

Consumer Protection Update

Newsletter of the Section on Antitrust Law's Consumer Protection Committee

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Editors

Lesley Fair
Federal Trade Commission
Washington, DC
lfair@ftc.gov

Thomas F. Zych
Thompson Hine LLP
Cleveland, Ohio
tom.zych@thompsonhine.com

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There have been a lot of parties at 600 Pennsylvania Avenue of late, as an unprecedented number of long-term Federal Trade Commission attorneys retire after impressive careers in government service.

If you practice in this area, you have had dealings – some pleasant and some not so pleasant — with many of these retirees. Louise Jung, a 30-year FTC vet, worked just about everywhere during her tenure: Attorney-Advisor to Commissioner Terry Calvani and Bureau Director Al Kramer, Assistant Deputy Director of BCP, and staff attorney with Ad Practices, Marketing Practices, and Enforcement. Renate Kinscheck served 28 years with the Division of Service Industry Practices and the Division of Enforcement and Elaine Kolish logged 25 years in BCP, nine of them at the helm of the Division of Enforcement. Beverly Thomas, perhaps the first person at the Bureau to log onto the Internet, retired after 29 years with the Division of Service Industry Practices and the Division of Advertising Practices. Brinley Williams devoted 44 years to federal service, including 24 years with the Division of Advertising Practices and the East Central Region in Cleveland. Sandra Wilmore, one of the agency's experts on credit law, retired after 32-years with the Division of Financial Practices. And Mel Orlans, one of the nation's pre-eminent consumer protection and antitrust litigators, stepped down from his present position in the Office of General Counsel, after almost 35 years with the Commission. [I regard Mel's 1998 deposition of Professor J. Howard Beales — a real Godzilla meets Rodan-like affair — to be one of the great square-offs in consumer protection litigation history.]

With these retirements goes more than 225 years of knowledge and experience, leaving a void that will eventually be filled, but not easily. On behalf of the Antitrust Section and its Consumer Protection Committee, we are pleased to offer these fine attorneys the figurative gold watch – Volume 12, No. 2, Spring Edition of *Consumer Protection Update*, dedicated to each of you in recognition of your substantial and superb effort over the years. Thank you all. And good luck. – *John E. Villafranco, Committee Chair*

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The Genesis of Consumer Protection Remedies Under Section 13(b) of the FTC Act

by David M. FitzGerald

Introduction

When I arrived at the Federal Trade Commission in 1976, no one imagined that Section 13(b) of the Federal Trade Commission Act¹ would become an important part of the Commission's consumer protection program. Section 13(b) had been on the books for three years, but had been used only once in a competition case, and not at all in the consumer protection arena. Moreover, it did not appear to have great promise as a consumer protection remedy. It gave the Commission authority to seek preliminary injunctions in aid of Commission administrative proceedings, but the Commission had had similar authority for many years in cases involving false advertising of food, cosmetics, drugs or medical devices, and had rarely used it. Section 13(b) also included a brief proviso authorizing the Commission to seek a permanent injunction "in proper cases," but it was generally assumed that in most cases the Commission would prefer to issue its own cease and desist order rather than seek a permanent injunction.

By the time I left the Commission in 1990, however, Section 13(b) – and in particular the permanent injunction proviso – had become a significant weapon in the Commission's fight against consumer fraud. It was well-established by then that Section 13(b) authorized the Commission to seek not only preliminary and permanent injunctions to halt deceptive practices, but also asset freezes, appointment of receivers, restitution and other relief to redress injury resulting from consumer frauds. As a federal appeals court explained in a 2002 decision, "The court's authority [under Section 13(b)] to order restitution to the victims [of a fraudulent scheme] and as an incident thereto to place the frozen assets in trust for them is not and cannot be questioned."²

Today Section 13(b) is a mainstay of the Commission's consumer protection program. As of June 30, 2004, the Commission had 86 cases pending in federal district courts in which the Commission sought permanent injunctions and consumer redress under Section 13(b), with another 11 cases pending in federal courts of appeals.³ In contrast, the Commission had fewer than a dozen administrative cases pending before its Administrative Law Judges, most of which involved allegations of anticompetitive practices rather than consumer deception.⁴

Below I offer a brief history tracing the development of the Commission's Section 13(b) authority during the period 1976 to 1990, from the perspective of one who litigated several of the early cases and later helped develop the Bureau of Consumer Protection's Section 13(b) program.

I. Background

To appreciate the development of Section 13(b) during this period, one must understand the Commission's enforcement authority as it stood in 1976. When it was enacted over 90 years ago, Section 5 of the Federal Trade Commission Act prohibited "unfair methods of competition."⁵ In 1938,

the Wheeler-Lea Act added the prohibition against "unfair or deceptive acts or practices" to Section 5, confirming the Commission's consumer protection mission.⁶

The Commission's principal tool for enforcing Section 5 was administrative proceedings leading to cease and desist orders. Penalties could be imposed only on those who violated cease and desist orders issued against them. This "one free bite" approach was deemed appropriate because the broad language of Section 5(a) was thought to give businesses little notice of the standards to which they would be held until the Commission applied Section 5 to specific conduct through a cease and desist order.

Many of the Commission's consumer protection cases, however, concerned consumer frauds accomplished through misrepresentations and deceptive omissions that clearly violated Section 5. In those types of cases the cease and desist order remedy had two serious shortcomings.

First, the administrative process leading to a final cease and desist order, including a trial before an Administrative Law Judge (ALJ), Commission review of the ALJ's decision, and a court of appeals' review of the Commission's decision, was a protracted process often taking several years to complete. In the meantime, the respondent remained free to employ the deceptive practices, causing continuing harm to the public.

Congress began to address this problem in the Wheeler-Lea Act. The Act added Section 12 to the FTC Act, making it unlawful to disseminate any "false advertisement . . . for the purpose of inducing or which is likely to induce, directly or indirectly, the purchase of food, drugs, devices, services, or cosmetics,"⁷ and gave the Commission authority to institute administrative cease and desist order proceedings against persons who were disseminating advertisements that the Commission had reason to believe violated Section 12. But Wheeler-Lea also added Section 13(a) to the FTC Act, which authorized the Commission to file an action in federal court to obtain a preliminary injunction to prevent the respondent from disseminating the challenged advertisements pending resolution of the Commission's administrative proceeding. As a result, for the first time the Commission could take immediate action to protect the public from on-going deception.⁸ In cases that did not involve food, drugs, devices or cosmetics, however, the Commission still had no authority to seek preliminary relief.

In 1973, Congress addressed the problem comprehensively through Section 13(b). Section 13(b) was originally part of broader proposed legislation to augment the Commission's enforcement authority, but it was dropped from that bill and inserted in the Trans-Alaska Pipeline Act,⁹ because of concern that the Commission needed immediate authority to seek preliminary relief to prevent the consummation of anticompetitive mergers, particularly among energy companies.¹⁰ As enacted, however, Section 13(b) was by no means limited to merger cases. It provided:

Whenever the Commission has reason to believe (1) that any person, partnership or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission thereon has become final, would be in the interest of the public the Commission by any of its attorneys designated by it for such

purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: Provided, however, that if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect; Provided further, That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction. ...

This language tracked Section 13(a) closely, with two notable exceptions. First, unlike Section 13(a), it applied to "any provision of law" enforced by the Commission; second, it authorized "a permanent injunction" in "proper cases."

The second shortcoming addressed by Section 13(b) was the lack of meaningful consumer redress. Ordering a respondent to cease and desist from using deceptive practices might protect the public from future harm, but it did not remedy the injury to the public caused by the respondent's past deceptions or deprive the respondent of the gains it had realized by employing them. In 1973, the Commission attempted to address this shortcoming through a creative application of Section 5. The Commission held that it was an unfair practice, in violation of Section 5, for a respondent to retain funds that it had received from consumers for a worthless product or service sold through deceptive or fraudulent practices. To remedy this "continuing violation" of Section 5, the Commission ordered that the funds be returned to the consumers – *i.e.*, restitution.¹¹

On review in *Heater v. FTC*, the Ninth Circuit set aside that portion of the Commission's order. Although the court acknowledged the Commission's broad authority to craft cease and desist remedies, it found that ordering restitution was "inconsistent and at variance with the over-all purpose and design of the [FTC Act]. In particular, it would permit the Commission to order private relief for harm caused by acts which occurred before the Commission had declared a statutory violation, and thus before giving notice that the prior conduct was within the statutory purview."¹²

In response, the Commission asked Congress to give it authority to order restitution. Instead, in 1975 Congress added Section 19 to the FTC Act, authorizing the Commission to seek consumer redress in federal district court for either (1) violations of FTC trade regulation rules, or (2) acts or practices as to which the Commission had issued a final cease and desist order, if the Commission "satisfies the court that the act or practice to which the cease and desist order relates is one which a reasonable man would have known under the circumstances was dishonest or fraudulent..." Section 19 expressly authorizes the court to award such relief as rescission or reformation of contracts, the refund of money or the return of property, or the payment of damages.¹³

II. Early Development of the Commission's Section 13(b) Authority

When I arrived at the Commission in June 1976, the principal remedy employed by the Commission was still the cease and desist order. Although

Section 13(b) had been enacted three years earlier, the Commission had made little use of it.

Certainly, the Commission wanted to use Section 13(b) to seek preliminary injunctions to prevent the consummation of mergers pending the completion of Commission administrative proceedings, as Congress had envisioned. Unfortunately, a practical difficulty had quickly emerged. To use Section 13(b) for such a purpose, the Commission needed enough advance notice of a planned merger to gather and analyze relevant data, decide whether to challenge the merger, file the Section 13(b) case and make a "proper showing" to the court to justify a preliminary injunction – all before the merger was consummated. The Hart-Scott-Rodino Antitrust Improvements Act of 1976¹⁴ addressed this problem by requiring parties planning a merger to provide advance notice to the Commission and the Justice Department, but when I arrived that Act had not yet taken effect. As a result, the Commission had brought only one Section 13(b) case, in which, without any reported opinion, the district court granted a limited "hold-separate" preliminary injunction after the acquiring firm had already purchased a 35% share of the acquired firm's stock.¹⁵

Shortly after I arrived, the Commission did receive enough advance warning of a planned merger of two regional supermarket chains to file its first Section 13(b) action to block a merger. In *FTC v. Food Town Stores, Inc.*, after the district court denied the Commission's request for a temporary restraining order, the Commission sought and obtained an injunction pending appeal from the Fourth Circuit. Judge Winter, sitting as a single circuit judge for purposes of the emergency motion, issued a decision emphatically supporting the Commission's right to obtain preliminary relief. In particular, and citing legislative history, he emphasized the preeminent importance of the public interest in "weighing the equities," as the court is required to do in deciding whether to order relief under Section 13(b).¹⁶ After Judge Winter granted an injunction pending appeal, the parties abandoned their planned merger, confirming the power of the Commission's Section 13(b) authority in the merger context.¹⁷

After the decision in *Food Town Stores*, Hart-Scott-Rodino came into effect. With notice of proposed mergers and a favorable opinion, the Commission began to use Section 13(b) aggressively, and, in many cases, successfully, and it quickly became an important part of the Commission's competition program. The Commission's success using Section 13(b) in competition cases led some Commission staff to consider how it might be used to advance the Commission's consumer protection mission, as well.

During the 1970's the Commission's consumer protection efforts were focused on trade regulation rulemaking proceedings, rather than case-by-case adjudication.¹⁸ These rulemaking proceedings, which would have significantly affected many areas of the economy if the proposed rules had ever become effective (few did), consumed most of the attention of the Commission's Bureau of Consumer Protection (BCP) policymakers and most of the Commission's BCP resources, but the Commission still brought some administrative consumer protection cases during this period. The question was whether and how the Commission could use Section 13(b) effectively in those cases.

On its face, Section 13(b) authorizes the Commission to seek preliminary injunctions to stop on-going deceptive practices pending the completion of the Commission's administrative process. Deceptive practices, however, typically are transitory. Often, by the time the Commission had completed its investigation and initiated its administrative proceeding, the respondent had abandoned the practices that the Commission intended to challenge. It made little sense to seek a preliminary injunction to halt practices that the respondent was no longer employing.¹⁹

In 1977 the Commission found an opportunity to use Section 13(b) in a more effective and creative manner when it filed suit against Australian Land Title, Ltd. (ALT) and its parent companies. The Commission alleged that ALT had sold interests in land in Australia to American consumers under long term sales contracts through deceptive sales practices, including misrepresentations and omission of critical information.²⁰ By the time the Commission completed its investigation and was prepared to file an administrative complaint, the sales had ended. The Commission was concerned, however, that the purchasers would continue to pay on their long term purchase contracts while the administrative proceedings were pending. In addition, the Commission believed that a Section 19 consumer redress case might be appropriate after the administrative proceeding concluded, but was concerned that by that time ALT might have dissipated the funds it had collected, making redress unfeasible.

In the Section 13(b) case, the Commission asked the district court to issue a preliminary injunction prohibiting ALT from continuing to collect payments under the contracts, or, alternatively, requiring ALT to deposit the payments in an escrow account, to ensure that the funds would be available for relief under Section 19. Before the court ruled, the parties reached a settlement under which the payments were placed in escrow, and ALT and its parent companies agreed to a Commission consent order that required them to forgo future payments under the contracts and to pay redress to consumers.²¹

In 1979, the Commission used the same approach in a similar case. The Commission issued an administrative complaint against Southwest Sunsites, Inc. and two related companies, alleging that they had employed a variety of misrepresentations and deceptive omissions in the sale of land in Texas under long-term sales contracts. As in *Australian Land Title*, the Commission also filed a Section 13(b) case in which it asked the district court to issue a preliminary injunction requiring, among other things, that the defendants escrow all funds paid by the purchasers to ensure that the funds would be available for relief under Section 19. In this case, however, there was no settlement and the district court held that Section 13(b) did not authorize it to "freeze" the respondents' assets as the Commission requested.

In January 1982, the Fifth Circuit reversed, holding that "a grant of jurisdiction such as that contained in Section 13(b) carries with it the authorization for the district court to exercise the full range of equitable remedies traditionally available to it." More specifically, the court held that a district court had authority under Section 13(b) to "order temporary, ancillary relief preventing the dissipation of assets or funds that may constitute part of the relief eventually ordered in the case." The court reasoned that, although consumer redress would require a separate Section 19 case after the conclusion of the administrative proceeding, "[s]imply

because the complete resolution of a matter will require a two-step process does not relieve a court of the task of determining how to preserve a state of affairs such that a meaningful decision can be rendered after full consideration of the merits."²²

Although *Southwest Sunsites* adopted a favorable interpretation of Section 13(b), the process envisioned in that case was inefficient and protracted. To obtain complete final relief, the Commission would need to litigate and win three separate actions: (1) a Section 13(b) preliminary injunction proceeding to obtain a preliminary asset freeze; (2) an administrative proceeding leading to a final cease and desist order; and (3) a district court action to obtain consumer redress under Section 19. Even before the *Southwest Sunsites* decision was issued, the Commission had begun to explore the possibility of using the permanent injunction proviso of Section 13(b) as a shortcut.

Although most of the text of Section 13(b) concerns its use as an ancillary remedy in aid of administrative cease and desist proceedings, Section 13(b) also provides that "in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction." The legislative history suggests that this was intended to "allow the Commission to seek a permanent injunction when a court is reluctant to grant a temporary injunction because it cannot be assured of a[n] early hearing on the merits [in the administrative proceeding]." In addition, it was intended to give the Commission "the ability, in the routine fraud case, to merely seek a permanent injunction in those situations in which it does not desire to further expand upon the prohibitions of the Federal Trade Commission Act through the issuance of a cease and desist order. Commission resources will be better utilized, and cases can be disposed of more efficiently."²³

In 1979, the Commission filed its first Section 13(b) permanent injunction suit, *FTC v. Virginia Homes Manufacturing Corp.*,²⁴ alleging that two mobile home manufacturers had issued written warranties to mobile homes purchasers that, on their face, misrepresented the purchasers' warranty rights under the Magnuson Moss Warranty Act.²⁵ The Warranty Act provides that a violation of any of its provisions is also a violation of Section 5 of the FTC Act,²⁶ so the Commission could have employed its traditional administrative process, but it was concerned that the purchasers' warranty rights would expire, or they would forgo warranty claims based on the misrepresentations, before the Commission could issue a final cease and desist order. And, in light of *Heater*, it was not clear whether the Commission would have authority to require the respondents to notify the past purchasers of their true warranty rights.

Instead of issuing an administrative complaint, the Commission filed in court under the permanent injunction proviso of Section 13(b) seeking an order requiring the defendants to notify their past purchasers of their full warranty rights. The court granted the Commission's motion for summary judgment. It held that this was a "proper case" for permanent injunctive relief under Section 13(b), noting that the Warranty Act was a provision of law enforced by the Commission and that the Commission's decision to file the case "was a legitimate exercise of prosecutorial discretion." Furthermore, the court found that it had authority to order notification to past customers even though such relief was not expressly authorized by Section 13(b), because "the powers of a court of equity to issue appropriate orders are, if anything, more expansive than the powers of the independent agencies . . . For these reasons, this Court finds that compulsory notice is implicitly authorized by § 13(b) so long as such notice would be essential to the effective discharge of the Court's responsibilities."²⁷

The Commission's next step was a bit bolder. In 1979, shortly after filing *Virginia Homes*, the Commission filed *FTC v. Kazdin*, precisely the sort of "routine fraud" case described in the legislative history of Section 13(b). The Commission alleged that an individual and two companies he controlled had marketed a "hair implant" process to more than 2,000 consumers through a variety of misrepresentations and deceptive omissions regarding the safety and efficacy of the process. The Commission sought not only a permanent injunction prohibiting the defendants from employing such practices in the future, but also "ancillary relief," including restitution to the injured consumers, a freeze of the defendants' assets pending payment of restitution, imposition of a constructive trust on certain real estate, and the appointment of a receiver to sell the property. After the court denied their motion to dismiss the Complaint, the defendants defaulted and the court entered judgment awarding the Commission the requested relief.²⁸

In 1980, the Commission continued this approach in *FTC v. H.N. Singer, Inc.* The Commission alleged that the defendants had violated the Commission's Franchise Rule²⁹ and employed deceptive practices in the sale of business opportunities. As in *Kazdin*, the Commission sought both a permanent injunction and ancillary relief, including restitution for injured consumers, and the Commission requested a preliminary order freezing the defendants' assets to ensure they would be available for redress. The district court issued the requested preliminary injunction and the defendants appealed.

