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Dietary Supplements

FDA - The watchdog gets some teeth

California's effort to strengthen food regulation falls short

Anne Andrews: Incoming OCTLA president takes on dietary supplement makers

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By Miles Corwin

Photo by Lori Shepler calishep@yahoo.com

Anne Andrews had graduated from law school, was sharing a small Santa Ana office with another young plaintiff's attorney, and was struggling to make it, handling appearances for other lawyers and scrambling for cases. When a hot air balloon crashed on a Fresno race track, injuring dozens of people and leading to the death of a number of horses, one of the trainers called her.

Andrews, a former equestrienne in high school who knew the steward at the track and some of the trainers, ended up representing more than 60 plaintiffs. On the eve of trial against the insurance carrier, she settled the case. That provided her enough of a financial cushion to set up a business plan, and establish a practice that ultimately led to one of her current specialties – suing manufacturers of dietary supplements that injure consumers who turn to them hoping to shed a few pounds or gain an extra boost.

The 1984 case against the manufacturer of the hot air balloon was her first product liability lawsuit. During the next twenty-five years, Andrews would file more than 5,000 product liability lawsuits, and now is considered one of the nation's leading plaintiff attorneys involved in dietary supplement litigation.

Her firm, Andrews & Thornton in Irvine, was at the forefront of the ephedra litigation, prosecuting numerous ground breaking lawsuits across the country for the past decade. Andrews was appointed by a judge in the Southern District of New York to be a member of the Plaintiffs' Coordinating Counsel in the ephedra product liability litigation.

Ephedra, a powerful herbal stimulant, had been sold in numerous weight-loss and energy enhancing products. Associated with heart problems, high blood pressure and strokes, and contributing to more than 100 deaths, the Food and Drug Administration banned the sale of ephedra in 2004. Because so many of the firms manufacturing ephedra went bankrupt, Andrews became a specialist in tort claims related to bankruptcy and is now leading seminars across the country on the subject.

"My clients were all compensated regardless of the bankruptcy," said Andrews, who will head the Orange Country Trial Lawyers Association next year. "We successfully resolved $300 million worth of claims from bankrupt companies through a plan of reorganization that was paid into from all co-defendants and contributors, including retailers, suppliers, insurers and owners of the companies who gave back personal money."

The next big product liability battle Andrews is fighting is over another weight-loss product, sold under the Hydroxycut brand. Her firm was approved by the American Association for Justice to co-lead the litigation – and organize a national database – against

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Iovate Health Sciences Inc. The company has said that the problems with the product are exaggerated and that it agreed to a recent recall "out of an abundance of caution and because consumer safety is our top priority." Andrews, however, contends, that Hydroxycut had led to serious health problems, including liver failure. She is representing more than 200 plaintiffs who claim to have been harmed by the product.

"Trial lawyers have been very influential in protecting the public," Andrews said from the conference room of the Irvine law firm she heads with her husband, John Thornton. "For years the world was asleep to the fact that ephedra combined with caffeine could cause the heart to stop and create heart attacks and strokes. This product continued to be sold, despite people dying, and nobody would ban it. If it weren't for the trial lawyers, ephedra would still be out there."

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Andrews grew up in Fullerton and her two high school passions – opera and horses – ended up playing a large part in her legal practice. She sang in a number of productions during high school and was a featured soloist for various orchestras. When she attended Stephens College – a women's school in Columbia, Mo. – she continued singing opera in chamber ensembles. The transition from the stage to the courtroom was an easy one for Andrews.

"In both worlds, it's all about preparation and focus, knowing the importance of language, loving the spotlight. In opera, I learned the rewards that come from hard work and accomplishment, and it's the same when you're preparing for trial. Being a plaintiff's attorney requires being a risk taker and having an incredible will. When you're on stage the question is: Can you hit the high notes? Do you have what it takes? Just like in court."

Andrews is a tall woman – five foot ten inches – with a commanding courtroom presence and a buoyant personality. After more than twenty-five years of practicing law she still discusses her legal battles with animation.

