

Product Liability Update

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Medicaid Fraud and Abuse Provisions of the Deficit Reduction Act of 2005 Signal Increased Government Scrutiny

By Carol Colborn Loepere, Wendy H. Schwartz and Kevin M. Madagan

Reed Smith's Product Liability Update provides in-depth analysis of important product liability developments as well as emerging issues in other fields that are of critical importance to our product liability clients.

On Feb. 8, 2006, President Bush signed into law the Deficit Reduction Act of 2005 ("DRA").¹ As the name implies, the DRA is expected to reduce federal spending on the Medicare and Medicaid programs over five years (although certain provisions would technically increase federal spending).

As part of this legislation, Congress included several provisions intended to eliminate fraud, waste and abuse in the Medicaid program. Two of the most significant provisions for companies receiving Medicaid reimbursement or making payments to state Medicaid programs are: (1) encouraging states to enact state false claims acts;

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Sweep On, You Fat & Greasy Citizens!

By Antony B. Klapper, Paul Llewellyn and Anthony E. DiResta

Shakespeare's happily permissive tone in *As You Like It* (Act 2, Scene 1), as quoted above in the title, is bad advice in today's brave new world of food & advertising.

It may not be a Perfect Storm, but the past year has seen a convergence of factors that are likely to result in the filing of more lawsuits, possibly the passage of more regulation, and even legislation against those who market so-called unhealthy foods to children.

It was approximately four years ago that the much-maligned *Pelman* lawsuit was filed against McDonald's, claiming a class of New York children and adolescents were deceived into repeatedly purchasing and consuming unhealthy Big Macs. See, e.g., <http://f1.findlaw.com/news.findlaw.com/hdocs/docs/mcdonalds/pelmanmcds21203acmp.pdf>. The behind-the-scenes litigator in charge of this Mac Attack was no other than Law Professor John Banzhaf, the same lawyer who made a career fighting Big Tobacco and who had now set his sights on so-called Big Food.

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“Sweep On, You Fat & Greasy Citizens!” – *continued from page 1*

On Dec. 6, 2005, the highly regarded Institute of Medicine of the National Academies announced the completion of its report, Food Marketing to Children and Youth. The authors of this government-sponsored study concluded that “television advertising influences children to prefer and request high-calorie and low-nutrient foods and beverages.”

Ever since the initial filing of the *Pelman* lawsuit, federal agencies have held conferences, scientific reports have been commissioned, and public advocacy groups have mobilized and dreamt up other lawsuits and strategies to compel changes in *what* food and beverage companies sell and *how* those foods and beverages should be advertised and marketed. During this period of exploration and what turned out to be years of legal wrangling in the *Pelman* suit, very little happened on the obesity litigation or regulatory fronts. This was in large part because of the lack of evidence of *causation*.

If advocates want to file a consumer fraud claim against food, beverage, or media companies for marketing alleged “unhealthy” foods to children, they must prove (even in the most liberal states) that the alleged fraud or unfair trade practices actually *caused* injury. See, e.g., *Pfizer, Inc. v. Superior Court*, 141 Cal. App. 4th 290 (2006); *Hershenow v. Enterprise Rent-A-Car Co. of Boston, Inc.*, 2006 WL 73594 (Mass. 2006). If advocates want to push forth legislation or regulation that would restrict the marketing and advertising of certain foods to children, they similarly must satisfy *causation* requirements. Under the Supreme Court’s interpretation of the First Amendment, restrictions of commercial speech must at a minimum advance the goal of combatting obesity without unnecessarily impeding information access to others. See, e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001). Up until 2005, well-respected scientific bodies had not identified or focused on any one particular factor as the *cause* or substantial contributing cause of obesity in today’s children. In late 2005, however, things changed.

On Dec. 6, 2005, the highly regarded Institute of Medicine of the National Academies announced the completion of its report, *Food Marketing to Children*

and Youth (“IOM Report”). The authors of this government-sponsored study concluded that “television advertising influences children to prefer and request high-calorie and low-nutrient foods and beverages.” *IOM Report* at 8. The authors stopped short of saying that television advertising *causes* children to get fat, but they did find an association. *Id.* at 9.