The Ninth Circuit affirmed, holding that the district court had authority to order the preliminary relief under both Section 13(b) and Section 19.³⁰ With respect to Section 13(b), the court upheld the Commission's authority to seek permanent injunctions in "routine fraud" cases, such as the one at bar, and the district court's authority in such cases "to grant whatever preliminary injunctions are justified by the usual equitable standards . . ." Most significantly, the court held:

Congress, when it gave the district court authority to grant a permanent injunction against violations of any provisions of law enforced by the Commission, also gave the district court authority to grant any ancillary relief necessary to accomplish complete justice because it did not limit that traditional equitable power expressly or by necessary and inescapable inference. In particular, Congress thereby gave the district court power to order rescission of contracts. Hence §13(b) provides a basis for an order freezing assets.³¹

The *Singer* opinion became the foundation of the Commission's Section 13(b) program in the consumer protection arena. Many other courts have followed *Singer*, holding that Section 13(b) gives the district courts broad remedial discretion, even though neither Section 13(b) itself nor its legislative history mentions any remedy other than injunctions; no court has disagreed.

The legal analysis that the Commission urged and the courts adopted is straightforward and well-established. It rests on the Supreme Court's 1946 decision in *Porter v. Warner Holding Co.* There the Court held that in an enforcement proceeding under the Emergency Price Control Act of 1942,³² the district court had authority to order restitution of rent collected in violation of the Act even though the Act expressly authorized only "a permanent or temporary injunction, restraining order, or other order." The Court explained that when Congress grants the district courts equitable jurisdiction to enjoin unlawful acts and practices,

[u]nless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction . . .

Moreover, the comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command. Unless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied. "The great principles of equity, securing complete justice, should not be yielded to light inferences, or doubtful construction."³³

The Supreme Court and the lower federal courts have applied this reasoning in many subsequent cases, upholding the district courts' authority to employ a broad range of equitable remedies in enforcement proceedings brought by an array of administrative agencies under statutes that, like Section 13(b), expressly authorize only injunctive relief.³⁴ The language of many of these statutory injunctive provisions is quite similar to the language of Section 13(b).³⁵

Critics, and defendants in Section 13(b) cases, have argued that Section 13(b) should be distinguished from the statutory provisions at issue in the *Porter* line of cases.³⁶ They point out that Congress squarely addressed the issue of consumer redress in Section 19, authorizing the district courts to award redress in specified circumstances.³⁷ They argue that, under the reasoning of *Porter*, this supports a "necessary and inescapable inference" that Congress intended to limit the equitable authority of the district courts under the permanent injunction proviso of Section 13(b) to injunctive relief.

The courts, however, have uniformly rejected these arguments, citing Section 19(e), a "savings clause" that provides: "Remedies provided in this section are in addition to, and not in lieu of, any other remedy or right of action provided by State or Federal law. Nothing in this section shall be construed to affect any authority of the Commission under any other provision of law."³⁸ The courts have reasoned that this provision forestalls any "inescapable" inference that Congress intended to limit the equitable authority of the courts under Section 13(b).³⁹ Therefore, they conclude, *Porter* applies, and the full range of equitable remedies is available under Section 13(b).

The Commission's success under Section 13(b), however, involved more than just articulating a well-supported legal theory. At the outset, the Commission presented those arguments in cases involving compelling facts. The Commission's argument was appealing because it gave the courts discretion to award the relief called for by the facts, "securing complete justice" in the words of *Porter*. It is, therefore, not really surprising that, in *Singer*, the same court that in *Heater* had concluded it would be "inconsistent and at variance with the over-all purpose and design" of the FTC Act for the Commission to order restitution found no similar limitation on the implied power of the *district courts* to order the same relief under the permanent injunction proviso of Section 13(b).

III. Development of the Section 13(b) Program

The early cases established that Section 13(b) had the potential to become an important element of the Commission's consumer protection program. Within the Commission, however, Section 13(b) consumer protection cases were still largely viewed as curiosities, while the consumer protection mission focused on rulemaking.

That changed in the early 1980's, after a new administration took control of the Commission. The new FTC leaders were philosophically opposed to the sweeping rulemaking efforts that had dominated the Commission's consumer protection program in the 1970's. Instead, they wanted the Commission to pursue its consumer protection mission primarily through case-by-case adjudication and believed the Commission could serve the public by taking aggressive action against consumer fraud.

Experience had shown, however, that traditional administrative adjudication leading to a cease and desist order was not effective in combating fraud, because the respondent might continue to employ fraudulent practices while the administrative proceeding was pending, and could retain the gains earned through those practices even after the Commission issued its cease and desist order. The Commission might have attempted to overcome these weaknesses by seeking preliminary relief under Section 13(b), as it had in *Southwest Sunsites*, coupled with a Section 19 consumer redress action after it issued a final cease and desist order, but such a three-part process would have been lengthy and cumbersome. The permanent injunction proviso of Section 13(b), as interpreted in *Singer*, offered a much more effective and efficient weapon against fraud, if the Commission could persuade other courts to follow *Singer*.

The Commission, therefore, embarked on an ambitious program to identify and pursue fraudulent schemes in federal district court, under the permanent injunction proviso of Section 13(b). *Singer* provided the legal framework to support this effort, but for the program to be successful the Commission needed to realign the BCP staff's efforts from rulemaking and administrative adjudication to an entirely different enforcement approach under Section 13(b).

As part of this effort, BCP created a new litigation office to encourage, evaluate and coordinate cases under Section 13(b). BCP attorneys, whose responsibilities had previously been limited to administrative litigation and rulemaking, were required to develop new skills to litigate Section 13(b) cases successfully in federal court. To accomplish this, BCP's litigation office devised and conducted in-house training programs, as well as programs provided by outside organizations such as the National Institute for Trial Advocacy (NITA), to help BCP attorneys hone their litigation skills. BCP also developed and implemented consistent litigation strategies and tactics for Section 13(b) cases.

To pursue consumer frauds effectively, BCP also needed to improve its ability to quickly identify and investigate fraudulent schemes. Recognizing this reality, BCP staff established working relationships with other state and federal law enforcement agencies, as well as non-governmental organizations, to help target widespread frauds as early as possible. Then BCP staff employed innovative investigatory techniques, such as posing as

potential customers and tape-recording misleading sales presentations, to obtain the evidence needed to support persuasive Section 13(b) cases. In some cases, BCP staff cooperated with other law enforcement agencies on joint investigations.

In this way, the Commission successfully developed and presented compelling cases, winning wide-spread acceptance of the principles first articulated in *Singer*. Over the next several years it became settled law that the district courts have authority under Section 13(b) to grant whatever preliminary or permanent equitable relief they deem necessary to secure complete justice under the particular circumstances presented.⁴⁰ Preliminary relief could include temporary restraining orders (with or without notice) and preliminary injunctions that freeze the defendants' assets, appoint receivers to take control of their businesses and require them to make an accounting. Final relief may include not only permanent injunctions, but rescission of contracts, restitution, disgorgement, or the imposition of constructive trusts and appointment trustees, as needed to redress injury to consumers.⁴¹ As a result, Section 13(b) has become an important component of the Commission's consumer protection program, allowing the Commission to address fraudulent practices much more effectively than was ever possible through the administrative process.

IV. Final Observations

Looking back may be nostalgic for those of us who were involved, but others may ask whether the development of the Commission's Section 13(b) authority offers any lessons for the future. On that topic, I offer a few closing thoughts:

- *Tend to the core mission.* Every successful organization focuses on achieving its core mission before extending outward. The development of Section 13(b) as an effective remedy allowed the Commission to improve significantly its ability to accomplish its core consumer protection mission. This benefited not only consumers, but the Commission itself, by advancing the public's perception of the Commission as an important and effective consumer protection agency, a perception that had been largely lost by the end of the 1970's.
- *Be sure you are making full and effective use of existing authority.* Section 13(b) was added to the FTC Act in 1973, but the Commission did not begin to explore its use in the consumer protection arena for several years, and did not employ it effectively until the 1980's. In the meantime, the Commission was asking Congress to give it additional authority, arguing that it lacked the tools it needed to protect consumers effectively.
- *Step cautiously when proceeding boldly.* In exploring its Section 13(b) authority, the Commission moved warily, selecting cases with compelling facts that established clear violations of well-established legal standards, and advancing well-supported legal arguments to support limited and clearly justified equitable relief. Through this carefully considered, step-by-step approach, the Commission established its basic Section 13(b) analyses and arguments, and obtained favorable decisions endorsing them, before pursuing a more ambitious agenda.

- *Don't overlook the value of basic research.* Neither the text of Section 13(b) nor its legislative history disclosed a basis to argue for broad equitable relief. Instead of stopping there, however, research into the case law interpreting statutes conferring similar injunctive authority on other agencies led to the *Porter* line of cases, providing critical support for a broad interpretation of Section 13(b).
- *Being out of the spotlight can be an advantage.* In the early years, the effort to employ Section 13(b) in the consumer protection arena received relatively little attention from those who were not directly involved, and even the Commission's litigation successes were not viewed as particularly significant developments for the consumer protection program. For those of us who saw the development of Section 13(b) as important, however, that was liberating, rather than frustrating, because it allowed us to pursue our efforts with little interference.
- *Don't let naysayers discourage pursuit of a promising theory or approach.* When the early cases were proposed, many people within the Commission predicted they would be unsuccessful, because Section 13(b) authorized only injunctive relief. If the doubters had stopped the Commission from filing the cases, the Commission might never have established the full range of remedies available to it under Section 13(b). Without those remedies, the Commission could not have become the aggressive and successful foe of consumer fraud that it is today.

Substantiating Dietary Supplement Claims – Guidance from the FDA

by Ivan J. Wasserman and Farah K. Ahmed

Since the passage of the Dietary Supplement Health and Education Act ("DSHEA") in 1994, dietary supplements have become a multi-billion dollar industry with major pharmaceutical and cosmetic corporations now investing in supplement product lines. According to Euromonitor, the United States's supplement industry reached \$6.4 billion in 2004.¹ Along with this industry growth has come a dizzying array of supplements making claims about "miraculous" weight loss and preventing and curing diseases, causing the Federal Trade Commission ("FTC" or "Commission") and the Food and Drug Administration ("FDA" or "Agency") to focus enforcement efforts on false, misleading, and unsubstantiated claims for dietary supplements.

Depending on where they appear, claims for dietary supplements are subject to regulation by the FDA or the FTC. FDA has primary jurisdiction over claims made on a dietary supplement's labeling (including the actual product label, package inserts, and other materials that "accompany" the product), and the FTC has primary jurisdiction over claims made in advertising. Both agencies assert jurisdiction over claims that appear on the Internet. The FTC and the FDA continue to develop their joint initiative entitled "Consumer Health Information for Better Nutrition," to more effectively take action against false and misleading claims. The agencies share information about supplement marketers and the safety and efficacy of their products.

In 1998, to help clarify what constitutes adequate substantiation for claims that appear in advertising, the FTC published guidance titled: *Dietary Supplements: An Advertising Guide For Industry* ("FTC Guide"). In the FTC Guide, the Commission provided guidance on the type of substantiation, whether it be in the form of clinical trials or otherwise, that is needed to support various types of claims. While that helps with advertising, without similar guidance from the FDA, the industry has been unclear about what substantiation is required to support claims made in a supplement's labeling.

As discussed in detail below, this changed in November 2004 when the FDA released its *Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act* ("Guidance"), which is expressly modeled after, and is intended to be consistent with the FTC Guide. FDA Guidance addresses the following issues in the context of labeling claims: (i) the meaning of the claim being made; (ii) the relationship of the evidence to the claim; (iii) the quality and quantity of the evidence; and (iv) the totality of the evidence.

By way of background, prior to the passage of DSHEA, dietary supplements were not defined and FDA regulated them as foods. However, in 1994, DSHEA amended the Federal Food, Drug and Cosmetic Act to include several dietary supplement provisions such as permitting the use of claims known as "Statements of Nutritional Support." DSHEA divides these claims into the following four categories:

1. Claims that declare a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such a disease in the United States (e.g., "vitamin C prevents scurvy, a disease that affects X% of Americans");
2. Claims that describe the role of a nutrient or dietary ingredient intended to affect the structure or function of humans ("structure/function" claims) (e.g., "helps promote urinary tract health," "helps maintain cardiovascular function," "for occasional relief of constipation," and "helps support cartilage and joint function");²
3. Claims that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function; or
4. Claims that describe general well-being from consumption of a nutrient or dietary ingredient.³

In order to make any of these statements, DSHEA explicitly requires that the manufacturer of the dietary supplement have "substantiation that such statement is truthful and not misleading."⁴

Unlike the FTC, the FDA imposes additional requirements on companies making these types of claims as a means to ensure that the public does not confuse a dietary supplement for a drug product. A "drug," by definition, is intended to treat or prevent disease⁵ and is subject to pre-market approval by FDA after it has demonstrated a high level of safety and efficacy, whereas a supplement does not require this type of evaluation and approval.

Specifically, DSHEA requires that such Statements of Nutritional Support be accompanied by the following prominently displayed disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."⁶ DSHEA also requires manufacturers to notify the Agency of any structure/function claims no later than 30 days after first marketing a supplement bearing the claim.⁷ The Agency does not evaluate these claims for substantiation, but rather looks to ensure that the claim is in fact a permitted structure/function claim and not a disease claim.⁸ Express or implied claims to treat, cure, prevent, or mitigate a disease (other than nutritional deficiency diseases) are not permitted for dietary supplements, regardless of the amount of substantiation possessed by the manufacturer (e.g., "helps prevent cancer," "reverses heart disease," "for relief of chronic constipation," and "reduces pain and stiffness associated with arthritis").⁹

The FDA Dietary Supplement Claim Substantiation Draft Guidance

On November 4, 2004, with the release of the Guidance, the Agency provided clarification on the types of substantiation that could be used to support Statements of Nutritional Support.¹⁰ This Guidance has adopted the FTC's standard of "competent and reliable scientific evidence"¹¹ and further recommends using four key factors for evaluating claims: (i) the meaning of the claim being made; (ii) the relationship of the evidence to the claim; (iii) the quality and quantity of the evidence; and (iv) the totality of the evidence. Similar to the FTC's approach, FDA did not specify a formula to determine what information is needed to support a claim; rather, the evidence required will depend on the claim.

Meaning of the Claim. In order to determine what evidence is needed to support a claim, the explicit and implicit message(s) of the claim, taken in context, should be identified using the "reasonable consumer" standard.¹² A "reasonable consumer" is the typical person who will see the ad, for example, if the ad is aimed at children, it will be analyzed from the viewpoint of a child. This will outline the parameters of the message requiring substantiation. To illustrate this point, the Guidance provided the following example:

The labeling states, in connection with the product's claim, that the dietary supplement has been "studied for years" in a particular country or region and is the subject of clinical or "university" research. Here, the labeling conveys the impression that the product has been studied and also conveys the impression that there is a substantial body of competently conducted scientific research supporting the claim. We recommend that manufacturers possess evidence to substantiate both the express statements and their implied meaning.

Relationship of the Evidence to the Claim. Of course, in order for a claim to be substantiated, there must be a direct relationship between the supporting evidence and the claim. FDA suggested considering the following threshold questions in determining the existence of this relationship:

1. Have the studies specified and measured the dietary supplement that is subject of the claim?

2. Have the studies appropriately specified and measured the nutritional deficiency, structure/function, or general well-being that is the subject of the claim?
3. Were the studies based on a population that is similar to that which will be consuming the dietary supplement product?
4. Does the claim accurately convey to consumers the extent, nature, or permanence of the effect achieved in the relevant studies and the level of scientific certainty for that effect?

The Guidance illustrates a number of issues pertaining to the relevance of evidence being used to support a claim. For example, studies examining the effect of an ingredient administered as a topical product may not support a claim for the same effect in a dietary supplement (which must be ingested) and studies demonstrating effects in foreign populations should take into account potential confounding differences from a US population (e.g., lower blood levels of a certain mineral).

Scientific Quality. The scientific quality of a study is important in determining whether the study adequately supports a claim. In determining the scientific quality of a study, FDA uses the following five criteria in its evaluation:

1. Study population, with larger sample sizes generally preferred;
2. Study design and conduct, with placebo controls giving added strength to the outcome;
3. Data collection methods;
4. Statistical analysis; and
5. Outcome measures.

The Agency recommended that when possible, a "randomized, double-blind, parallel group, placebo-controlled trial design" conducted on human subjects is the "gold" standard. The Guidance also provided a more detailed outline of commonly accepted scientific principles in evaluating the quality of scientific evidence.

FDA generally prefers intervention studies¹³ over observational studies¹⁴ because they evaluate the product's direct effect on the human body. In addition, the Guidance states that the following would generally be considered background information, but alone may not be adequate to substantiate a claim: animal and *in vitro* studies; anecdotal evidence; meta-analysis; review articles; and comments and letters. The following was given as an example of a quality study:

A dietary supplement label claims, "Randomized, double blind, placebo-controlled studies demonstrate that herbal extract 'Z' is beneficial in relieving menopausal symptoms." The firm is relying on the results of more than one randomized, double blind, placebo-controlled intervention study using menopausal women as subjects, and the results of those studies are in general agreement. The claim would likely be substantiated because it relies on high quality studies in humans that directly addressed conditions described in the claim.

Totality of the Evidence. In determining whether there is adequate evidence to substantiate a claim, firms should consider the entire body of evidence, including “quality, quantity, consistency, relevance of exposure and persuasiveness.” Studies presenting conflicting or inconsistent results may weaken the substantiation, however, verifying positive study results can be helpful. It is ideal if the evidence used to substantiate a claim is consistent with the surrounding body of evidence. The Guidance provided the following as an example to illustrate this point:

A company plans to promote its product containing ingredient X to athletes to improve endurance performance. There are some well-designed published studies demonstrating that other products containing ingredient X are effective, but other well-designed studies show no effect for certain products containing ingredient X. The firm sponsored a randomized, blinded, six-month study comparing its product to four other products containing ingredient X in a dose (serving size)-response fashion. The findings demonstrate that the firm’s product and two other products that provided the highest amount of ingredient X per day produced substantial, statistically significant improvements in athletic endurance. When the firm compared the results of this study to prior studies, the firm concluded that the explanation for previous conflicting study results is that when the serving size of ingredient X is below a certain amount, there is no measurable benefit. Taken together, the positive results from their study, and the identification of a plausible explanation to explain why some studies showed no positive effects, would likely provide evidence to substantiate adequately the endurance performance claim for the dietary supplement.

