substantiated with studies, but required clarification from the endorsement that Armstrong used the product in his everyday life and not as a part of his professional training.

In an inquiry into the One-A-Day All Day Energy multivitamin, NAD found that even the name of the product was a representation that it deemed unreliable because the energy claimed was based on caffeine, which is not a source of extended energy.[15] NAD recommended a name change for the product and was affirmed on appeal to the NARB.

Levine added that not all NAD investigations result in more restrictions. For example, an investigation of Relaxane, a product marketed for the relief of "everyday stress" by Indigene, resulted in a finding that "clinically proven claims" were substantially supported with at least three scientific research projects and, thus, appropriate.[16]

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[10] Press Release, Food & Drug Admin., Internet Marketers of Dietary Supplement for Weight Loss Agree to Pay $150,000 (Dec. 3, 2008), *available at* http://www.ftc.gov/opa/2008/12/ultralife.shtm.

[11] Biotech Corp. Int'l (Cognivin), NAD/CARU Case Reports, Report#4821 (Apr. 2008).

[12] Living Essentials (5-Hour Energy), NAD/CARU Case Reports, Report#4749 (Nov. 2007).

[13] CALPIS USA (Ameal BP), NAD/CARU Case Reports, Report#4891 (July 2008).

[14] The FRS Company (FRS Energy), NAD/CARU Case Reports, Report#4904 (Sept. 2008).

[15] Bayer Heathcare (One-A-Day All-Day Energy), NAD/CARU Case Reports, Report#4684 (June 2007).

[16] Indigene Pharm, Inc. (Relaxane), NAD/CARU Case Reports, Report#4756 (Nov. 2007).

Trent Norris

Partner, Arnold & Porter LLP

Trent Norris is a partner with Arnold & Porter LLP's Litigation and Antitrust/Consumer Protection practice groups. He specializes in consumer protection cases brought under state laws and California's Proposition 65.[17] Norris detailed why bringing cases under consumer protection laws (i.e., a misleading marketing action) is often more attractive for plaintiffs from an evidentiary standpoint than bringing product liability (i.e., failure to warn) cases, and, as such, represents a growing trend.

Challenges to dietary supplements based on Prop. 65, whether brought by the California Attorney General's office, local prosecutors, or private plaintiffs, are on the rise and, thus, on the minds of many industry participants. Prop. 65 creates additional liability for companies whose products are sold in California by requiring a "clear and reasonable warning" on products that contain one or more of 800 listed chemicals in excess of specified threshold amounts. The scope of the statute is limited to companies with at least ten employees, which may exempt many of the smallest dietary supplement firms. However, companies are covered regardless of whether they are located in California or sell products directly to consumers in California. For those firms covered by the law, which can include not only retailers but also suppliers and distributors, the impositions can be quite significant. For example, with Progesterone creams, FDA enforcement has resulted in restrictions on some advertising claims, but the chemical Progesterone is on the Prop. 65 list and therefore companies must evaluate whether to add a warning that the product is a known carcinogen.

Prop. 65 warnings are only required if the listed chemical is present in the product at levels that would result in an average daily exposure exceeding certain "safe harbor" limits. For carcinogens, that level is the level at which there is "no significant risk" of cancer, i.e., less than 1 in 100,000 excess cancer risk. For reproductive toxicants, that level is 1/1000th of the level that has been shown to cause "no observable effect" in laboratory animals. The defendant is required to prove that the level of chemicals in its product is below those levels.

For dietary supplement companies, a key exemption under Prop. 65 applies to levels of substances that can be shown to be "naturally occurring." Furthermore, if the chemical is also a contaminant, as opposed to an intended ingredient, it may be present only at the "lowest level currently feasible." For most dietary supplements, lead is the primary chemical at issue, but it can have two sources: nature, i.e., from geologic or climatic origins, or man-made, i.e., from pollution or the use of lead-based agricultural chemicals. As a result, this is a difficult showing for most dietary supplement companies, and so most who are challenged have settled. The levels set by such settlements are instructive, but binding only on the settling parties. Nevertheless, a recent suit by the California Attorney General and several local prosecutors against several dozen makers of multivitamins may provide a vehicle for establishing a more widespread and consistent standard for lead in dietary supplements.

Katie Bond

Associate, Kelley Drye & Warren LLP

Katie Bond, an associate with Kelley Drye & Warren LLP's Advertising and Food & Drug practice groups, concluded the panel presentation by discussing recent federal dietary supplement enforcement and regulatory actions by both the FTC and FDA. Bond elaborated on FDA warnings to consumers in December 2008 and January 2009 about 69 weight loss pill products that may contain undisclosed active drug ingredients.[18] Some of the adulterating substances were sibutramine (a controlled substance indicated for obesity treatment), rimonabant (a drug not approved in the U.S.), phenytoin (an anti-seizure drug), phenolphthalein (used for titration in chemical lab experiments and a suspected carcinogen), and bumetanide (a diuretic used to treat heart failure).

In other FDA news, Bond discussed two warning letters issued in October 2008, regarding products that combined dietary supplement product ingredients with aspirin.[19] One product, positioned for women, combined calcium and low-dose aspirin. The other product, marketed as a "heart advantage," combined phytosterols with low-dose aspirin. FDA took the position that the products constituted new drugs requiring approval under the drug regime before being marketed.

Regarding FDA's new rules on Current Good Manufacturing Practices (CGMPs) for dietary supplement companies, Bond noted a recent FDA announcement that it has commenced inspections of large companies (500 or more employees). FDA also recently announced that, depending on resources, it intends to issue a small business compliance guide on the CGMPs sometime in 2009.

Bond discussed the recent FTC campaign against various cold treatment and prevention products. The agency has targeted claims that it alleges lack the requisite substantiation of competent and reliable scientific evidence. The FTC settled with makers of Airborne in 2008 and issued public closing letters regarding cold-related advertising for five other products. The closing letters noted that the extent of enforcement is based on a variety of factors, including the duration of advertising campaigns and sales revenue.

Because many dietary supplement companies use celebrity or consumer endorsements, Bond discussed the FTC's proposal to modify its Guides Concerning the Use of Endorsements and Testimonials in Advertising.[20] Among other proposed changes, the FTC is suggesting that marketers should be required to disclose the results that average consumers can expect, rather than simply using the "results not typical" disclaimer.

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The dietary supplement field has grown dramatically in recent years. As a result of the increased market and high number of participants, great competition exists for the effective marketing and positioning products. As a corollary to that increasingly competitive environment, the need to more carefully regulate the industry has grown as well. FDA, FTC, state authorities and even the industry members themselves are playing a role in regulating and enforcing checks on the industry's conduct for the benefit of consumers. Manufacturers, marketers and retailers of dietary supplements, as well as their counsel, have to be aware of the many issues raised in this increasingly regulated environment, and hopefully this presentation has provided a useful tool for beginning to spot potential pitfalls.

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[17] Safe Drinking Water & Toxicity Enforcement Act of 1986, Cal. Code Regs. tit. 27.

[18] FDA Jan. 8, 2009 Press Release, *supra* note 8.

[19] Press Release, Food & Drug Admin., FDA Issues Warning Letters to Bayer HealthCare for Illegally Marketing Two Unapproved Drugs (Oct. 28, 2008), *available at* http://www.fda.gov/bbs/topics/NEWS/2008/NEW01907.html.

[20] The text of the proposes revisions to the FTC's Guides Concerning the Use of Endorsements and Testimonials in Advertising can be found at http://www.ftc.gov/os/2008/11/P034520endorsementguides.pdf.