Although there are serious flaws and limitations to this study, its importance cannot be denied. Whether it is a legislative/regulatory or a litigation strategy, even *some proof* that marketing to children contributes to obesity improves the chances that a piece of legislation or regulation can withstand First Amendment scrutiny, or that a consumer fraud class action can survive a dispositive motion. Standing alone, the IOM Report is probably not enough. In fact, the authors acknowledge the report’s limitations, noting how in formulating their opinions they could only rely on publicly available information, not internal, proprietary company documents. *IOM Report* at xiv. But, in highlighting this limitation, the IOM set the stage for what has become the next battleground: The hunt for *internal documents* in the halls of America’s largest food and beverage companies. Here are just a few events since the publication of the *IOM Report* that illustrate this trend:

- On Jan. 18, 2006, the Center for Science in the Public Interest (CSPI), a nonprofit advocacy group, issued a notice of intent to sue the Kellogg company and Viacom Inc. in Massachusetts state court for alleged unfair and deceptive trade practices with respect to the marketing and sale of foods of so-called “poor nutritional quality” to children under 8 years of age. CSPI proclaimed in its Notice that it needed access to both companies’ *internal documents* in order to

calculate damages. See http://cspin-et.org/new/pdf/viacom___kellogg.pdf.

- On March 1, 2006, the Federal Trade Commission (“FTC”), expressly acknowledging the data gaps of the *IOM Report*, issued a Notice requesting that food and beverage manufacturers document and disclose their target marketing practices to children and adolescents. See 71 Fed. Reg. 10535 (March 1, 2006), available at <http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/E6-2812.pdf>
- On Sept. 16, 2006, Judge Robert Sweet ordered McDonald’s to answer the plaintiffs’ amended complaint, thus paving the way for discovery of McDonald’s internal documents. See <http://www2a.cdc.gov/phlp/docs/Order-m-dism-3.PDF>.
- On Oct. 23, 2006, unhappy with the completeness of responses to its March 1 notice, the FTC issued a Second Notice, expressing its intent to subpoena information, including documents, about the marketing practices and expenditures targeted to children and adolescents of the 50-largest food and beverage manufacturers and quick-serve restaurants. See 71 Fed. Reg. 62109 (Oct. 23, 2006), available at <http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/E6-17666.pdf>.
- From Nov. 3–5, 2006, the Public Health Advocacy Institute (PHAI) held its 4th Annual Conference where participants and speakers applauded their “successful” litigation strategies and their continued focus on stemming the tide of marketing and advertising to children. Materials handed out at the conference included a 2006 article by Richard Daynard, a former tobacco warrior, who wrote that “[t]he food

industry may be concerned that litigation could reveal similar documents or industry practices [similar to tobacco] that would tarnish its public image.” (*Emphasis added.*) J. Alderman & R. Daynard, “Applying Lessons from Tobacco Litigation to Obesity Lawsuits, 30 *Am J. Prev. Med.* 82, 85 (2006).

Those who oppose the current marketing practices of food, beverage, and media companies hope that those companies’ internal documents and witnesses strengthen their consumer fraud claims and their pleas for legislative and regulatory changes. They hope to find evidence that supports their claim that food marketing influences children to prefer so-called “unhealthy” foods; that young children cannot activate their defenses against advertising; that choice is an illusion because companies intentionally capitalize on the influence that children have over their parents’ purchasing decisions; that companies

use neuro-marketing techniques to control choice; that they manipulate ingredients to addict consumers into consuming more of their products; and that they disproportionately market “unhealthy” foods to minority groups.

The revived hunt for documents is, of course, not the only catalyst. On Nov. 7, 2006, Democrats took over both the House and the Senate in the United States Congress. As a result, Democratic leaders, like Senators Harkin, will be better positioned to advance legislative and regulatory restrictions that may push the limits of what the First Amendment allows. The American Academy of Pediatrics, in fact, recently issued recommendations asking Congress to do just that, calling for a complete ban on “junk-food advertising during programming that is viewed predominantly by young children.” www.pediatrics.org/cgi/con

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In Europe, where the cabining effects of the First Amendment do not exist, changes have already taken place. On Nov. 17, 2006, the United Kingdom’s Office of Communications (“Ofcom”), a quasi-governmental agency responsible for regulating the communication industry, proposed that foods advertised on children’s television meet strict government nutrition criteria, including limits on sugar, salt and saturated fat. See <http://www.ofcom.org.uk/media/speeches/2006/11/foodslides.pdf>. Other countries, like Norway and Sweden, have already instituted general restrictions on marketing to children. See *IOM Report* at 472–73.