Active Enforcement Against Unsubstantiated Dietary Supplement Claims

FDA enforcement actions typically take the form of warning letters and do not result in monetary penalties. FDA warning letters are released to the public as a formal means of identifying non-compliant companies. The Agency generally issues one warning letter before taking more serious action (although it is under no obligation to provide one before doing so) such as product seizure or injunction.

Since 2002, the FTC and FDA have issued over 200 warning letters, cyber letters, and e-mail advisories to various dietary supplement companies. The agencies have taken action not only against supplement distributors, but also against manufacturers, retailers, and advertisers of these products. For example, in 2003, the FTC and FDA took action against marketers of coral calcium supplements. The Commission filed a complaint against Kevin Trudeau and others for violating the FTC Act by claiming, falsely and without substantiation, that their coral calcium supplements can treat or cure cancer and other serious diseases. The FTC and FDA then sent warning letters to a large number of web site operators marketing coral calcium supplements. The FTC letters stated that the Commission was not aware of any competent and reliable scientific evidence supporting the anti-cancer and other disease treatment claims. Similarly, the FDA warned web operators that making “disease claims” and unsubstantiated structure/function claims cause their products to violate the Federal Food, Drug and Cosmetic Act. In an FTC press release, then FDA Commissioner Mark B. McClellan, stated “FDA and FTC are working together to maximize our efforts to combat health fraud. We are trying to be particularly vigilant

concerning fraudulent [I]nternet promotion, because this is emerging as an increasingly insidious way to exploit the public.”¹⁵

In 2004, both agencies took enforcement actions against Window Rock Enterprises, Inc. and other parties involved in making unsubstantiated weight loss and stress reduction claims for the dietary supplement products CortiSlim and CortiStress.¹⁶ FDA acted first by sending a warning letter to the company, citing several of its claims for lack of substantiation. The FTC then filed a complaint against the company, charging it with violating the FTC Act by making deceptive efficacy claims for the products. The complaint sought permanent injunctive relief, including redress for consumers who purchased the products. This collaborative action was the latest in the FTC/FDA’s joint enforcement effort.

FDA also appears to have independently increased its enforcement efforts against unsubstantiated claims. On October 22, 2004, FDA sent eight warning letters to dietary supplement distributors for making unsubstantiated claims on the Internet for their weight loss products.¹⁷ The Agency determined that the claims were false and misleading as they lacked adequate substantiation. The FDA also sent letters to major retailers of dietary supplements informing them that products making unsubstantiated claims are misbranded and that the Agency intended to start a program inspecting retail establishments to identify products making unsubstantiated claims in their labeling.¹⁸

Looking Ahead

As the FTC and FDA continue their joint enforcement efforts and with further clarification in the area of dietary supplement claim substantiation, it is increasingly important for supplement marketers to understand both agencies’ regulations. With a more clear and consistent FDA substantiation standard, those counseling supplement companies should emphasize the importance of obtaining competent and reliable scientific evidence before going to market.

Planning for a Privacy Breach in a Global Company: Understanding the Multi-Jurisdictional Issues Can Make the Difference Between a Privacy Incident and a Privacy Crisis

By Nava Bat-Avraham, Laura Becking, Andre J. Jaglom, Leigh Feldman, John P. Beardwood and Michael Peeters

U.S. companies involved in processing personally identifiable information in either domestic or cross border transactions are faced with diverse, and sometimes conflicting, privacy and data protection laws and regulations. Even the best-prepared enterprise faces the potential for a privacy breach and the resulting adverse legal and business consequences. How, and how successfully, a company handles a privacy breach in large part will depend on the measures it has taken to implement a culture of privacy awareness prior to the breach and, particularly, the efforts it has put into creating a

response plan. It is imperative for every company to develop and implement a privacy breach tracking method and response plan.¹

A “privacy breach” can be defined as the unauthorized disclosure or access to: (i) customer data; (ii) employee records and data; or (iii) other personally identifiable information as to which the company has a legal or contractual obligation to keep confidential. Although a company’s primary focus is typically on the first two types of data, it is important to note that most companies collect and retain a substantial amount of personal data relating to individuals who are not customers or employees, including vendors and suppliers.

Privacy breaches occur as a result of: (i) unauthorized access of databases/systems; (ii) unauthorized access to documents; (iii) loss or theft of documents; (iv) loss or theft of physical equipment (such as laptops and PDAs); and (v) breaches of data streams and/or transmissions (such as interceptions of unencrypted email or non-SSL transmissions).²

As we will discuss below, it is imperative that a privacy breach is reported promptly to people within the company who know what to do. Notification should be directed to the appointed person or team, within the company, who is responsible for privacy and knows how to respond appropriately to the breach.

This person or team of privacy professionals must respond in accordance with the laws, rules and regulations of any jurisdiction that may be applicable. The primary focus of the response should be to protect the individuals whose information has been compromised and limit any further damage. This should generally go hand in hand with the obvious need to minimize the damage to the company (e.g. reputational damage, regulatory fines, litigation, criminal penalties and the like.).

While these principles seem proper (if not obvious) implementing them in the real world can present a host of challenges. In this article we will explore a scenario that would result in a privacy breach, the laws that would be applied, and whether typical processes adequately respond to the privacy breach. A reasonable response to a particular privacy breach will depend on the industry, the type of breach, type of data compromised, and applicable law. There are however general processes and procedures that companies can implement prior to the occurrence of any breach that will increase the likelihood of an adequate response and minimize legal risk exposure. Our hypothetical will illustrate each of these facets.

The Breach

Jack is a senior salesman working for a large multinational corporation. His office is located in California, the company’s headquarters. While preparing for a business trip to the firm’s London office, Jack decides he needs his customer files to maintain contact with some of his clients. In London, Jack will train a number of new employees, and will need access to personal information about these trainees. Jack’s files, which include personal identifiable information, are related exclusively to individuals.

Jack decides to download customer data for his 1,500 clients onto his personal laptop computer. The only information Jack needs is his clients’ names and phone numbers. Jack, in his diligence, decides to download all

the data in the records, and all of his customer files, rather than to take the time to segregate the data. As a result, Jack downloads the names, addresses, phone numbers, social security numbers (SSNs), account numbers, credit card numbers and other data relating to his 1,500 individual clients, who are located in California, Washington, Oregon and Canada. Jack also downloads the names, office phone numbers, home addresses and home phone numbers of the twenty new London-based salespeople he will be training in the firm’s London office.

Jack thinks that firm policy may prohibit putting this type of unencrypted personal information onto his laptop, but feels assured he can secure the firm’s data, which he has taken without the permission of his supervisor or the company’s privacy team.

After loading his luggage onto a baggage carrier, he uses his cell phone to make the call to the hotel while looking for his car. When Jack is about to get into his car, he notices that his laptop bag is not with his other luggage. A short time later when Jack arrives at the firm’s London office he has to decide what to do about his stolen laptop and the data it contained.

The Response

A. Reporting The Breach To The Right People

Several months before Jack lost his laptop, senior executives at his firm decided to establish a privacy team to address compliance issues relating to existing privacy and data protection laws, rules, and regulations. One of the team’s initiatives was to establish a central location for employees and customers to report privacy breaches, regardless of where the breach took place.

This system would serve two important purposes: (i) the privacy team would have a global view of the types of breaches taking place within the company to help identify unfavorable trends and security risks; and (ii) the privacy team would be able to help the firm develop the proper mechanisms to respond effectively to specific privacy breaches.

Shortly before Jack lost his laptop, the privacy team developed a simple one-page web-based Privacy Breach Report Form accessible from the Privacy link on the firm’s intranet site. The report was developed to collect basic information about each breach to enable the team to begin its response.

Based on the information collected on the Privacy Breach Report Form, the response team would include the privacy team, senior executives, client call center representatives, the fraud group, the data security group, the physical security group, website administrators, audit and compliance representatives, HR representatives, union or other employee representatives, outside counsel and public relations representatives.

Fortunately, Jack had a friend and colleague in the legal department. He decided she would be the best person to call to help with his situation. The company attorney told Jack to complete the Privacy Breach Report Form immediately. She directed Jack to the Privacy link on the firm’s Intranet to report the privacy breach. She then called the privacy team to alert it to the situation.

Jack completed the report detailing what had happened, and hit the send button. Within a few minutes the privacy breach report hit the privacy team’s mailbox and was read by one of the team members who had been

waiting for its arrival. Jack received a reply by email immediately indicating that things were in motion. After reading the report, the privacy team member began making phone calls to mobilize the team for the appropriate response.

B. Protecting The Individuals Whose Information Was Compromised

The first call by the privacy team was to Jack to gather more detailed information about the breach. Jack reported the breach to the authorities at the airport, but the laptop had not been found. The team assumes the laptop has been stolen and will not be recovered. While the laptop is password protected, none of the data has been encrypted. The team must assume an unauthorized person has accessed all customer and employee data that was downloaded to the laptop.

Following the initial response plan, Jack is asked for a list of all clients that have been affected by this security breach. Jack directs the team to the central database containing all of the data on his clients and the employees he downloaded to his laptop. The customer data is immediately sent to the firm's call centers so that enhanced security can be put on all accounts.

This enhanced security requires anyone calling a company call center to access one of the affected accounts to answer additional authentication questions either to gain access to any information about the account, or to initiate any activity on the account. The call center representative will be on notice, based on the data on the call center system, to ask these additional authentication questions and will have a heightened awareness for any suspicious or unusual behavior.

The team has notified all geographic locations about the security breach. The team has determined it is not necessary to block website access for affected clients, since no website passwords were compromised. The online group, however, will monitor the stolen accounts for unusual activity. The firm's fraud group is also notified, and will increase its surveillance on these accounts for any suspicious activity.

The team must now address the more difficult questions of whether to notify the 1,500 clients and twenty employees whose information has been compromised, and if so, how this should be done.

C. Complying With The Law and Other Decisions

Most of the customers whose data was compromised live in California, Oregon, Washington, and Canada. The employees whose information was compromised all live in London. The first question is whether the firm is required by law to notify the customers and employees. Once this is determined, if notification is either required by law or considered good business practice, the team must decide how the customers and employees should be notified.

1. State-Specific Issues

In Oregon and Washington there are currently no state law requirements to notify residents that their information has been compromised.³

In California, a law adopted in 2002⁴ requires notice when certain personal information is compromised. The law applies to any enterprise that conducts

business in California, regardless of whether the business is located within or outside of California (and even outside the United States) that maintains certain elements of personal information in computerized form regarding California residents.

The notification requirement is triggered if there is an unauthorized acquisition of computerized data that compromises the security, confidentiality or integrity of unencrypted first name or initial and last name, as well as unencrypted: (1) Social Security number; (2) driver's license number; **or** (3) financial account number, credit or debit card number in combination with any required security code that would permit access to an individual's financial account.

The law requires notification to affected persons upon discovery of a privacy breach "in the most expedient time possible and without unreasonable delay."⁵ The California Office Of Privacy Protection has published a document⁶ that recommends notification within ten business days after the breach. Additional time in disclosure is permitted where necessary for purposes of a law enforcement investigation and will generally be deemed reasonable where required to complete further internal analysis to determine the scope of the breach.

The disclosure notice may be either written or electronic. A substitute notice may be used if the cost of disclosure is greater than \$250,000, if the number of affected parties exceeds five hundred thousand, or if adequate contact information of affected parties is not available. Substitute notice must be provided by: (1) email if the company has addresses; (2) web site posting; and (3) major statewide media notification.

Although the California law does not provide a standard notice form or guidance on the content, the team has decided that, in order to comply, the notice will include the following information: (1) date of security breach; (2) information compromised; (3) whether the term is certain that the information is in the hands of a specific party; and (4) a point of contact within the company.

2. Canadian Issues

In Canada, there are at least three potential causes of action resulting from the loss. First, the client information may be subject to a duty of confidence, whether expressly in contracts with each client, or implicitly under common law. Second, the five provinces of British Columbia,⁷ Saskatchewan,⁸ Manitoba,⁹ Quebec,¹⁰ and Newfoundland and Labrador¹¹ have enacted privacy acts, that enable civil action to be taken for violations of privacy.

Thirdly, a patchwork of additional federal privacy law (the *Personal Information Protection and Electronic Documents Act* or PIPEDA)¹² and provincial privacy law (as of date of writing, in Quebec, Alberta and British Columbia¹³) has developed in Canada that regulates the protection of personal information. In addition, Alberta, Saskatchewan, and Ontario have legislation protecting specifically personal health information.¹⁴

This Canadian privacy legislation requires that personal information be protected with appropriate security measures and PIPEDA, for example, requires that sensitive information —such as the credit card numbers and

the Social Security Numbers that were on the laptop — must be protected by a higher level of security reflective of the greater sensitivity of this information.

With respect to any requirement to provide the clients with notice of the loss, currently, of these three mechanisms, only certain Canadian personal health information legislation requires that an individual be notified where their personal health information is subject to theft, lost or accessed by unauthorized persons. Since there was no personal health information on the laptop, there is no legal requirement in Canada that the corporation notify the individuals that their data were stolen.

However, once an affected client becomes aware of the loss, the client may bring a claim for breach of confidence, a civil claim for breach of privacy in Canada under the Privacy Acts, or make a complaint to the applicable privacy commissioner under the Private Sector Privacy Laws and face the possibility of significant fines, personal liability for directors and officers, and public disclosure by the privacy commissioner of the breach.

3. *UK Issues*

In the UK, there are a number of pieces of both domestic and European legislation that potentially could apply to this scenario. In our scenario we need to distinguish between those likely to cause problems with the regulatory authorities (assuming they are notified) and those giving the aggrieved clients or employees a right of redress against the company in a civil claim. Additionally, we need to distinguish between issues surrounding the UK employee data versus the United States client data.¹⁵

The most relevant regulatory regime is the Data Protection Act of 1998.¹⁶ This Act would apply if the company in the UK acts as a “data controller” in respect of the data that have been lost, or otherwise uses equipment in the UK for the processing of such data. According to the Act, a data controller is “a person who determines the purpose for and the manner in which any personal data are, or are to be, processed.” The UK company will generally be seen as a data controller of the employee’s data as it concerns data of employees in the London office, and the UK office is presumed to control the processing of such data.

With respect to the United States client’s data, however, as long as the UK company does not have any authority with respect to the purpose for which and the manner in which these data are being processed, the company should be able to take the position that the UK company is not a data controller under the UK Act and the UK Act should, in principle, not apply. Following the same line of reasoning, while it is true that Jack would have been able to access this information through the company’s secure computer system in London, it should be reasonable to take the position that the UK company will be deemed merely a data processor for purposes of the UK Act and not a data controller.

Although there are obligations under the Data Protection Act to notify the UK employees of certain information relating to the processing, this obligation only relates to when the data are first processed. There is no express obligation for a data processor to notify the data subjects of a breach in security or subsequent disclosure of their data to third parties. All

processing of data must, however, adhere to the general data protection principles as outlined in the Act.

One of these principles provides that companies should always take measures to maintain an adequate level of security to protect against, amongst others, unlawful processing, loss or destruction of personal data. These measures must ensure a level of security appropriate to the harm that might result from a breach of security and the nature of the data to be protected.

The technical and organizational measures appropriate to secure data will depend on the circumstances of each case. It could be argued that to comply adequately with this principle, the company should implement a notification procedure to ensure that, to the extent possible, any unlawful acts are avoided or limited in the event of a privacy breach. Additionally, if it is found that the company did not have adequate security controls and that its employees were not trained properly, which resulted in Jack’s inappropriate use of data, the privacy breach may qualify as a breach of the Act. This could prove to be the basis for claims against the company and Jack by the UK employees — and possibly sanctions from the DPA authorities.

Finally, the employees could potentially bring a successful claim in the UK courts against the UK company for the breach of a contractual duty of confidence, whether this is express or implied. There is little directly analogous case law, but a professional client or employee-employer relationship in the UK involving confidential data will be likely to imply not only a duty of care over the data, but possibly a duty to inform the data subject in the event of loss.

D. The Right Thing To Do

If there are no legal requirements for notification, the firm must then examine whether any contractual obligations exist to notify the affected customers and employees that their data were compromised. Neither the firm’s privacy statement or online privacy statement contain any mention of notification. Customer application forms and all other relevant agreements and documentation are also silent on the question of notification.

Good business practice may require notification to clients in Oregon, Washington and Canada, despite the fact that notification is not required by statute or contractual obligation. In London, the firm should contact the U.K. Data Protection Information Commissioner regarding the security breach.

Another factor considered by the team was its concern about the firm’s exposure to future litigation. Although the firm’s privacy policy was silent on the issue of notice, there is a possibility that the Federal Trade Commission could consider lack of notification an “unfair and deceptive trade practice” violation, despite the absence of legislative authority.

By notifying all clients, the company’s actions (i) reduce the possibility of a complaint being made by an affected client to the applicable data protection regulatory authority in each jurisdiction, and (ii) place the firm in a better position in a case where a regulatory authority made a decision to investigate the privacy breach.

The company concluded that its response should be considered fast, reasonable in light of the circumstances, and fair to all of its customers. The

firm drafted one notice that satisfied California law and that was sensitive to the needs of all affected customers. The notice was sent within the statutory timeframe. Since the London employees are not residents of California and there were only twenty of them, they were advised verbally by the company's Human Resources function. The privacy team, the business unit, and the legal department also prepared a standard internal script and FAQ to the extent Jack or the firm received any calls on the matter.

An important element of the notice was that each client was asked to address their questions or concerns to a specific contact person at the firm; that person was prepared to respond appropriately to different levels of concerns, and to escalate serious concerns to a higher level of response in the company.

The firm anticipated that the media might pick up on the story. It was hoped that the team's rapid response, and the company's determination to notify all customers of the security breach, would play a role in how the breach was portrayed to the public. The team debated whether to contact the media first in order to try to manage media coverage, but in the end decided against this strategy.

Conclusion

All companies are vulnerable to a privacy breach. The companies that fare best will be those that have high-level support in the protection of personal information and dedicated resources that focus on thinking about these issues. Those companies that can respond rapidly, limit damage to the individuals whose data have been compromised, comply with all laws and go beyond what the law requires in ensuring that clients and employees are treated fairly when breaches occur should be able to navigate these types of breaches the best.

When a privacy breach occurs, a good privacy program can make the difference between a company being perceived as the wrongdoer as opposed to the victim that did all that it reasonably could to protect against the breach occurring and to minimize the damages that follow from it. The cost of litigation, lost customers and lost business opportunities outweigh compliance costs.

The risk that a privacy breach will occur certainly can be reduced, but the possibility of a breach is unlikely ever to be fully eliminated. As these breaches occur, companies who have a good privacy infrastructure will be less likely to face legal consequences and damage to their reputations, while companies that do not devote the necessary resources and planning to privacy will not only suffer these losses, but client defection.

At the end of the day good corporate privacy processes and procedures will help ensure that a privacy breach is only a privacy incident and not a privacy crisis.

Going Global: International Developments in Government-Facilitated Redress

by Stacy Feuer

In the United States, the Federal Trade Commission's ability to obtain monetary redress for consumers in federal district court actions under Section 13(b) of the FTC Act has been a centerpiece of the FTC's consumer protection agenda for the past few decades.¹ Developed largely through federal court jurisprudence, the FTC's authority to obtain monetary relief to redress injury from "unfair and deceptive practices" is now firmly fixed in United States case law.² The FTC routinely uses this authority to obtain redress on behalf of consumers in consumer protection cases, including cases involving false and misleading health claims³, bogus business opportunities,⁴ pyramid schemes,⁵ foreign lotteries⁶ and advance fee loans.⁷ With the help of third party contractors, the FTC has distributed millions of dollars in redress funds to wronged consumers. For example, from April 2004 through February 2005, the FTC filed 83 actions in U.S. federal district courts and obtained 75 judgments ordering the return of more than \$474 million in redress to consumers.⁸

Governmental redress authority is a critical component of an effective redress system for consumers. Although injunctive relief protects the public from future harm, it does not remedy the injury to consumers caused by a defendant's past actions or deprive a defendant of monetary gains from illegal conduct. By depriving wrongdoers of their wrongful gains and distributing them to wronged consumers, monetary consumer redress serves a compensatory function as well as a deterrent one. It is an important tool to alleviate consumer injury and restore consumer confidence.

These policy considerations are particularly true in the context of cross-border commerce. Although there are other mechanisms that can be used to provide redress to consumers domestically and across borders (e.g., alternative dispute resolution/online dispute resolution, payment card chargeback mechanisms, small claims courts and private collective/class actions), such mechanisms are not feasible for cases of fraudulent or deceptive practices affecting large numbers of consumers such as sweepstakes and lottery scams, pyramid schemes and Internet-based frauds. In these types of cases, government agencies may have a unique ability to bring complex lawsuits against fraud operators who have harmed large numbers of consumers.

For example, government agencies may have investigative and enforcement powers, relationships with foreign counterparts and the ability to track and freeze assets that is not available to private litigants. Government agencies also may have the resources and incentives to bring cases that would not necessarily be brought by private actors. In the United States, private consumer class actions are an established method for recovering damages for defective products, false and misleading advertising and violations of federal credit, securities and antitrust laws. But almost none challenge fraudulent practices such as advance fee loan scams, pyramid schemes and lottery/sweepstakes scams. And government agencies may be able to bring cases for violations of unfair and deceptive commercial practices laws that

might be barred in the private class action context by legal devices such as mandatory arbitration clauses.⁹

Despite the benefits of government-obtained consumer redress, currently only a small number of countries — primarily the United States and Australia — can use direct governmental civil actions to obtain redress for consumers.¹⁰ In some other countries, government consumer protection agencies may act as the representative party in lawsuits seeking damages and other remedies.¹¹ And in very few countries — again, the United States and Australia — can government agencies distribute redress funds to foreign consumers.¹² (At last count, the FTC has provided funds to consumers in more than 100 countries.)

In the past few years, however, there has been an explosion of interest in government-facilitated consumer redress, due in large part to an increase in fraudulent schemes that exploit advances in telecommunications and the Internet to target consumers worldwide. Numerous governments have recognized that the ability of governments to obtain redress for victims of cross-border fraud is especially important to increase consumer trust in the global marketplace.

In 2003 the Organization for Economic Cooperation and Development (OECD), a multilateral organization of the world's thirty most developed economies, issued *Guidelines for Protecting Consumers from Fraudulent and Deceptive Commercial Practices across Borders* that encourage member states to include within their domestic frameworks "[e]ffective mechanisms that provide redress for consumer victims of fraudulent and deceptive commercial practices"¹³ The Guidelines also recommend that member countries "study the role of consumer redress in addressing the problem of fraudulent and deceptive commercial practices, devoting special attention to the development of cross-border redress systems."¹⁴ The 2003 Guidelines build on earlier work, including the OECD's *Guidelines for Consumer Protection in the Context of Electronic Commerce*¹⁵ and the *Findings on Cross-Border Remedies* issued by the International Consumer Protection and Enforcement Network in 2000.¹⁶

Spurred in part by the 2003 OECD Guidelines, several OECD member countries are considering direct government-facilitated consumer redress. Both Canada and the United Kingdom are seeking to expand their consumer protection agencies' existing law enforcement powers to include redress as a remedy for violations of consumer protection laws.

In November 2004 the Canadian government introduced legislation amending Canada's Competition Act to provide the federal Commissioner of Competition with the power to obtain court-ordered restitution for certain types of deceptive advertising practices.¹⁷ The Commissioner of Competition testified that the legislation addressed the OECD's recommendation to "ensure effective redress for victimized consumers" and "will bring our regime into line with those of other countries, such as the United States and Australia, who have a restitution remedy."¹⁸ Specifically, the bill empowers the Competition Tribunal or a court to order offenders who engage in deceptive marketing to provide restitution to consumers in an amount that does not exceed the amount paid for the products.¹⁹ The legislation also allows the Tribunal or court to issue a temporary freezing order, similar to the Mareva injunction used in common

law countries, to preserve defendants' assets for redress.²⁰ Another provision permits the Competition Tribunal or a court to allocate undistributed or unclaimed money from the restitution fund to a non-profit organization for the benefit of persons in similar situations.²¹ The bill has had a first reading in the Canadian House of Commons, and is currently before the Committee on Industry, Natural Resources, Science and Technology. It is expected to be considered further this year.

Similarly, the Department of Trade and Industry in the United Kingdom, which generates U.K.-wide consumer policy, has made a proposal to give certain government agencies the authority to obtain court redress orders and return the proceeds directly to consumers. In June 2004, it issued a consultation paper on consumer protection strategy for the next decade.²² The consultation paper includes a number of proposals on consumer redress mechanisms, including "public redress." The consultation paper recognizes that there is no redress mechanism in the United Kingdom, and further recognizes the need to "consider new mechanisms to enable the sequestration of assets in cross-border cases and to allow government agencies to seek redress on behalf of consumers who are victims of cross-border fraud."²³ Citing the positive United States and Australian experience with "enhanced redress and sequestration powers," the consultation paper includes a proposal for redress authority for government agencies:

We propose that certain agencies should be given new powers to work with the courts and with traders found guilty of offences or liable in a civil action, to recover and redistribute, to the consumers affected, the proceeds of the traders' wrongful trading. This provision would also provide a mechanism by which monies recovered in a successful action in another country could be returned to consumers in the UK.²⁴

The Department of Trade & Industry will continue to work on this initiative in the next year.

Other OECD countries have already begun to innovate with new legislation, particularly through collective or class action procedures available to both government and private litigants. In Sweden, for example, the Group Proceedings Law came into effect in January 2003. The law permits collective actions by private physical or legal persons, organizations (mainly labour unions or consumer associations), and specially designated public authorities for certain types of consumer and environmental claims. So far, the Swedish Consumer Ombudsman and the Swedish Environmental Protection Agency are the only two specially designated public authorities.²⁵ Last December the Swedish Consumer Ombudsman filed a case against an electricity company under the new law. The Swedish court is in the process of determining whether this case is appropriate for a group action.

There also has been movement on public redress outside the OECD. The Committee on Juridical and Political Affairs of the Organization of American States is considering including monetary consumer redress as a topic for its Seventh Inter-American Specialized Conference on Private International Law.²⁶ Chile recently passed an amendment to its consumer law to allow SERNAC (its national consumer protection agency), authorized consumer associations and groups of at least 50 consumers to file collective lawsuits for monetary redress.²⁷ Many of the rules came into effect in January 2005. SERNAC currently is reviewing several cases to decide whether they are appropriate public collective actions under the new legislation. Under the legislation in Chile, however, consumers will still have to present

individual claims establishing their entitlement to damages once SERNAC (or another plaintiff) establishes the defendant's liability and the judge orders redress.²⁸

The increased focus on developing new redress mechanisms for violations of consumer laws has a parallel in the competition area. The European Commission currently is considering whether to increase private enforcement of the antitrust laws in member states to provide additional avenues for enforcement of competition law and the possibility of restitution for consumers.²⁹ To date, the level of private enforcement of national and European Competition law has been extremely limited. Neelie Kroes, the European Commissioner for Competition, recently underscored the connection between this initiative and the issue of consumer redress:

There have been only a very limited number of successful damages awards for breaches of EU competition law in the last forty years. This means that the comprehensive enforcement of the competition rules is not yet complete — not enough use is made of the courts. *More importantly, the victims of anti-competitive activity are not being compensated for their losses.*³⁰

By the end of this year, the European Commission will present a Green Paper setting out options for improving the current system of private enforcement in order to obtain feedback from stakeholders. The paper will likely address issues of redress and restitution for consumers.

As globalization proceeds, many governments are likely to consider obtaining authority to provide redress to consumers through direct governmental legal action. Government-facilitated redress will become more common in cases of large-scale fraudulent and deceptive practices, where government's investigative and enforcement powers will prove to be valuable in obtaining and distributing redress to consumers. Nonetheless, there are many challenges in ensuring that court ordered monetary remedies ultimately result in compensation to consumers, particularly in cross-border cases. The OECD has identified some of the most pressing issues:

There may also be legal obstacles to obtaining provisional measures, such as asset freezes, in foreign courts or against overseas assets. Finally, where a domestic judgment is obtained awarding monetary compensation to consumer victims, it may not be possible to obtain enforcement of that judgment in the country where the defendant or his or her assets are located.³¹

Through the OECD and other forums, these issues are beginning to be addressed. In the United States, the FTC is supporting legislation that contains provisions designed to enhance information-sharing and investigative assistance about foreign parties and assets. The bill, introduced in 2003 as the International Consumer Protection Act, passed the Senate last year, and is expected to be reintroduced in both houses of Congress later this year.³² In the meantime, it is clear that several countries are taking the first step in obtaining redress authority to benefit consumers and deter wrongdoing in the global marketplace.

Easing The Burden: Recovery of Damage Control Costs After Balance Dynamics Corporation v. Schmitt Industries

by D. Jeffrey Ireland and Brian D. Wright

Businesses routinely confront aggressive competitors in their marketplace. Many times aggressive and overzealous competitors resort to the use of false and misleading advertising as a means to unfairly compete for customers. Such wrongful conduct can result in a significant damage to a business. The harm that false and misleading advertising can inflict upon the bottom line of a business oftentimes is exacerbated by the cost spent on the work necessary to respond to and ameliorate the harmful effects of false advertising, which can include the need for corrective advertising. Not only must businesses expend resources to determine whether the claims made by a competitor are false, but it also may be expensive to develop responsive advertisements to address (or rebuild) the damaged customer relationships that inevitably follow from a competitor's wrongful advertising. From a purely economic standpoint such costs, known as "damage control costs," can be just as expensive as the damage to the business's bottom line.

Businesses often turn to the courts to stop a competitor's false and misleading advertising and to assist with the recovery of damages suffered as the result of wrongful advertisements. The Lanham Act is a tool that can be used to address the competitor's wrongful advertising campaign.¹ However, the practical realities of the business world and the expense of litigation often work to make a recovery of meaningful damages under the Lanham Act impractical, if not impossible. This point is especially true when a business must prove that false advertisements actually confused customers and that as a result it suffered some quantifiable marketplace injury.² Recognizing the practical difficulties of proving marketplace damage and actual confusion, the Sixth Circuit eased that burden on victims of false advertising in *Balance Dynamics Corporation v. Schmitt Industries, Inc.*, 204 F.3d 683 (6th Cir. 2000). *Balance Dynamics* recognizes the appropriateness of a lesser burden of proof for recovery of damage control costs and the cost of corrective advertising than the one applied to other types of damages. The Sixth Circuit has added a weapon to the arsenal of self-defense to which businesses now can turn when they have been harmed by a competitor's wrongful advertising.

Traditional False Advertising Claims Under the Lanham Act

The Lanham Act makes it unlawful for any person to make false or misleading representations of fact about another person's or entity's goods or services.³ To establish liability under the Lanham Act, a plaintiff must prove that: (1) defendant made false or misleading statements of fact concerning its own products or plaintiff's products; (2) the statements actually deceived, or were intended to deceive, a substantial portion of plaintiff's customers or potential customers; (3) the statements are material in that they likely will influence the deceived consumer's purchasing decisions; (4) the false and misleading advertisements were introduced into interstate commerce; and (5) there is a causal link between the challenged statements and the harm to plaintiff.⁴

Whether a plaintiff is required to prove that the statement actually deceived or was intended to deceive a substantial portion of consumers turns upon the type of remedy sought.⁵ In addition to injunctive relief, plaintiffs may recover — subject to equitable principles — defendant’s profits, any damages sustained by plaintiff, and the fees and costs of the action.⁶ Individually, these types of damages are referred to respectively as: (1) disgorgement, (2) actual damages, (3) damage control costs, and (4) attorneys’ fees.⁷ Collectively, they are referred to as monetary damages.⁸

Lanham Act jurisprudence had given rise to a distinction between the type of proof necessary when a plaintiff seeks only an injunction and the type of proof required when a plaintiff seeks monetary damages. Historically, when a plaintiff sought only injunctive relief against continuing false advertising, it needed only meet a lower burden of proof by showing that the false advertising had a “tendency to deceive”⁹ and that there was a “reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the [defendant’s] false advertising.”¹⁰ In practice, this standard required a plaintiff to show only that an advertising campaign had a “tendency to deceive” and a “likelihood of damage.”¹¹ The lower standard was justified, according to courts, because “when an injunction is sought, courts may protect the consumer without fear of bestowing an undeserved windfall on the plaintiff.”¹²

However, when a plaintiff sought to recover monetary damages, rather than merely requiring proof that the advertisement had the “tendency to deceive” and a “likelihood of damage,” it has been required to show actual confusion created by the advertisement and resulting monetary damage.¹³ Not only was meeting this higher burden more difficult, but in addition the practical realities of business and business litigation often made meeting the higher standard prohibitively difficult.¹⁴ The higher burden often required a plaintiff to retain experts in order to study financial statements or other data in order to prove monetary damages. This expense was compounded by the costs of hiring consumer survey experts, who are necessary to prove a competitor’s ambiguous or misleading messages created actual confusion among consumers.

More importantly, even where monetary damage and actual confusion are provable in theory, practicalities often make providing such proof impossible. Actual confusion often could be proven only by testimony of plaintiff’s own customers.¹⁵ Of course, asking a customer to testify often had negative business consequences because the customer then inevitably would be subpoenaed by defendant.¹⁶ Businesses also may be hesitant to bring a claim and to put monetary damages such as lost sales at issue because that might entitle a competitor to discover commercially sensitive information.¹⁷ Businesses often are justifiably hesitant to begin such litigation where they know that the litigation is likely to result in the unneeded extra expense and the added risk of upsetting (or even alienating) their own customers.¹⁸

Recognizing both the practical realities of business and the difficulty of presenting proof of a monetary damage and actual confusion as necessary proof in order to recover monetary damage, the Sixth Circuit has made headway in easing this often impractical, if not impossible, burden.

Marketplace v. Monetary Damage

As a result of the Sixth Circuit’s decision in Balance Dynamics Corporation v. Schmitt Industries, Inc., a plaintiff now may be able to recover damage control costs and the cost of corrective advertisements without a showing that the false advertising created actual confusion or actual damages in the marketplace.¹⁹ In other words, the historical distinction in Lanham Act cases between the proof necessary to allow for the recovery of monetary damage and that required to obtain injunctive relief has now been changed significantly. The higher burden — proof of deception and actual monetary damage — need only be met when plaintiff seeks “marketplace damages,” i.e., lost sales, lost profits, or loss of goodwill.²⁰ The higher standard of proof is a necessary prerequisite to an award of “marketplace damages,” as the Court reasoned, as actual confusion tends to show that these “hard-to-prove” damages actually exist.²¹ However, when a business is seeking to recover its damage control costs and the cost of corrective advertising, the higher burden is neither justified nor necessary. Unlike marketplace damage, rather than being “hard-to-prove,” proof of damage control costs and the costs of corrective advertising are already in the possession of plaintiff.²²

Moreover, the Court reasoned that damage control costs and recovery of the cost of corrective advertising should be treated differently from marketplace damage because, like an injunction and unlike monetary or other damages, damage control costs and corrective advertising costs are spent to prevent lost sales, lost profits, and lost goodwill.²³ As is the case with parties seeking injunctive relief, businesses engaging in damage control and corrective advertising are still at the stage where it remains uncertain whether any marketplace damage is being inflicted by the wrongful competitor’s false or misleading advertisements.²⁴

The Court further determined that the more lenient standard is justified because it is unreasonable to expect a plaintiff to stand idly by until the competitor’s false and misleading advertising harms the business by creating actual confusion in the marketplace.²⁵ As the Court stated, “[t]he law should encourage quick responses and the mitigation of damage, and should not require parties to suffer an injury before trying to prevent it.”²⁶

The higher standard of proving actual confusion for the recovery of damage control costs is also unjustified. The recovery of damage control costs and corrective advertising costs, upon meeting only the lower burden, do not have the same risk of a business gaining an “underinsured windfall” as the business could only recover the reasonable and necessary expenses that it can prove that were incurred to mitigate the detrimental effects of the competitor’s wrongful false and misleading advertising.²⁷

Finally, the lower standard created by the Court is more rational. From a legal standpoint, the higher standard potentially could penalize a successful effort by a business to mitigate marketplace damage.²⁸ For example, a business that is successful in preventing marketplace damage would not be able to recover under the Lanham Act its damage control costs and costs of corrective advertising because it would not be able to prove that it suffered any marketplace damage,²⁹ while a business that is unsuccessful in its damage control and corrective advertising would be permitted to recover its damage control costs and the costs of corrective advertising, since the business would presumably be in a better position to show marketplace damage.³⁰

Following the direction of the Sixth Circuit in Balance Dynamics, at least two district courts have recognized that it is no longer necessary for a plaintiff to present proof of some monetary damage and actual confusion in order to recover damage control costs and the costs of corrective advertisements. The Iams Company v. Nutro Products, Inc., Case No. 3:00-CV-566, 2004 U.S. Dist. LEXIS 15134, at *11-12 (S.D. Ohio July 3, 2004) (“The difference in standards of proof is that a court can grant injunctive relief which protects both the consumer and the competitor, and indeed damage control costs which reimburse the competitor, without creating a windfall to the plaintiff.”); Plastic Molded Techs., Inc. v. Cinpres Gas Injection, Ltd., 290 F. Supp. 2d 793 n.14 (E.D. Mich. 2003).