Will these activities across the pond further increase the tidal pressures for change here in America? Many companies hope not and point to recent self-regulatory initiatives as obviating the need for regulation or litigation in the United States. For example, the Council of Better Business Bureaus (“CBBB”) and the National Advertising Review Council (“NARC”) announced on Nov. 14, 2006, the establishment of the Children’s Food and Beverage Advertising Initiative. The Initiative is touted as being designed to shift the mix of advertising messaging to children to encourage healthier dietary choices and lifestyles. See <http://www.cbbb.org/initiative/ProgramDocument.pdf>.

But while 10 large companies signed on as charter members of this Initiative, many more did not, and most significantly public advocacy groups like CSPI and PHAI were clearly not appeased. For example, CSPI’s Executive Director, Michael Jacobson, issued this statement: “CARU and CBBB should scrap this initiative and start from scratch. I hope that next year, leaders in Congress take a fresh look at the industry’s practices. In the meantime, junk food marketers should ex-

pect more lawsuits—not praise—from health advocates.” <http://www.cspinet.org/new/200611141.html>. And, PHAI called the Initiative a “public relations ploy.” http://phaionline.org/downloads/phai_caru_press_release_11142006.pdf.

Given the current regulatory, legislative and litigation climate, this is a critical time for companies to consider their options, strategies and alternatives. For example, companies should consider an audit, where they evaluate their liability exposure and identify strengths, weaknesses and potential areas of change. Companies facing the threat of legislation, regulation, or litigation directed at their marketing and advertising practices to children need to determine what battles can be fought, should be fought, or should be avoided, and what alternatives are available. Such an analysis and effort will also help companies avoid taking public positions that may be inconsistent with what their internal documents and witnesses may say or not say. As part of its risk management strategy, companies should consider evaluating themes and allegations that plaintiffs or government regulators might present, and determine what potential defenses are currently available and prospectively implementable. This effort should involve a multi-disciplinary team (e.g., legal, PR, legislative/government affairs) and might include preliminary interviews of key company personnel, identification of key pieces of information, and the retention of experts and consultants.

As the events of the past year demonstrate, storm clouds are thickening and companies would be wise to batten down their hatches.

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“Medicaid Fraud and Abuse Provisions of the Deficit Reduction Act of 2005...” – *continued from page 1*

and (2) requiring employee education on state whistleblower and false claims recovery laws. These provisions are generally effective Jan. 1, 2007 and warrant the attention of any company whose business involves Medicaid funds or payments.²

Promoting State False Claims Acts

The first material portion of the DRA is that it encourages states to enact false claims legislation similar to the Federal False Claims Act.³ While some new state legislation will mirror the Federal False Claims Act, other state legislative proposals could be broader in scope. Accordingly, companies receiving or making Medicaid payments should track all new false claims legislation in their respective jurisdictions. Reed Smith attorneys are maintaining up-to-date information on pending state legislation as well; please contact the authors for current information.

Under the Federal False Claims Act, any person who knowingly submits a false or fraudulent claim to a state Medicaid program is liable to the federal government for three times the amount of the federal government's damages, plus penalties of \$5,500 to \$11,000 for each false or fraudulent claim.⁴ Any damages recovered for a state Medicaid program under the Federal False Claims Act are shared by the federal government with the state in the same proportion as the state's total share of the Medicaid program costs. The federal government's share generally varies between 50 percent and 83 percent, depending on each state's per capita income.

Notably, the DRA modifies the shared proportion, in an attempt to entice states to enact their own false claims act. States that have false claims acts that meet certain enumerated requirements will receive 10 percentage points more of any amount recovered under a

state action brought under such a law. For example, if a state has a qualifying state false claims act and the state's Medicaid share is 50 percent, the state would be entitled to 60 percent of the amount of any recovery the state obtains by pursuing a state law false claim act, while the federal government would receive the remaining 40 percent.