Taking Advantage of the New Weapon in the Arsenal of Self-Defense

By easing the burden, the Sixth Circuit has made the threat of Lanham Act litigation a more practical and more rational weapon, which businesses can now justifiably use without the fear that the litigation might do more harm than good. Given the lower standard and the easing of the burden that a business must now meet to justify the grant of injunctive relief and damage control costs, businesses should now be aggressively pursuing litigation against competitors under the Lanham Act when faced with false or misleading advertisements.

Obesity and the Carbohydrate Connection - the NAD's Approach to Low Carb Claims

by Annie Ugurlayan

The United States and, increasingly, the world face an obesity epidemic. Globally, 1.7 billion people are considered overweight and 312 million are obese (i.e., at least 30 pounds over their highest recommended weight).¹ In 1999-2000, 64% of adults in the U.S. were overweight, an 8% increase from a 1988-1994 survey, and 30% of adults were considered obese, a 7% increase.² Alarming, 15% of children between 6 to 19 are considered overweight, an increase of 5%.³ The health effects of obesity are wide-ranging and cost the U.S. \$117 billion annually.⁴

During the last decade, “low carb” diets such as the Atkins® diet and The South Beach Diet™ have emerged at the forefront of the weight loss industry. During the first six months of 2004, food companies introduced 1,863 low carb products into the marketplace⁵, nearly three times the number of low carb products introduced in all of 2003. Sales were expected to approach \$30 billion in 2004. Although recent data suggests that the low carb trend has cooled somewhat, it continues to impact the food and weight loss industry.⁶

Efforts of the Regulatory World

In recognition of the growing public health crisis posed by obesity, government agencies, such as the Food and Drug Administration and Federal Trade Commission have undertaken efforts to educate consumers on food advertising claims and sensible food intake. The FTC has been educating consumers and media about detecting bogus weight loss claims in national advertisements (FTC’s “Red Flag” initiative and “Operation Big Fat Lie”⁷) and the FDA established a working group to examine the causes of obesity and how they can be remedied through, among other things, changes in food

labeling⁸ and serving sizes.⁹ Recently, the FDA released a proposal that requires food manufacturers, for the first time ever, to list the percentage of a product’s daily recommended calories on the product packaging and has also requested public comment on two proposals relating to nutrition labeling, serving size information (stating the nutritional information for the entire package) and the prominence of calories as they are listed on a food label.¹⁰ In 2005, the Department of Health and Human Services and the Department of Agriculture issued the new “Dietary Guidelines for Americans” updating the 2000 Guidelines. Both Guidelines encourage consumers to make informed choices from all food groups, encourage them to get the most nutrition from the calories consumed, and stress the importance of physical activity. However, the revised Guidelines differ from the 2000 Guidelines in recommending that whole grains¹¹ comprise half of one’s grain servings and suggesting food plans that would comport with the Guidelines.¹² Moreover, unlike the 2000 Guidelines, the 2005 Guidelines recommend substituting whole grain foods for refined grain foods.¹³

The NAD’s Self-Regulatory Approach to Low Carb Claims

In response to the advertising claims for diet plans and products, the National Advertising Division (“NAD”), the advertising industry’s self-regulatory forum charged with the responsibility to ensure the truthfulness and accuracy of advertising claims, has offered guidance to help advertisers craft well-supported and accurate claims. One thing is clear, however: if consumers are to be successful in losing weight by reducing carbohydrates in their diet, they must receive truthful information in advertising. The accuracy of low carb and carb reduction claims is vital to enhance public health and assist consumers in making well-informed purchasing decisions. As Americans struggle to find the “right” answer to healthy eating and effective and long-lasting weight loss, the NAD has taken on a key role by reviewing advertising for products touted as low carb to help consumers make better informed food choices. Advertisers would be wise to consider the guidance from recent NAD actions directly related to low carb claims.

The popularity of “low carb” diets has generated a wide variety of complementary low carb foods. However, the sheer volume of low carb products on the market and the different ways of characterizing carbohydrates – for example, the use of phrases such as “net carb” or “impact carb” – have produced confusion among consumers who do not necessarily understand different advertisers’ use of terminology. In the absence of specific regulatory guidance defining those terms, low carb plans such as Atkins® are informally regarded as an important source of information concerning the meanings of these terms. In reviewing advertising for these products, NAD has sought to determine whether the claims are accurate according to, among other things, these diets’ guidelines for daily carbohydrate intake. Eight recent NAD decisions shed light on its approach to low carb claims.

1. Tropicana Products, Inc. (Tropicana® Light ‘n Healthy)¹⁴

In this case, NAD requested substantiation for nutrition claims made by Tropicana in a television commercial for its Light ‘n Healthy beverage. The commercial features a Tropicana training facility in which oranges are shown exercising. The voiceover stated, “Counting Carbs? Introducing Tropicana®

Light 'n Healthy. It has 1/3 less sugar and calories than orange juice.”¹⁵ NAD requested substantiation for the implied claim that Tropicana® Light 'n Healthy is a low carbohydrate beverage.

In response, Tropicana noted that its commercial includes no explicit reference to carbohydrate content, but instead highlights the nutritional differences between Light 'n Healthy and regular orange juice. Tropicana argued that its ad informs carbohydrate conscious consumers about a product that may be of interest to them, given that sugars are a type of carbohydrate and Light 'n Healthy contains less sugar than regular orange juice. Tropicana maintained that even if a low carb claim were implied, it would be truthful given that Light 'n Healthy contains more than 30% fewer carbohydrates than regular orange juice and that the “Counting Carbs?” reference is fully consistent with the policies of the Food Safety and Inspection Service (FSIS) and the FDA.

In its decision, NAD observed that the question “Counting Carbs?” is directed to carbohydrate conscious consumers and that the visual of exercising oranges conveys a reasonable takeaway that Light 'n Healthy is a low carbohydrate beverage. NAD looked to the amount of carbohydrates in one serving of Light 'n Healthy and determined that at 17 grams of carbohydrates in an eight-ounce serving, it was not a low carbohydrate product given the strict carbohydrate restrictions on the Atkins® diet which allow only 20 grams of carbohydrates daily in the initial two-week induction phase.¹⁶

In addition, NAD was not persuaded by the advertiser’s reference to the FSIS Statement of Interim Policy on Carbohydrate Labeling Statements given that it applies to the labeling of meat and poultry products, or to the FDA’s regulations on nutrient content claims since these do not address carbohydrate claims. Though the FDA has defined terms such as “reduced,” “fewer,” “lower” or “less” as they relate to the sugar, fat or caloric content of foods¹⁷, it has not defined those terms as they pertain to the carbohydrate content and it is not clear whether such definitions would mirror or differ from the regulations relating to sugar, fat or calorie content. NAD added that even if the FDA determined that a 25% reduction in carbohydrates is sufficient to support a “reduced,” “fewer,” “lower” or “less” carbohydrate claim (consistent with other nutrient content claims), it would not be the same as the claim conveyed by the advertisement, namely that Light 'n Healthy is a low carbohydrate beverage. NAD recommended that the advertiser either discontinue its “Counting Carbs” claim or modify its advertising to clearly disclose that there are 17 grams of carbohydrates in one serving of Light 'n Healthy. In its advertiser’s statement, Tropicana commented that while it disagreed with NAD’s determination, it would consider NAD’s recommendation and clearly disclose the amount of carbohydrates per serving in the Light 'n Healthy product when formulating future advertising.¹⁸

2. Nestlé USA, Inc.

(Carnation Instant Breakfast for the Carb Conscious)¹⁹

NAD requested substantiation for print advertising by Nestlé for Carnation Instant Breakfast for the Carb Conscious, which included the claim “0g Sugar Carbs Added.”²⁰ NAD also requested substantiation for the product packaging claim “And since it has no sugar carbs added, it’s a great way to

watch carbohydrates” and for what it construed as a possible implied claim that the product contains no, or very few, carbohydrates.

Nestlé maintained that the advertisement does not imply that its product contains no or few carbohydrates. The advertisement, argued Nestlé, accurately states that Carnation Instant Breakfast for the Carb Conscious is a reduced carbohydrate version of the original Carnation Instant Breakfast that is responsive to consumer interest in limiting carbohydrate intake. Noting that the Carb Conscious product has significantly fewer carbohydrates than many “traditional” meals, Nestlé maintained that the product addressed a consumer concern as to the source of carbohydrates (here, sugar), as reflected in the Atkins® diet and The South Beach Diet™. According to Nestlé, both diets suggest that consumers choose a product that has no added sugar carbohydrates over a similar product containing added sugar carbohydrates, a difference addressed in the advertiser’s disclaimer (“One serving contains 7g sugar carbs from lactose, a natural milk sugar, and has 55% less total carbs than original”). Nestlé also noted that the “0g Sugar Carbs Added” claim is truthful and similar to the FDA-defined “no sugar added” nutrient content claim. It maintained that when read in context, the statement on the label “And since it has no sugar carbs added, it’s a great way to watch carbohydrates” does not convey that the product has little or no carbohydrates since the “0g Sugar Carbs Added” claim on the front panel refers consumers to the Nutrition Facts panel which lists the total carbohydrate content in the product. The advertiser added that future advertising containing the “0g Sugar Carbs Added” claim would include a statement of the total carbohydrate content in the product.

As it did in the Tropicana case, NAD began its analysis with an examination of the total carbohydrates in one serving. Noting that the product is a powder intended to be mixed with one cup of skim milk, NAD observed that the total carbohydrates in one serving of the product as prepared is 24 grams, 19 of which are from sugar.²¹ NAD also determined that the overall impression of the ad may suggest to consumers the product is low in or contains zero carbohydrates. In support of its conclusion, NAD cited the advertiser’s invitation to “Fuel up” and “Carb Down,” references that introduce the product as one of interest to carbohydrate conscious consumers. NAD cited other representations that reinforced a low carb message: 1) the “0g Sugar Carbs Added” claim, with the “0g” reference shown prominently and in significantly larger type than the “Sugar Carbs Added” to which it is adjacent; 2) the statement “Complete Nutrition, less carbs”; 3) the statement “CARNATION® INSTANT BREAKFAST® for the Carb Conscious is the delicious way to get up and running while you cut down on carbs”; and 4) the statement “And since it has no sugar carbs added, it’s a great way to watch carbohydrates.” Given that carbohydrate intake is severely curtailed on the Atkins® diet and The South Beach Diet™, one serving of Carnation Instant Breakfast for the Carb Conscious as prepared constitutes nearly an entire day’s worth of carbohydrates and cannot, under any reasonable definition, be considered a low carb beverage. Accordingly, NAD recommended that the advertiser modify its print ad and product packaging to avoid conveying a low carb message and correct its comparative carbohydrate content claims to accurately reflect the carbohydrate differences in the products (original vs. Carb Conscious) as prepared. NAD further recommended that any future advertising with the “0g Sugar Carbs Added” claim prominently disclose in immediate proximity to the claim that there are 24 grams of carbohydrates per serving.

In its advertiser’s statement, Nestlé agreed to include a statement of the total carbohydrates per serving on an “as consumed” basis when a “0 sugar carbs added” claim is made in future advertising. It also agreed to review the

prominence of the referral statement on the front of the package that directs consumers to the Nutrition Facts panel's listing of total carbohydrates.

3. Atkins Nutritionals, Inc. (Atkins Food Pyramid)²²

The Atkins Food Pyramid, advertising by Atkins Nutritionals, Inc. modeled after the 1992 USDA Food Guide Pyramid, has also been the subject of NAD scrutiny.²³ The Atkins Food Pyramid provides guidance to consumers about limiting carbohydrate consumption and the types of foods they should consume to ensure that their nutritional needs are satisfied. As such, consumers rely on the Atkins® diet and the Atkins Food Pyramid both as a diet regimen and as a source of information on reduced carbohydrate consumption. NAD expressed concern about the depiction of the Atkins Food Pyramid, particularly an extension to the pyramid in the form of a triangle featured to the right of the pyramid.

The Atkins Food Pyramid depicted a pyramid with protein at the base of the triangle and whole grain products at the top. Next to the pyramid the advertiser had superimposed an extension of the triangle depicting at the top a loaf of bread, a muffin and what appears to be a bowl of rice, foods potentially high in carbohydrates and fat. Adjacent to the extension was the phrase "increase options with additional exercise." NAD expressed concern that the visual and copy implied that dieters who exercise can include many more portions of carbohydrates than advised under the Atkins Nutritional Approach and not have to give up their favorite high carb foods.

The advertiser argued that neither claim is implied by the pyramid and that the pyramid represents well-established nutritional practices, such as increasing food options if one exercises regularly. The advertiser also maintained that the "increase options with additional exercise" statement refers consumers to food options within the Atkins Food Pyramid and that the statement is supported by numerous studies and Dr. Atkins' own clinical experience.

While NAD did not contest the general premise that exercise allows consumers to increase their food intake, it expressed concern with the depiction of a loaf of bread, a muffin, and a bowl of rice – noticeably enlarging the whole grain section of the pyramid while the extensions to the vegetables and fruits sections are smaller – conveys to consumers that whether or not they follow the Atkins® diet, they can consume many more of these high carb foods as long as they exercise. NAD also looked to the instructions shown below the pyramid ("limit and control certain carbohydrates to achieve and maintain a healthy weight"; "[c]hoose carbohydrates wisely") and noted that while certain statements are helpful, other statements ("Eat until you are satisfied" and "to maintain weight, eat in proportion to the pyramid. [T]o lose weight, focus on protein, leafy vegetables and healthy oils.") are problematic and inconsistent as they relate to the pyramid, given that the addition of the extension de-emphasizes vegetable and fruit options and emphasizes whole grain foods (represented by a loaf of bread, a muffin and a bowl of rice). Accordingly, NAD recommended that the advertiser modify the food pyramid to avoid referencing the extended triangle, though it determined that the arrow and the "Increase Options With Additional Exercise" statement are appropriate in the context of the Atkins Food Pyramid alone.

Despite the advertiser's disagreement with NAD's recommendations, it agreed to modify the advertising such that the extension would depict only one food item from each layer of the pyramid to illustrate possible additional food choices available to consumers.²⁴

4. Russell Stover Candies, Inc. ("Low Carb" Line of Confectionary Products)²⁵

In both competitor challenges and in its own monitoring cases, NAD attempts to harmonize its efforts with the guidelines and enforcement actions of regulatory agencies, such as FTC and FDA. Russell Stover Candies, Inc. posed questions of continuing controversy involving advertisers' use of phrases such as "net carbs" or "net effective carbs." The "net carb" concept is based on how different types of carbohydrates affect the body (e.g., refined starches and sugars are absorbed rapidly and cause the blood sugar to rise after eating whereas other carbohydrates, such as fiber in whole grains, are absorbed more slowly, if at all). The amount of net carbs in a food is calculated by subtracting the amount of fiber and sugar alcohols from the total carbohydrates because they are thought to have little impact on blood sugar levels.²⁶

In that case, Hershey Foods challenged Russell Stover's nutrient claims relating to the carbohydrate content of its "Low Carb" line of confectionary products. Among the claims at issue were "Low-Carb candies good enough to be called Russell Stover," "Carbs per piece – 0.2 g*," and "Net Effective Carbs [per serving size] – 0.4 g." According to Hershey, the "low carb" packaging claims constituted nutrient content claims which are prohibited because the FDA has not yet defined "low carb." Referring to an FDA warning letter to Russell Stover, Hershey argued the carbohydrate amounts in Russell Stover's "low carb" candies are not substantially lower than the amounts in comparable candies.²⁷ Hershey also asserted that the carbohydrate information is conveyed in a confusing manner because consumers are directed to another panel where the "carbs per piece" are calculated by looking to the "net effective carbs." In addition, the challenger noted the carbs per piece of the Russell Stover products are less than the declared level of total carbohydrates in the Nutrition Facts panel.

Russell Stover responded that it had discussions with the FDA and had agreed to change its product's brand name from "Low Carb" to "Net Carb" and to change the "carbs per piece" reference to "net carbs per piece." Russell Stover also argued that the "net carb" or "net effective carb" references are meaningful for carb conscious consumers and accurate in that the total amount of carbohydrates are disclosed on the Nutrition Facts Panel and in the Net Carb Calculation Chart.

In its decision, NAD noted that the advertiser's actions in response to the FDA's warning letter resolved the issues in the proceeding. NAD stated that while it retained jurisdiction over the "net carb" and related carbohydrate claims, it would not review them given that the FDA is currently in the process so doing. NAD also recommended that the advertiser avoid making any implied low carbohydrate claims such as "Enjoy many of your Russell favorites without the carbohydrates" in future advertising. The advertiser accepted NAD's decision.