To be eligible for the financial incentive, states generally have until Jan. 1, 2007 to enact new legislation.⁵ However, before the recovery percent is adjusted, the Department of Health and Human Services (“HHS”), Inspector General, in consultation with the Attorney General, must first certify that the state legislation:⁶

- Establishes liability to the state for false or fraudulent claims described in the Federal False Claims Act with respect to Medicaid expenditures;
- Contains provisions that are at least as effective in rewarding and facilitating *qui tam* (whistleblower) actions as those in the Federal False Claims Act;
- Contains a requirement for filing an action under seal for 60 days with review by the state attorney general; and
- Contains a civil penalty that is not less than the amount authorized by the Federal False Claims Act, which is currently three times the government's damages, plus civil penalties of \$5,500 to \$11,000 per false claim.⁷

Manufacturers and others should note that, under the “No Preclusion of Broader Laws” provision, the DRA will not be construed as prohibiting a state from having a law that is *broader* in scope than the Federal False Claims Act.⁸ As of November 2006, about one-half of all states have civil false claims acts, and the DRA has prompted

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Tucked away in the DRA is a provision requiring all entities that make or receive at least \$5 million in annual Medicaid payments to establish specific written policies and procedures to inform employees and others about certain federal and state false claims and whistleblower laws.

legislative action in other states.⁹ Accordingly, manufacturers and others should become familiar with any new or amended state false claims acts in their respective jurisdictions to ensure compliance after Jan. 1, 2007.

Employee Education Requirements

While the DRA false claims act provision warrants awareness by companies of new state false claims acts—and potentially enhanced enforcement by state Medicaid agencies and state attorneys general—another provision of the DRA requires companies falling within the DRA Medicaid education requirement to quickly update employee training materials on federal and state false claims laws.

Tucked away in the DRA is a provision requiring all entities that *make* or *receive* at least \$5 million in annual Medicaid payments to establish specific written policies and procedures to inform employees and others about certain federal and state false claims and whistleblower laws.¹⁰ With a compliance deadline of Jan. 1, 2007,¹¹ entities having significant interactions with state Medicaid programs (including through participation in the Medicaid rebate program), should be reviewing and quickly adjusting, or creating, education materials for employees, contractors, and representatives in accordance with the DRA.

The stakes are high. These DRA education requirements are prerequisites to Medicaid reimbursement, and entities failing to comply could lose Medicaid funding, along with other funding under state-administered federal health care programs. As noted, the new requirements apply to any entity that *receives* or *makes* annual payments of at least \$5 million under a state Medicaid plan. The inclusion of entities that make and receive payments makes these provisions applicable to

a broad array of entities in the health care industry, including, for example, pharmaceutical manufacturers that pay rebates to state Medicaid programs, along with providers that receive Medicaid payments for services rendered.

The Centers for Medicare & Medicaid Services (“CMS”) has not formally issued guidance to state Medicaid agencies regarding implementation of the education requirement. While some parts of the law are relatively clear, there are some ambiguities that are expected to be clarified (such as whether “entity” refers to a single provider or company, or includes all entities under a single legal entity). Affected companies thus should monitor CMS developments in this area as well.

More specifically, the DRA’s five new employee education obligations are:

- **Written Policies and Procedures.** The DRA requires detailed *written* policies and procedures about state and federal whistleblower laws. Training is not specifically required, but the provisions contemplate that entities dealing with state Medicaid programs will inform their employees (including management), and any contractor or agent of the entity, of their policies.
- **Informing Specified Parties.** The policies and procedures must inform *all employees, including management*, and anyone who could be considered a *contractor* or *agent* of the entity, about whistleblower laws. Draft guidance from CMS suggests that this will include anyone “which or who, on behalf of the entity, furnishes, or otherwise authorizes the furnishing of, the delivery of Medicaid health care items or services, performs billing or coding functions, or is involved in the monitoring of health care provided by the facility.” Each company will

need to decide how to inform its covered contractors and agents once the definitions are finalized.