This case raised issues relating to NAD's jurisdiction over claims and the circumstance in which NAD will defer to a government agency. Outright deferral is rare and typically occurs when NAD lacks jurisdiction.²⁸ NAD strives to strike a balance, deciding which claims it can and should review while also ensuring that its decisions complement – but do not supersede (or confuse) – relevant regulatory authority.

5. DNA Dreamfields LLC (Dreamfields Pasta)²⁹

In reviewing claims for low carbohydrate products, NAD follows its usual practice of adopting a flexible approach and is willing to consider new test methodologies and scientific evidence as they emerge. In DNA Dreamfields, the Low Carb Consumers League, a not-for-profit corporation that helps protect the interests of low carbohydrate food consumers, challenged the truthfulness and accuracy of claims made by DNA Dreamfields in advertising and packaging for its Dreamfields Pasta. Among the claims at issue were:

- Dreamfields is “authentic pasta made with premium durum wheat semolina”;
- “Our unique pasta recipe means fewer carbohydrates get absorbed into your system, much like whole grains, so Dreamfields is a delicious way to enjoy healthy carb living”;
- “Dreamfields pasta is a healthy and delicious way to watch your carbs”; and
- “Finally, Great Tasting Pasta With Healthy Carbs! DNA Dreamfields Company Introduces Pasta With Authentic Taste And Texture And Only 5 Grams of Digestible Carbs.”

The challenger contested the advertiser’s use of the term “net digestible carbs,” arguing that the advertiser’s product testing was flawed because it was not double-blinded and did not have a placebo control or a statistical analysis demonstrating the significance of the test results. The challenger also disputed the advertiser’s contention that glycemic load³⁰ correlates to the amount of carbohydrate considered “digestible” and raised concerns about the accuracy of any methodology that purported to measure the glycemic load.

The advertiser responded that its patent-pending technology uses a proprietary manufacturing process blending dietary fibers and proteins to bypass the small intestine and enter the colon where some of the carbohydrates are fermented but not digested (i.e., they are not converted into blood glucose) thus preventing an increase in blood glucose levels. It claimed that the “protected” carbohydrates provide health benefits akin to those provided by dietary fiber. The advertiser maintained that its scientific study was designed to determine the “glycemic load.” Based on the blood glucose levels of the test subjects who consumed the pasta (as compared to the blood glucose levels of the subjects who consumed solely white bread), the mean level of digestible carbohydrates in the product was approximately five grams per 56 grams of dry weight of the product, demonstrating that the product contains “protected carb” technology.

NAD determined that the advertiser provided a reasonable basis for its claims that Dreamfields Pasta contains five grams of digestible carbohydrates per serving by calculating the product’s glycemic load and, hence, determining the product’s impact on blood glucose levels. In addition, the NAD concluded that the challenger failed to demonstrate that the advertiser’s methodology and research were materially flawed. This case illustrates that, despite the confusion concerning how carbohydrates are

described, NAD recognizes the importance of sound science in providing a reasonable basis for advertising claims of this kind.

6. Health & Nutrition Systems International, Inc. (Carb Cutter)³¹

Also popular with carb-conscious consumers are dietary supplements which claim to block carbohydrate absorption from food.³² As with low carb food claims, NAD’s concerns lie with the implied and express messages conveyed, especially those that may encourage reckless eating with little or no regard to exercise. In Health & Nutrition Systems International, Inc., NAD challenged print advertising for a dietary supplement called Carb Cutter. The ad featured the bold heading “I CHEAT. Don’t you?” followed by the text “Sometimes I just have to give in. So when I indulge, I don’t want to have to count carbs. That’s why I depend on Carb Cutter.” The ad also featured claims such as “The Original Low Carb Diet Pill” and “Carb Cutter allows for occasional consumption (‘cheating’) of carb rich, high sugar foods and beverages including popular energy and soft drinks.”

Pointing to the statement in the ad “effective weight loss requires a restrictive diet and exercise.” Health & Nutrition Systems maintained that Carb Cutter is not promoted as a magic pill that allows users to eat whatever they want, but rather serves to complement a low carbohydrate diet. The advertiser also contended that all of its advertising claims are supported by competent and reliable scientific evidence, including a well-controlled, randomized, double-blind, placebo-controlled clinical trial conducted by an independent outside testing agency and scientific studies on Banaba, an herbal extract contained in Carb Cutter, that show that the substance converts glucose into glycogen rather than fat. It further argued that the statements, “The Original Low Carb Diet Pill” and “Have more freedom with Carb Cutter!” are puffery, and that it was in fact the first company to sell a “low carb supplement” to the mass market. The advertiser contended that its product permits occasional “cheating” based on its clinical trial that showed participants that took the Carb Cutter Product lost more weight (even though some strayed from the diet) than those on a low carb diet taking a placebo.

In reaching its decision, NAD appreciated the advertiser’s willingness to discontinue its claim that “Carb Cutter also works great on alcoholic beverages such as mixed drinks, beer and wine, making any drink a ‘diet drink.’” However, it recommended that the advertiser discontinue its claim that “Carb Cutter allows for occasional consumption (‘cheating’) of carb rich, high sugar foods and beverages including popular energy and soft drinks” because the study upon which the claims were based contained significant limitations (e.g., small sample size, lack of statistically significant results, and a limited duration of only six weeks), factors that precluded its consideration as competent and reliable scientific evidence sufficient to support a weight-loss claim. Citing the depiction of a woman who says “So when I indulge, I don’t want to have to count carbs,” NAD also determined that within the context of the ad, it would be reasonable for consumers to understand that individuals who take Carb Cutter could freely deviate from the carbohydrate restricted diets without consequence – a misimpression not likely cured by a fine-print disclosure at the bottom of the page that the product is intended to be used in conjunction with a low carb diet and exercise program).

Moreover, NAD concluded that the product is advertised as a “diet pill” rather than as a low carb dietary supplement, implying that the product helps consumers lose weight. As to the claim that Carb Cutter converts

carbs into energy, NAD determined that there was insufficient evidence to extrapolate the conclusions from the studies on Banaba and corosolic acid to the formulation in Carb Cutter. Based on limitations in the advertiser's clinical testing which supported a qualified claim, NAD also recommended that the advertiser discontinue the unqualified claim "Whether you are on a strict low carb diet or maintaining your results, clinically tested Carb Cutter is the perfect companion for men and women on any low carb lifestyle" or modify it to clearly delineate the relevant limitations of the clinical testing. While NAD agreed that the claim "Have more Freedom with Carb Cutter!" may be seen as puffery when viewed in isolation, in the context of the overall advertising it contributed to the message that individuals who take Carb Cutter can lose weight even when not following a low carbohydrate diet, a statement that was not supported by competent and reliable evidence. NAD also determined that the advertiser had a reasonable basis for claims to be the "original" because in 1999, no other low carbohydrate dietary supplements were in mass distribution or nationally advertised.

In its advertiser's statement, the advertiser stated that while it was pleased that NAD agreed that Carb Cutter was the "original" low carb diet pill, it disagreed with NAD's conclusion that its other claims were unsubstantiated. However, it agreed to modify its advertising and to take NAD's recommendations into account in future marketing of Carb Cutter.

7. Natrol, Inc. (Carb Intercept with Phase 2™)³³

Other "carb blocking" cases centered on the significance of a particular active ingredient derived from white kidney bean extract and marketed as "Phase 2™". Several scientific studies suggest a role for this particular ingredient in inhibiting carbohydrate absorption. In Natrol, Inc. (Carb Intercept with Phase 2™), NAD requested substantiation for claims made by Natrol in print and internet advertising for its carb blocker product. The advertiser claimed that its supplement is "Scientifically Proven to Neutralize Starch" and "Supports Weight Loss." In support of these claims, the advertiser provided in vitro and in vivo studies of Phase 2™, one of the product's ingredients. However, no clinical studies of the actual product were produced. In its decision, NAD cited to the well-established rule concerning establishment claims (e.g. "scientifically proven," "clinically proven"), namely that such claims require reliable, well-controlled and verifiable clinical testing on the product in question and, in the absence of such testing, that testing of the product's ingredients (at the same levels and proportions) can be offered.³⁴ In this case, the testing on Phase 2™ used doses different from the dosage found in Carb Intercept as well as a different form of Phase 2™ (powder form instead of capsule). In addition, the results in many of the studies were considered by the test administrators to be preliminary rather than conclusive. Accordingly, NAD requested that the "scientifically proven" claims be discontinued or modified in the absence of "competent and reliable scientific evidence."

Concerning the "supports weight loss" claim, NAD observed that it was presented as akin to a "structure/function" claim³⁵ instead of a "health claim," but noted that these claims also necessitate truthful and non-misleading substantiation as support. In this case, the studies contained limitations in terms of dosage amount, administration of Phase 2™ (e.g., prior to the carbohydrate meal as opposed to with the meal, according to the product use instructions) and the presence of other ingredients in the product that precluded a conclusive determination of the extent of Phase 2™'s contribution to weight loss. As a result, NAD recommended that the claim's qualifying language ("this product is to be used in conjunction with

a healthy calorie reduction and exercise program") appear in close proximity to the "supports weight loss claim" or, in the alternative, that the claim be discontinued. In its advertiser's statement, Natrol, while disagreeing with the NAD's conclusion, agreed to discontinue or modify the claims in question as recommended.

8. Leiner Health Products (Starch Away®)³⁶

NAD continues to monitor advertising for carb-blocking dietary supplements, particularly those that expressly or by implication tout their products as an alternative, instead of a complement, to a well-balanced diet and exercise. For example, in Leiner Health Products (Starch Away®), the advertiser made the following claims for its product:

- "Take control of your weight with the scientifically proven Calorie Blocker!";
- "Now you can lose weight sensibly, and drop down a size or two, without eliminating the starchy foods you love"; and
- "You can enjoy starchy foods like pasta, bread and potatoes without any of the guilt. Simply take two delicious soft chews before a starchy meal."

One of the advertisements showed a picture of pink and yellow bikini placed on a bed of sand with concave lines and a dot drawn in the sand to mimic a small waist and bellybutton, with the claim below the picture: "Draw your own lines in the sand." Another print advertisement featured a woman in a dressing room, with only her arm shown holding a size 10 red dress with the statement "Can you bring me an 8, please?" featured directly above the picture.

As support for its performance claims, the advertiser cited to in vitro and in vivo studies of white kidney bean extract illustrating the inhibition of starch. The advertiser also produced a double-blind, placebo-controlled clinical study of the actual product on 60 overweight individuals. The individuals were not placed on a specific diet plan, but were instructed on proper eating habits and the importance of exercise. After 12 weeks, the Starch Away group lost nearly seven pounds compared with a gain of almost one pound in the placebo group, with individual weight loss ranging up to over 30 pounds.

NAD noted that during the pendency of the challenge, the advertiser voluntarily discontinued the claim "Take control of your weight with the scientifically proven Calorie Blocker!," an action which it deemed necessary and proper. As in the Natrol case, NAD held that the studies on the Phase 2 ingredient are insufficient to substantiate the specific performance claims at issue given that well-established precedent states that test results on a particular ingredient (same or similar to the one used in the advertised product) at a varying dose does not necessarily permit extrapolation to the product (which contains additional ingredients and varying instructions for use). NAD also noted certain methodological flaws in the study such as the lack of controls over the subjects' diets, disparities in the diet plan provided with the product and the one given to the participants during the study, and the lack of significant differences in body composition or waist/hip

circumferences between the active and placebo groups. NAD further remarked on the limitations of the studies' conclusions to support the claims at issue. While noting the promising results of Phase 2, the NAD added that more studies would be needed to determine how Phase 2 assists in weight reduction. Accordingly, NAD recommended that the challenged claims be discontinued or significantly modified to reflect the evidence in the record. In response, the advertiser stated that while it disagreed with NAD's conclusions regarding its clinical study, it would take NAD's recommendations into consideration when formulating future advertising.

Conclusion

As weight loss choices increase, so too does the potential for consumer confusion about how to effectively achieve their weight loss goals. Recognizing the importance of providing consumers with accurate information to make informed food choices, especially in light of the recent low carb dietary trend, NAD has examined a variety of food and dietary supplement advertising to determine whether certain claims were supported. The guidance provided by NAD's decisions, together with regulatory efforts to educate the media about deceptive weight-loss advertising³⁷, provide ample direction to enable marketers to creatively and truthfully promote their products and to ensure that consumers receive accurate carbohydrate-related information.

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Julie Brill (802) 828-2154 jbrill@atg.state.vt.us
Lesley A. Fair (202) 326-3081 lfair@ftc.gov
August T. Horvath (212) 310-8283 ahorvath@hewm.com
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ENDNOTES

The Genesis of Consumer Protection Remedies Under Section 13(b) of the FTC Act

by David M. FitzGerald

Mr. FitzGerald served as a litigation attorney in the Federal Trade Commission's Office of General Counsel from 1976 to 1982, and as Assistant Director for Litigation in the Commission's Bureau of Consumer Protection from 1982 to 1990. He is currently Senior Vice President and Deputy Chief Hearing Officer for the National Association of Securities Dealers (NASD). The views expressed here are his own, not those of NASD.

¹ 15 U.S.C. § 13(b).

² *FTC v. Think Achievement Corp.*, 312 F.2d 259, 262 (7th Cir. 2002).

³ Quarterly Federal Court Litigation Status Report, <http://www.ftc.gov/ogc/status/status.pdf>. Section 13(b) cases represented 72% of the Commission's total court litigation docket, which also included two petitions for review of Commission cease and desist orders, 17 civil penalty cases, seven suits to enjoin Commission action or other defensive litigation, and 11 cases in which the Commission had filed amicus curiae briefs.

⁴ Information concerning pending administrative proceedings may be found at <http://www.ftc.gov/os/adjpro/index.htm>.

⁵ Federal Trade Commission Act, ch. 311, § 5, 38 Stat. 719 (1914).

⁶ Wheeler-Lea Act, ch. 49, § 3, 52 Stat. 111 (1938). Section 5, as amended, is codified at 15 U.S.C. § 45.

⁷ 15 U.S.C. § 52.

⁸ 15 U.S.C. § 53(a). *See, e.g., FTC v. Thompson-King & Co.*, 109 F.2d 516 (7th Cir. 1940). The Commission's *Statutes and Court Decisions* volume covering the period 1938 to 1940 includes many Section 13(a) injunctive orders, not otherwise reported, that the Commission obtained to halt false advertising of quack drugs, remedies and devices pending the completion of administrative proceedings. After 1940, however, the Commission used Section 13(a) rarely, although it brought two notable cases in the 1970's, *FTC v. National Com'n on Egg Nutrition*, 517 F.2d 485 (7th Cir. 1975) (respondent preliminarily enjoined from making certain representations concerning the state of scientific evidence linking the consumption of eggs with heart disease) and *FTC v. Simeon Management Corp.*, 532 F.2d 708 (9th Cir. 1976) (preliminary injunction prohibiting claims relating to the safety and efficacy of a weight loss plan employing a drug not approved for that purpose by the Food and Drug Administration denied).

⁹ Trans-Alaska Pipeline Act, P.L. 93-153, § 408, 87 Stat. 592 (1973).

¹⁰ By 1973, it was well-recognized that, once a merger was consummated, if the Commission later found the merger unlawful, it was very difficult to fashion a remedy that restored the balance of competition as it had existed before the merger. *See FTC v. Dean Foods Co.*, 384 U.S. 597, 607 (1966) ("experience shows that the Commission's inability to unscramble merged assets frequently prevents entry of an effective order of divestiture"). With the nation in the midst of an energy crisis and gasoline prices increasing rapidly, maintaining competition in the energy industry was a pressing concern.

¹¹ *Universal Credit Acceptance Corp.*, 82 F.T.C. 570 (1973).

¹² 503 F.2d 321, 323 (9th Cir. 1974).

¹³ Magnuson Moss Warranty – Federal Trade Commission

Improvements Act, P.L. 93-637, § 206(a), 88 Stat. 2201 (1975) (codified at 15 U.S.C. § 57b).

¹⁴ Hart-Scott-Rodino Antitrust Improvements Act of 1976, Pub. L. 94-435, § 201, 90 Stat. 1390 (1976) (codified, as amended, at 15 U.S.C. § 18a).

¹⁵ *FTC v. British Oxygen Co.*, No. 74-31 (D. Del.) (unreported). *See FTC v. British Oxygen Co.*, 529 F.2d 196 (3d Cir. 1976) (*en banc*) (vacating a provision of the order because the district court's findings were inadequate). Ultimately, the cease and desist order entered by the Commission in the underlying administrative proceeding was set aside on review, leading the district court to dissolve the hold-separate preliminary injunction. *FTC v. British Oxygen Co.*, 437 F. Supp. 79 (D. Del. 1977).

¹⁶ 539 F.2d 1339 (4th Cir. 1976).

¹⁷ *See FTC v. Food Town Stores, Inc.*, 547 F.2d 247 (4th Cir. 1977) (vacating the district court's order denying the Commission's motion for a temporary restraining order, and remanding with instructions to dismiss the case as moot, in light of the defendants' abandonment of the planned merger).

¹⁸ In the 1960's, the Commission began using its rulemaking authority under Section 6(g) of the FTC Act, 15 U.S.C. § 46(g), to define specific acts and practices that it considered to violate Section 5. In 1975, the Magnuson Moss Warranty – Federal Trade Commission Improvements Act, P.L. 93-637, § 202(a), 88 Stat. 2201, added Section 18 to the FTC Act (codified, as amended, at 15 U.S.C. § 57a), confirming the Commission's authority to issue such trade regulation rules. *See United States v. JS&A Group, Inc.*, 716 F.2d 451 (7th Cir. 1983) (reviewing the history of Commission trade regulation rulemaking under Section 6(g) and the enactment of Section 18).

¹⁹ *See FTC v. Evans Prods. Co.*, 775 F.2d 1084, 1087-88 (9th Cir. 1985) (holding that the Commission cannot obtain an injunction under Section 13(b) against conduct that the defendant has ceased, absent evidence that the conduct is likely to recur).

²⁰ *FTC v. Australian Land Title, Ltd.*, No. 77-0199 (D. Hawaii).

²¹ *Australian Land Title, Ltd.*, 92 F.T.C. 362 (1978).

²² *FTC v. Southwest Sunsites, Inc.*, 665 F.2d 711, 717-18 (5th Cir.), *cert. denied*, 479 U.S. 828 (1982).

²³ S. Rep. No. 93-151, at 30-31 (1973).

²⁴ 509 F. Supp. 51 (D. Md.), *aff'd mem.*, 661 F.2d 920 (4th Cir. 1981).

²⁵ Magnuson-Moss Warranty – Federal Trade Commission Improvements Act, P.L. 93-637, Title I, 88 Stat. 2183 (1975) (codified at 15 U.S.C. §§ 2301 *et seq.*).

²⁶ 15 U.S.C. § 2310(b).

²⁷ 509 F. Supp. at 55.

²⁸ No. C 79-1857 (N.D. Ohio June 26, 1980).

²⁹ "Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures," 16 C.F.R. Part 436.

³⁰ *FTC v. H.N. Singer, Inc.*, 668 F.2d 1107 (9th Cir. 1982).

³¹ *Id.* at 1111-13.

³² 56 Stat. 23, 33.

³³ 328 U.S. 395, 398 (1946).

³⁴ See, e.g., *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291-92 (1960) (reimbursement for lost wages); *ICC v. B&T Transp. Co.*, 613 F.2d 1182, 1186 (1st Cir. 1980) (restitution); *CFTC v. Hunt*, 591 F.2d 1211, 1222 (7th Cir.), cert. denied, 442 U.S. 921 (1979) (disgorgement); *University of S. Cal. v. Cost of Living Council*, 472 F.2d 1065, 1070 (Em. Ct. App. 1972), cert. denied, 410 U.S. 928 (1973) (restitution); *SEC v. Manor Nursing Ctrs., Inc.*, 458 F.2d 1082, 1103-04 (2d Cir. 1972) (restitution and appointment of a receiver); *CAB v. Scottish-American Ass'n*, 411 F. Supp. 883, 888 (E.D.N.Y. 1976) (refunds).

³⁵ See, e.g., 15 U.S.C. § 78u(d)(1), giving the SEC authority to seek permanent or temporary injunctive relief against any person who is engaged in or is about to engage in acts or practices in violation of the Exchange Act.

³⁶ See Peter C. Ward, *Restitution for Consumers Under the Federal Trade Commission Act: Good Intentions or Congressional Intentions?*, 41 Am. U. L. Rev. 1139 (Summer, 1992).

³⁷ Under Section 19, the Commission may obtain redress for consumers only if (1) the defendant's actions either violated a Commission trade regulation rule, or were the subject of a final cease and desist order and involved conduct that "a reasonable man would have known under the circumstances was dishonest or fraudulent," and (2) the Commission commences the redress action within certain time periods specified in Section 19(d).

³⁸ 15 U.S.C. § 57b(e).

³⁹ See, e.g., *Singer*, 668 F.2d at 1113. Note, however, that under *Porter* the issue is whether Congress intended to restrict the remedial authority of the courts, while Section 19(e) addresses the authority of the Commission.

⁴⁰ See, e.g., *FTC v. U.S. Oil & Gas Corp.*, 748 F.2d 1431 (11th Cir. 1984); *FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020 (7th Cir. 1988); *FTC v. Amy Travel Service, Inc.*, 875 F.2d 564 (7th Cir.), cert. denied, 493 U.S. 954 (1989); *FTC v. Security Rare Coin & Bullion Corp.*, 931 F.2d 1312 (8th Cir. 1991).

⁴¹ See, e.g., *FTC v. Kitco of Nev., Inc.*, 612 F. Supp. 1282 (D. Minn. 1985) (restitution); *FTC v. Wilcox*, 926 F. Supp. 1091 (S.D. Fla. 1995) (asset freeze, appointment of receiver, consumer redress); *FTC v. Atlantex Assocs.*, 872 F.2d 966 (11th Cir. 1989) (asset freeze, consumer redress); *FTC v. World Wide Factors, Ltd.*, 882 F.2d 344 (9th Cir. 1989) (asset freeze, receiver); *FTC v. Gem Merchandising Corp.*, 87 F.3d 466 (11th Cir. 1996) (restitution, disgorgement); *FTC v. Febre*, 128 F.3d 530 (7th Cir. 1997) ("damages," disgorgement); *In re National Credit Mgmt. Group, L.L.C.*, 21 F. Supp. 2d 424 (D. N.J. 1998) (asset freeze, receiver); *FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263 (S.D. Fla. 1999) (consumer redress, performance bond); *FTC v. Capital City Mortgage Corp.*, 2004 U.S. Dist. LEXIS 9184 (D.D.C. May 6, 2004) (constructive trust); *FTC v. Direct Marketing Concepts, Inc.*, 2004 U.S. Dist. LEXIS 11628 (D. Mass. June 23, 2004) (accounting).

Substantiating Dietary Supplement Claims – Guidance from FDA

by Ivan J. Wasserman and Farah K. Ahmed

Mr. Wasserman is a member of the law firm Collier Shannon Scott in Washington, D.C.

Ms. Ahmed is an associate with the firm.

¹ NOVIS, NutraIngredients-USA.com, press release, 2/14/05 (citing Euromonitor, Vitamins and Dietary Supplements in the USA, Jun. 2004) (<http://www.nutraingredients-usa.com/news/printNewsBis.asp?id=58057>).

² Final Rule: Statements Concerning Effect on Structure or Function, Federal Register, January 6, 2000 (<http://www.cfsan.fda.gov/~lrd/fr000106.html>), and FDA's Structure/Function Claims Small Entity Guide (<http://www.cfsan.fda.gov/~dms/scfmguid.html>).

³ 21 U.S.C. § 343(r)(6).

⁴ 21 U.S.C. § 343(r)(6)(B).

⁵ 21 U.S.C. § 201(g)(1).

⁶ 21 U.S.C. § 343(r)(6)(C).

⁷ *Id.*

⁸ If the FDA determines that the claim is a disease claim (and not a structure/function claim), the 30-day notification submitter will receive a "courtesy letter" to this effect and will be asked to remove the claim at issue.

⁹ 21 CFR 101.93(f) and (g).

¹⁰ FDA Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, November 2004.

¹¹ "Competent and reliable scientific evidence" is defined by the FTC as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."

¹² For more information on this standard, see FTC Policy Statement on Deception, October 14, 1983 (<http://www.ftc.gov/bcp/policystmt/ad-decept.htm>).

¹³ *Id.* (In intervention studies, an investigator controls whether the subjects receive the treatment or intervention of interest in order to test whether the intervention or treatment supports a pre-determined hypothesis.)

¹⁴ *Id.* (In observational studies, the investigator does not have control over the exposure to the treatment or intervention of interest. In prospective observational studies, investigators recruit subjects and observe them before a particular outcome occurs. In retrospective observational studies, investigators review the records of subjects and interview subjects after the outcome has occurred.)

¹⁵ FTC press release, June 10, 2003 (www.ftc.gov/opa/2003/06/trudeau.htm).

¹⁶ FTC press release, October 5, 2004 (<http://www.ftc.gov/opa/2004/10/windowrock.htm>).

¹⁷ Warning Letter for Unsubstantiated Weight Loss Claim, October 22, 2004 (<http://www.cfsan.fda.gov/~dms/wl-ltr22.html>).

¹⁸ Advisory Letter to Dietary Supplement Distributors about Unsubstantiated Weight Loss Claims, October 22, 2004 (<http://www.cfsan.fda.gov/~dms/wl-ltr26.html>).

Planning for Privacy Breach in Global Company: Understanding the Multi-Jurisdictional Issues can Make the Difference between a Privacy Incident and a Privacy Crisis

By Nava Bat-Avraham, Laura Becking, Andre J. Jaglom, Leigh Feldman, John P. Beardwood and Michael Peeters

The authors are leaders and members of the Interpractice Privacy Law Committee of the ILPS.

¹ See D. Bender. *Recent Developments in Data Protection Law*, PLI Ninth Annual Institute for Intellectual Property Law (2003) 15. Bender describes three approaches to privacy law taken by U.S. corporations, including: the "Ostrich" Approach, where companies "solve a problem by ignoring it"; the "Just in Time" Approach, where companies solve problems "on a case-by-case piecemeal basis"; and the "EU Gambit" Approach, where companies "assume that compliance with the EU Data Protection Directive... will assure compliance with all data protection laws worldwide."

² A. Saita, *Identity Management: Finding the right balance between rights and responsibilities*, http://searchsecurity.techtarget.com/originalContent/0,289142,sid14_gci994963,00.html (22 July 2004); D. Becker, *UCLA laptop theft exposes ID info*, http://att.com.com/UCLA+laptop+theft+exposes+ID+info/2100-1029_3-5230662.html (10 June 2004); AP Breaking News, *Japan's financial regulator warns Citigroup's Japanese affiliate on customer data*, <http://www.sfgate.com/cgi-bin/article.cgi?file=/news/archive/2004/06/11/financial1051EDT0055.DTL> (11 June 2004); PriceWaterhouseCoopers, *Identity Theft and Security Breach Notifications: Reporting on Request*, <http://www.pwc.com/extweb/service.nsf/docid/38D0975DE5CFCC9785256EBA005F49FA> (2004).

³ Specific industries, such as banking, may have industry specific regulations that require disclosure. See http://searchsecurity.techtarget.com/originalContent/0,289142,sid14_gci994963,00.html.

⁴ California Senate Bill no. 1386.

⁵ *Id.*

⁶ Recommended Practices on Notification of Security Breach Involving Personal Information <http://www.privacy.ca.gov/recommendations/secbreach.pdf>.

⁷ *Privacy Act*, R.S.B.C. 1979, c.336.

⁸ *Privacy Act*, R.S.S. 1978, c.P-24.

⁹ *Privacy Act*, R.S.M. 1970, c.74.

¹⁰ *Charter of Human Rights and Freedoms*, R.S.Q. 1977, c. C-12, ss. 5 and 9; art. 1053 C.C.Q.

¹¹ *Privacy Act*, R.S.N.L. 1990, c.P-22.

¹² S.C. 2000, c.5.

¹³ Quebec: the privacy regime is composed of two elements: (i) amendments to Chapter 3 of the *Civil Code of Quebec*, and (ii) the enactment of a statute to expand on the Civil Code entitled *An Act respecting the protection of personal privacy* (S.Q. 1993, c. 17). Alberta: the *Personal Information Protection Act* (R.S.A. 2003, Ch.P-6.5) British Columbia: the *Personal Information Protection Act* (S.B.C. 2003, Ch.63).

¹⁴ Alberta: *Health Information Act*, RSA 2000, Ch. H-5.

Saskatchewan: *Health Information Protection Act* (S.S. 1999, Ch. H-0.021 (effective 1 September 2003, except for subsections 17(1), 18(2)

and (4) and section 69) as amended by S.S. 2002, c.R-8.2; and 2003, c.25.). Ontario: *Personal Health Information Protection Act*, 2004, S.O. 2004, c. 3 Sched. A.

¹⁵ See *Durant v. Financial Services Authority*, <http://www.courtservice.gov.uk/judgmentsfiles/j2136/durant-v-fsa.htm>. See also *European Commission Suggest UK's Data Protection Act Is Deficient*, http://www.out-law.com/page.php?page_id=europeancommission1089896924&area=news (www.out-law.com, May 2004)

¹⁶ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31995L0046&model=guichett

Going Global: International Developments in Government-Facilitated Redress

by Stacy Feuer

Ms. Feuer is a Legal Advisor for International Consumer Protection in the Federal Trade Commission's Bureau of Consumer Protection. The opinions expressed herein are her own and do not necessarily reflect the opinions of the Federal Trade Commission.

¹ 5 U.S.C. § 13(b).

² One federal appellate court underscored the established nature of the FTC's redress authority in a 2002 decision: The court's authority to order restitution to the victims [of a fraudulent scheme] and as incident thereto to place the frozen assets in trust for them is not and cannot be questioned.

FTC v. Think Achievement Corp., 312 F.3d 259, 262 (7th Cir. 2002).

³ See, e.g., FTC Press Release, *Canadian Marketers of Fraudulent Weight-Loss Products Pay Redress to Settle FTC Charges* (Oct. 12, 2004), available at <http://www.ftc.gov/opa/2004/10/fsagroup.htm>; FTC Press Release, *Bodyflex Marketers Settle FTC Charges of False and Unsubstantiated Inch and Fat Loss Claims: FTC Settlement Requires \$2.6 Million Consumer Refund Program* (Sept. 1, 2004), available at <http://www.ftc.gov/opa/2004/09/bodyflex.htm>; FTC Press Release, *Rexall Shutdown to Pay up to \$12 Million to Settle Charges Regarding Cellulite Treatment Product* (Mar. 11, 2003), available at <http://www.ftc.gov/opa/2003/03/rexall.htm>.

⁴ See, e.g., FTC Press Release, *Two Companies Deceptively Marketing Computer Systems To the Hispanic Community Settle FTC Charges: \$545,000 in Redress Funds Available to Consumers* (Apr. 1, 2005), available at <http://www.ftc.gov/opa/2005/04/unicvber.htm>; FTC Press Release, *Canadian Telemarketers Banned from Selling Business Directories and Office Supplies: Settlement With the FTC Also Requires the Defendants to Pay Consumer Redress* (Jan. 20, 2004), available at <http://www.ftc.gov/opa/2004/01/hansonpubs.htm>.

⁵ See, e.g., FTC Press Release, *Skybiz Pyramid Settlement to Provide \$20 Million for Consumers* (Apr. 1, 2003), available at <http://www.ftc.gov/opa/2003/03/skybiz.htm>; FTC Press Release, *Equinox*

International Settles Case with FTC, Eight States: Nearly \$40 Million in Restitution for Alleged Pyramid Victims (Apr. 25, 2000), available at <http://www.ftc.gov/opa/2000/04/equinox.htm>.

⁶ See, e.g., FTC Press Release, *Cross-Border Law Enforcement Yields \$1.5 Million in Redress for U.S. Consumers* (Nov. 18, 2004), available at <http://www.ftc.gov/opa/2004/11/emptor.htm>; FTC Press Release, *FTC Crackdown on Illegal Canadian Lottery Sellers* (July 29, 2004) (announcing court order awarding \$19 million in consumer redress), available at <http://www.ftc.gov/opa/2004/07/worldetal.htm>.

⁷ See, e.g., FTC Press Release, *FTC Wins Permanent Injunction Against Defendants In Bogus Credit Card Offer Case: Court Orders More Than \$12 Million in Consumer Redress; Bans the Defendants from Selling Credit-Related Products or Services and from Telemarketing* (May 13, 2004), available at <http://www.ftc.gov/opa/2004/05/bayarea.htm>; FTC Press Release, *Canadian Telemarketers to Pay for Duping U.S. Consumers into Buying Bogus Credit-related Products* (Sept. 22, 2003), available at <http://www.ftc.gov/opa/2003/09/firstbenefit.htm>.

⁸ Federal Trade Commission, *The FTC in 2005: Standing Up for Consumer and Competition*, at 17 (Apr. 2005), available at <http://www.ftc.gov/os/2005/04/0504abareportfinal.pdf>.

⁹ Cf. *EEOC v. Waffle House*, 534 U.S. 279, 295-96 (2002) (mandatory binding arbitration clause did not prohibit EEOC from seeking victim-specific judicial relief, such as backpay, reinstatement, and damages, in an statutory enforcement action).

¹⁰ See Organisation for Co-operation and Development, *Background Report for OECD Workshop on Consumer Dispute Resolution and Redress in the Global Marketplace* [hereinafter, *OECD Background Report*], at 33 (Apr. 2005), available at <http://www.oecd.org/dataoecd/59/21/34699496.pdf>.

Australia's governmental redress procedures are more restrictive than those used by the FTC. Under Australian law, the Australian Competition and Consumer Commission (ACCC) can make an application to the courts, under its Trade Practices Act, seeking compensation for one or more persons who have suffered loss or damage as a result of infringement of certain provisions of the Act. Before making the application, the ACCC must receive the express consent of each person on whose behalf it seeks to act. The ACCC also may file a collective action under the representative proceedings provisions of the 1976 Federal Court Act. This procedure is similar to a U.S.-style "opt-out" class action and the ACCC does not need to obtain the consent of consumers on whose behalf it files the case. *Id.* Australia is currently considering enhancements to its redress authority.

¹¹ *Id.* at 33-34. The *OECD Background Report* identifies the following countries with this type of redress authority: Australia, Denmark, Finland, Mexico, Portugal, and Sweden. (Sweden is discussed in more detail below.) The authority to initiate collective action lawsuits has also been proposed for the future government consumer protection agency in the Netherlands. France is currently considering whether to adopt a class action law that would provide monetary redress for consumer disputes. France currently permits very limited actions by consumer associations or the public prosecutor. See Denis Waelbroeck, Donald Slater & Gil Even-Shoshan (Ashurst), *A Study on the Conditions of Claims for Damages in Case of Infringement of EC Competition Rules: Comparative Report* [hereinafter, *Ashurst Report*], at 45 (Aug. 31, 2004),

available at http://europa.eu.int/comm/competition/antitrust/others/private_enforcement/comparative_report_clean_en.pdf. See also accompanying National Report (France), available at http://europa.eu.int/comm/competition/antitrust/others/private_enforcement/national_reports/france_en.pdf.

¹² *Id.* at 34.

¹³ Organisation for Economic Co-operation and Development, *Guidelines for Protecting Consumers from Fraudulent and Deceptive Commercial Practices Across Borders*, at VI (2003), available at <http://www.oecd.org/dataoecd/24/33/2956464.pdf>.

¹⁴ *Id.* To this end, the OECD held a workshop on *Consumer Dispute Resolution and Redress In the Global Marketplace* on April 19 and 20, 2005 at the FTC's headquarters in Washington, D.C. The agenda from the workshop, panelist bios, and presentations are available on the website of the OECD Committee on Consumer Policy. See www.oecd.org/sti/consumer-policy.

¹⁵ Organisation for Economic Co-operation and Development, *Guidelines for Consumer Protection in the Context of Electronic Commerce* (1999), available at <http://www.oecd.org/dataoecd/18/13/34023235.pdf>.

¹⁶ International Consumer Protection and Enforcement Network, *Findings on Cross-Border Remedies* (2000), available at <http://www.icpen.org/imsn/cross%20border%20findings.htm>. ICPEN was formerly the International Marketing Supervisors Network (IMSN).