- **Information on Certain Laws.** The policies and procedures must provide information on the following laws, including the role of such laws in preventing and detecting fraud, waste, and abuse in federal health care programs:
 - The Federal False Claims Act;
 - Federal administrative remedies for false claims and statements;
 - State laws pertaining to civil or criminal penalties for false claims and statements; and
 - Whistleblower provisions under the federal and state laws.
- **Describing the Entity's Policies and Procedures.** The policies and procedures must also provide details

regarding the entity's own internal policies and procedures for protecting against fraud, waste, and abuse.

- **Employee Handbook Provisions.** The entity must include in its employee handbook, if it has one, (a) specific discussion of applicable fraud and abuse laws; (b) rights of employees who are whistleblowers; and (c) the entity's policies and procedures for detecting and preventing fraud, waste, and abuse.

Next Steps

Companies must walk a fine line in terms of how they communicate with their employees, contractors and agents about whistleblower activity. As noted, the statute requires providing detailed information to employees, yet companies will want to be careful not to encourage abuse of the whistleblower provisions. While there may be limited

instances in which the federal or a state false claims law is appropriate, our experience has been that most of the time, employee use of internal compliance procedures will allow the company to better and more quickly address any issues it may have, and companies should encourage employees to make use of those internal procedures.

Moreover, employees need to recognize the potential difficulties before jumping into a lawsuit in terms of creating an adversarial relationship with their employer, the length of time to achieve resolution, and the uncertainties of a recovery. Such actions also, of course, can cause great harm to the employer, as they are expensive, consume large amounts of resources, and can alienate employees from each other and from the company. This can be as damaging for the whistleblower as it is for the employer.

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Thus, under the DRA’s mandates, whistleblower options should be objectively described with both their benefits and risks, so employees can make informed choices about how to pursue potential fraud and abuse issues that they believe they see. The focus must remain on the employee or agent seeking to do what is right, whether that means using the internal compliance procedure, or going outside. Whistleblower provisions should be viewed as only one tool of many. Communicating this to employees, yet still complying with state provisions enacted under the DRA, will not be an easy task.

The DRA Medicaid provisions are a product of a Congress that is heavily pressuring the OIG, CMS and the states to combat fraud, waste, and abuse. Given this regulatory environment, continued proactive compliance and monitoring is vital. Entities implicated under these new provisions will need to act quickly to comprehend multiple state, federal, civil, criminal, and administrative provisions and to determine the best way to efficiently educate employees, contractors, and other representative entities. Even then, everyone interacting with a Medicaid program can expect an exhilarating next few years of increasing industry investigations and actions, and increasingly strict interpretations and compliance expectations.

¹ *The Deficit Reduction Act of 2005*, Pub. L. No. 109-171, 120 Stat. 72 (2006); H.R. Conf. Rep. No. 109-362 at 304-305 (2005), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_reports&docid=hr362.pdf.

² The DRA mandates that, as a condition of receiving Medicaid funding, state Medicaid programs must generally enact the state false claims act provisions by Jan. 1, 2007. The same timeframe applies to the employee education requirement.

³ 31 U.S.C. § 3729-3733.

⁴ *Id.* at § 3729(A)(7). This section provides for civil penalties ranging from \$5,000 to \$10,000 per claim. These penalties were adjusted for inflation in 1999 pursuant to 28 U.S.C. § 2641(4)(1), as implemented by 28 C.F.R. § 85.3(9).

⁵ 42 U.S.C. § 1396h.

⁶ On Aug. 21, 2006, the HHS Office of the Inspector General (“OIG”) published a notice announcing evaluation guidelines for state false claims acts. 71 Fed. Reg. 48552 (Aug. 21, 2006). The guidelines establish how the OIG will determine whether a state law meets the DRA’s requirements.

⁷ 42 U.S.C. § 1396h.

⁸ *Id.*

⁹ Currently, several states have already enacted a False Claims Act, including California, Delaware, Florida, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, New Hampshire, New Mexico, Nevada, Ohio, Tennessee, Texas, Virginia, and the District of Columbia.

¹⁰ *The Deficit Reduction Act of 2005*, Pub. L. No. 109-171, § 6032, 120 Stat. 73 (2006) amending 42 U.S.C. § 1396a(a).

¹¹ 42 U.S.C. § 1396a.

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