¹⁷ *An Act to amend the Competition Act and to make consequential amendments to other Acts*, Bill C-19, 1st Sess., 38th Parliament, 53 Elizabeth II (Can. 2004), available at http://www.parl.gc.ca/38/1/parlbus/chambus/house/bills/government/C-19/C-19_1/C-19_cover-E.html. The Canadian Competition Bureau has powers of restitution under various criminal statutes for victims of deceptive mail and telemarketing and pyramid schemes, although their experience using this power is limited. The Canadian Competition Bureau has successfully obtained voluntary restitution in civil cases through consent agreements. Upon registration with the court, consent agreements have the same effect as a court order.

¹⁸ See Speaking notes for Sheridan Scott, Commissioner of Competition, Competition Bureau, to the Standing Committee on Industry, Natural Resources, Science and Technology (Can. Nov. 18, 2004), available at <http://competition.ic.gc.ca/epic/internet/incb-bc.nsf/en/ct02993e.html>.

¹⁹ Bill C-19, *supra* note 16, Cl. 5(3) (amending ' 74.1 with a new ' 74.1(1.1)).

²⁰ *Id.* at 4(6)(amending ' 74.11 with a new section 74.111).

²¹ *Id.* at 4(3) (amending ' 74.1 with a new section 74.1(1.2)).

²² Department of Trade & Industry, *Extending Competitive Markets: Empowered Consumers, Successful Business (Consultation)* (U.K. July 2004), available at <http://www.dti.gov.uk/ccp/consultpdf/consumerstrat.pdf>.

²³ *Id.* at 7.32.

²⁴ *Id.* at 7.33.

²⁵ Fact Sheet, Ministry of Justice, Sweden, Group Proceedings (Dec. 2002), available at <http://www.regeringen.se/content/1/c4/34/47/6cd3ccdf.pdf>. The Swedish group action uses an "opt-in" mechanism for class members.

²⁶ See www.oas.org.

²⁷ Law No. 19.955, Art. 51 (Chile 2004) (on file with author).

²⁸ The Chilean law is similar to the collective action procedure that has been part of Brazil's Consumer Code since 1990. Brazil's law gives a variety of government actors, including the office of the Attorney

General, and private consumer associations the power to bring collective actions. As in Chile, once the defendant's liability is established in the collective proceeding, each individual class member must prove causation and the amount or extent of the individual damages suffered. See generally Antonio Gidi, *Class Actions in Brazil, a Model for Civil Law Countries*, 51 Am. J. Comp. Law 311 (Spring 2003).

²⁹ The European Commission maintains a web page on private enforcement. See http://europa.eu.int/comm/competition/antitrust/others/private_enforcement/index_en.html#green. It has commissioned an extensive study on the status of claims for damages, both for breaches of competition law and for other types of law violations, including unfair trading laws and consumer protection rules. The report contains a summary of all private enforcement mechanisms in member states. See *Ashurst Report*, *supra* note 11.

³⁰ Neelie Kroes, *Taking Competition Seriously B Anti-Trust Reform in Europe*, Speech at the International Bar Association / European Commission Conference (Mar. 10, 2005) (emphasis added), available at <http://europa.eu.int/rapid/pressReleasesAction.do?reference=SPEECH/05/157&format=HTML&aged=0&language=EN&guiLanguage=en>.

³¹ *OECD Background Report*, *supra* note 10, at 35.

³² S. 1234, 108th Cong. (2003). The House adjourned before the bill could be considered on the floor. The bill reported out by the House Judiciary Committee on September 30, 2004 was H.R. 3143, 108th Cong. (2003)

Easing The Burden: Recovery of Damage Control Costs After Balance Dynamics Corporation v. Schmitt Industries, Incorporated

by D. Jeffrey Ireland and Brian D. Wright

Mr. Ireland is a partner in the law firm of Faruki Ireland & Cox P.L.L. in Dayton, Ohio. Mr. Wright is an associate in that firm. Both have considerable experience in the litigation of unfair competitive activity, including Lanham Act cases.

¹ This article is limited to a discussion of the recovery of damage control costs and similar type damages under the Lanham Act. It does not address additional remedies that may be available under other analogous state statutes such as the Uniform Deceptive Trade Practices Act, which has been adopted by several jurisdictions, and common law causes of action.

² *PPX Enters., Inc. v. Audiofidelity Enters., Inc.*, 818 F.2d 266, 272-73 (2d Cir. 1987); *U-Haul Int'l, Inc. v. Jartran, Inc.*, 793 F.2d 1034, 1041 (9th Cir. 1986).

³ 15 U.S.C. § 1125(a)(1) The Lanham Act states: "Any person who, on or in connection with any goods or services, . . . uses in commerce any word, term, name, symbol, or device . . . or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact which . . . (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her foods, services, or commercial activities by another person, or . . . (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act."

⁴ *Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery*, 185 F.3d 606, 613 (6th Cir. 1999) (citing *U.S. Healthcare, Inc. v. Blue Cross of Greater Philadelphia*, 898 F.2d 914, 922-23 (3d Cir. 1990) and *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958, 964 (D.C. Cir. 1990)).

⁵ *Id.* at 618.

⁶ *Id.*

⁷ Disgorgement includes the profits and sales that a defendant gained from false and misleading advertising. Actual damages equal the harm a plaintiff suffered as the result of a defendant's actions. Damage control costs are the costs associated with responding to defendant's false statements. Finally, attorneys' fees are the costs of litigation, including counsel fees.

⁸ *Am. Council of Certified Podiatric Physicians & Surgeons*, 185 F.3d at 618.

⁹ *Id.* at 614 ("a violation can only be established by proof of actual deception (i.e., evidence that individual consumers perceived the advertisement in a way that misled them about the plaintiff's product").

¹⁰ *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 595 (3d Cir. 2002).

¹¹ *Am. Council of Certified Podiatric Physicians & Surgeons*, 185 F.3d at 618. Where a false or misleading representation is made in a comparison of a competitor's product, irreparable harm is presumed. *McNeilab, Inc. v. Am. Home Prods. Corp.*, 848 F.2d 34, 38 (2d Cir. 1988) ("This case, by contrast, presents a false comparative advertising claim A misleading comparison to a specific competing product necessarily diminishes that product's value in the minds of the consumer Consequently, the district court did not err in presuming harm from a finding of false or misleading advertising."). However, if the advertising is non-comparative and does not make any reference to a competitor's product, irreparable harm is not presumed. *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 129 F. Supp. 2d 351 (D.N.J. 2000), *aff'd*, 290 F.3d 578 (3d Cir. 2002).

¹² *Am. Council of Certified Podiatric Physicians & Surgeons*, 185 F.3d at 618.

¹³ *Id.*

¹⁴ *Balance Dynamics Corp.*, 204 F.3d at 692 (citing *PPX Enters.*, 818 F.2d at 271-72; *U-Haul Int'l*, 793 F.2d at 1041 ("[M]arketplace damages and actual confusion are notoriously difficult and expensive to prove."))

¹⁵ *Id.*

¹⁶ *Id.* ("[E]ven where marketplace damages or actual confusion are provable in theory, such proof often requires that a plaintiff solicit its own customers for affidavits, which puts the customers at risk of being subpoenaed by the defendant.")

¹⁷ *Id.* ("[P]laintiffs may hesitate to put marketplace damages at issue because that would entitle a defendant to discover information about plaintiff's business.")

¹⁸ *Id.*

¹⁹ *Id.* at 691-92.

²⁰ *Id.* at 692.

²¹ *Id.*

²² *Id.* at 691.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.* ("This rule recognizes that it is unreasonable to expect a

businessperson faced with a Lanham Act violation to sit idly by until a customer manifests actual confusion.”)

²⁶ *Id.*

²⁷ *Id.* at 691-92

²⁸ *Id.* at 692

²⁹ *Id.*

³⁰ *Id.*

Obesity and the Carbohydrate Connection - The NAD's Approach to Low Carb Claims

by Annie Ugurlayan

Ms. Ugurlayan is an attorney with the National Advertising Division of the Council of Better Business Bureaus, Inc.

¹ “Globesity” gains ground as leading killer, ASSOCIATED PRESS (May 10, 2004).

² *Counting Calories: Report of the Working Group on Obesity*, U.S. FOOD AND DRUG ADMINISTRATION (March 12, 2004) <http://www.cfsan.fda.gov/~dms/owg-rpt.html>, at 1. The working group was established to “outlin[e] an action plan covering critical dimensions of the obesity problem as outlined in the charge and to help consumers lead healthier lives through better nutrition.” *Id.* at 3.

³ *Id.*

⁴ *Id.*

⁵ Source: Productscan Online, a packaged goods tracker.

⁶ Janet Adamy, *Low-Carb Craze Is Cooling Off; Growth of Specialty Goods Slows*, WALL ST. J. (Oct. 27, 2004), at D9 (noting that major food companies, such as Coca-Cola Co. and American Italian Pasta Co., have acknowledged that their low carb offerings have fallen below their expectations); see also Janet Adamy, *Some Food Makers Trim Low-Carb Plans as Trend Slows*, WALL ST. J. (July 12, 2004), at B1; Daniel Kadlec, *The Low-Carb Frenzy: Nutritionists are Horrified, But They Can't Stop the Force Reshaping The Food Industry – And Our Bodies*, TIME, Vol. 163 (18) (May 3, 2004), at 46.

⁷ *FTC Launches “Big Fat Lie” Initiative Targeting Bogus Weight-loss Claims*, FEDERAL TRADE COMMISSION (November 9, 2004) (noting that the December 2003 Red Flag initiative encourages media “to adopt standards that would screen out weight-loss advertisements that contain false claims” and that “Operation Big Fat Lie” is “a nation-wide law enforcement sweep against six companies making false weight-loss claims in national advertisements”).

⁸ See generally <http://www.cfsan.fda.gov/~dms/foodlab.html> (guidance on food labeling – updated November 2004); see also, *supra* note 2, at 13-21.

⁹ See *supra* note 2, at 13, 17-18.

¹⁰ Lisa Richwine, “U.S. Food Labels Need Calorie Clarity – FDA Chief,” REUTERS (November 5, 2004).

¹¹ See *Dietary Guidelines for Americans 2005*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. DEPARTMENT OF AGRICULTURE (<http://www.healthierus.gov/dietaryguidelines>), at 25 (“Whole grain” refers to the entire grain seed (“kernel”), which consists of the bran, the germ and the endosperm, and any breakage of the kernel requires that nearly the

same proportions of the kernel’s components remain intact.”).

¹² *Id.* at Appendix A-1, A-2.

¹³ *Id.* at 25, 54 (“More whole grain up to all of the grains recommended may be selected, with offsetting decreases in the amounts of other (enriched) grains”; “daily intake of at least 3 ounce [one ounce = one serving] equivalents of whole grains per day is recommended by substituting whole grains for refined grains”). The Guidelines explain the difference between whole grains and refined grains as follows: “Whole grain refers to the entire grain seed (“kernel”), which consists of the bran, the germ and the endosperm, and any breakage of the kernel requires that nearly the same proportions of the kernel’s components remain intact. Refined grains result from grain processing, in which most of the bran and some of the germ is extracted. The result is a loss of dietary fiber, vitamins and minerals, among other things. Most refined grains are enriched with, among other things, folic acid, thiamin and iron, before being processed further and used in foods.” *Id.* at 25. The Guidelines also suggest that consumers choose “folate-fortified products, such as folate-fortified whole grain cereals,” instead of enriched grains, linking the consumption of at least 3 or more ounce-equivalents of whole grains per day to possible reductions of several chronic diseases and assistance in weight management. *Id.* at 25.

¹⁴ *Tropicana Products, Inc. (Tropicana® Light ‘n Healthy)*, Report # 4192, *NAD Case Reports* (June 2004).

¹⁵ NAD agreed that the product contained 1/3 less sugar and calories than orange juice and thus did not address the advertiser’s discussion on this point.

¹⁶ See *What Induction Can Do For You*, <<http://atkins.com/Archive/2001/12/15-285697.html>>; see also *Phase 1: Kick Starting Your Weight Loss*, <http://www.southbeachdiet.com/public/about-the-south-beach-diet/diet-phases.asp#phase1> (“What you won’t eat: No bread, rice, potatoes, pasta, or baked goods. Not even fruit. Before you panic: You’ll begin adding those things back into your diet in two weeks. But for right now, they’re to be avoided. No candy, cake, cookies, ice cream, or sugar for two weeks, either.”). After the induction phase of the Atkins® diet, carbohydrates can be gradually reintroduced (with an emphasis on fruits, vegetables and nuts) and intake may increase to 25 grams of carbohydrates a day for the first week, increasing each week (an additional five grams of carbohydrates a day the second week; another five grams a day in the third week, etc.) until one reaches a number of carbohydrates after which there is no additional weight loss. The South Beach Diet™ states that in Phase 2 (after the first two weeks), “right carbs,” such as “whole-grain breads and pasta,” may be consumed and that in Phase 3, one continues to follow the principles learned in Phase 1 and Phase 2 for life.

¹⁷ See 21 C.F.R. §§ 101.60(b) and (c), 101.62(b)(c).

¹⁸ In a television commercial that aired after NAD’s decision, the amount of carbohydrates per serving was referenced prominently and for adequate duration.

¹⁹ *Nestlé USA, Inc. (Carnation Instant Breakfast for the Carb Conscious)*, Report # 4203, *NAD Case Reports* (July 2004).

²⁰ There is a reference to “no added sugar carbs” next to this claim after which an asterisk directs consumers’ attention to the following disclaimer appearing in extremely small print at the bottom of the advertisement: *One serving contains 7g sugar carbs from lactose, a natural milk sugar, and has 55% less total carbs than original.

²¹ NAD noted that the “One serving contains 7g sugar carbs from lactose, a natural milk sugar, and has 55% less total carbs than original” qualification is incorrect when calculating the amount of carbohydrates

for the product as intended to be prepared (24 grams of carbohydrates vs. 39 grams of total carbohydrates for the original, a difference of approximately 39%, not 55%). It also added that this disclosure was neither clear nor conspicuous as it does not qualify the “0 Sugar Carbs Added” claim, which is qualified by the statement “See back panel for nutritional information” (in small type) that directs consumers to the nutrition panel for the following mice-type disclosure: “From lactose, a natural milk sugar.”

²² Atkins Nutritionals, Inc. (Advertising for The Atkins Food Pyramid), Report # 4230, *NAD Case Reports* (September 2004).

²³ The USDA Food Pyramid was replaced earlier this year by the MyPyramid Plan.

²⁴ A few months after issuing its decision, NAD opened a compliance proceeding as it found an unmodified version of the food pyramid on the advertiser’s website. In response, the advertiser indicated that the unmodified pyramid was no longer referenced and that the modified version, showing one food product in the extension for each food group, was now being shown.

²⁵ Russell Stover Candies, Inc. (“Low Carb” Line of Confectionary Products), Report # 4235, *NAD Case Reports* (October 2004).

²⁶ See Jennifer Warner, *When a Carb’s Not a Carb: The Net Carb Debate*, <http://my.webmd.com/content/Article/92/101603.htm>.

²⁷ Russell Stover’s “low carb” *Pecan Delight, Solid Milk Chocolate and Toffee Squares* contain 24, 22 and 16 grams of carbohydrates, respectively.

²⁸ Under section 2.2 (B)(vi) of the *NAD/NARB Procedures*, mandatory deferral by the NAD occurs only when language used in an advertisement, product packaging or labeling that is at issue has been “mandated or expressly approved by federal law or regulation.” See, e.g., Kraft Foods, Inc. (Kraft Grated Parmesan Cheese), Report # 4239, *NAD Case Reports* (October 2004) (deferring to the Federal standard for labeling grated cheese product). Deferral is an option where, as in Russell Stover Candies, Inc., a government agency currently has an issue under consideration or has also weighed in on the advertising claims either through a warning letter or by other means.

²⁹ DNA Dreamfields LLC (Dreamfields Pasta), Report # 4271, *NAD Case Reports* (December 2004).

³⁰ “Glycemic load” is defined as the amount approximately equal to the amount of carbohydrate in a portion of food that is digested and absorbed (“digestible carbohydrates”).

³¹ Health & Nutrition Systems International, Inc. (Carb Cutter), Report # 4212, *NAD Case Reports* (July 2004).

³² While the FTC has explicitly warned against misleading claims relating to “fat blockers” in its “Red Flag” initiative, it has not issued a similar warning with respect to “carb blockers,” though it has investigated weight loss claims relating to carb blocking dietary supplements. See F.T.C. v. Pinnacle Marketing, L.L.C., FTC File No. 022-3009, Civil Action No. 04-cv-185-P-C (District of Maine) (2004), <http://www.ftc.gov/os/caselist/0323151/0323151.htm>.

³³ Natrol, Inc. (Carb Intercept with Phase 2™), Report # 4158, *NAD Case Reports* (March 2004).

³⁴ NAD also cited to the FTC which recommends that dietary supplement manufacturers also consider the following: 1) How does the dosage and formulation of the advertised product compare to what was used in the study?; 2) Does the advertised product contain additional ingredients that might alter the effect of the ingredient in the study?; 3) Is the advertised product administered in the same manner as the ingredient used in the study?; 4) Does the study population reflect the characteristics and lifestyle of the population targeted by the ad? “*Dietary Supplements: An Advertising Guide for Industry*, Federal Trade Commission, at 9-10. <http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>.

³⁵ Structure/function claims describe the impact of a nutrient or dietary ingredient on the functioning of the body (e.g., “calcium builds strong bones”), as well as how the nutrient or dietary ingredient works to “maintain” the body’s structure or function (e.g., “fiber maintains bowel regularity”) and the benefits of the consumption of a particular nutrient or dietary ingredient. *Food Labeling & Nutrition – Dietary Supplements, Label Claims (Structure Function Claims)*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.cfsan.fda.gov/~dms/labstruc.html>.

³⁶ Leiner Health Products (Starch Away®), Report # 4190, *NAD Case Reports* (June 2004).

³⁷ *FTC cites drop in fraudulent diet ads*, ADVERTISING AGE (February 7, 2005), at 16 (quoting FTC Chairman Deborah Majoras who, at a Good Housekeeping Institute luncheon, stated that FTC’s campaign to prevent fraudulent weight-loss ads resulted in a decrease in such advertisements from 50 percent in January 2004 to 15 percent in May 2004).