Andrews, who majored in history and political science in college, took a few years off after graduation and worked for a family business before attending Western State University College of Law in Fullerton. She was immediately attracted to plaintiff's work.

"The notion of equal justice and a level playing field for victims was something I liked. Regardless of the size of a person's wallet, they could hire a lawyer, and a small lawyer like me had a voice just like the big firms."

In 1981, when Andrews graduated from law school, there were few female partners in Orange County. Many young female lawyers, she said, gravitated to family law, wills and trusts, adoption law or went to work for the government. The glass ceiling was immediately apparent to her. Andrews "wanted to go where the action was," and she determined that was plaintiff's work. She discovered that there was very little sexism – but a lot of camaraderie – among Orange County trial lawyers. When she had a difficult case, she could call big name plaintiff's attorneys and they would always offer help and support.

"The trial lawyers here didn't want to exclude women then – they wanted to *in*clude us. It was a lot harder for young women elsewhere. I felt immediately at home. There was never a time when a senior member of the trial bar wasn't willing to help or teach me. They were my senior partners. The Orange Country Trial Lawyers Association was like a small regional family."

The Fresno race track case not only provided her with the financial resources to launch her practice, but also a large client base. Because she was knowledgeable about horses, racing people felt comfortable with her and word spread among the grooms, exercise riders and others who worked at racetrack backstretches throughout the state.

They soon began bringing personal injury cases to her. Eventually, jockeys and trainers and owners, accused of violating regulations, asked her to represent them in hearings before the California Horse Racing Board. She had to learn about medication rules for horses and drug testing and analysis and be conversant enough to explain her cases to a panel of racing judges. Since many horses are given herbal remedies, she became an expert on the subject. This expertise ended up becoming a specialty when she began handling dietary supplement cases.

In the early 1990s, she began litigating her first large product liability cases – women who had undergone silicone breast implants. She represented about 2,000 women – in individually filed cases – who claimed they were harmed as a result of silicone leaking from their implants. Eventually she was named a member of the California steering committee, appointed by the courts, to represent the interest of the claimants in the settlement with implant makers.

Former state Sen. Joe Dunn, the trial attorney who recently stepped down as CEO of the California Medical Association, met Andrews when he was the plaintiff's liaison counsel for the California implant litigation cases.

"I saw a lot of players, and with many of the lawyers, their ego got in the way and they didn't want any guidance. Anne was different. She was very willing to learn and she learned very well. A lot of new players on the plaintiff side take large number of marginal cases. ... Anne is extremely disciplined. She takes only the best and most solid cases. ... Once she learned the chess game of mass torts she became a master at it. It's due to her discipline, tenacity and just plain stubbornness in breaking into a world of law that doesn't accept newcomers easily. She's now one of the most prominent mass tort players in the U.S."

Her first dietary supplement case was in the late 1990s, when she represented a client who had taken fen-phen, a diet drug combination. Fen-phen plaintiffs, the majority of whom were women, claimed the product caused primary pulmonary hypertension, a lung disease that is often fatal. Andrews ended up handling more than 100 cases, the majority of which settled.

A few years ago she began representing women who claimed they were harmed after taking Ortho Evra birth-control patches, which delivered more estrogen than birth control pills and have increased the risk of strokes and blood clots. She ended up litigating about fifty cases and settling all of them.

"Women's issues, getting justice for women, is very important to me," Andrews said. "A lot of times, particularly with the silicone breast implants, women who were harmed by these products are more comfortable talking to a female attorney. If there's a device or a drug that's hurting women, I'll be at the forefront." ■

The watchdog gets some teeth

By Rick Schmitt

For years, the Food and Drug Administration has been the agency in Washington that consumer advocates love to hate, attacked and reviled for failing to protect the public against dangerous drugs and medical devices, and threats against the food supply.

But now, at least in the case of one of its most hotly debated responsibilities, the FDA may be in the early stages of shedding its paper tiger image.

The cautious optimism among public health and consumer law experts, stems from a recall that the FDA triggered this spring against the makers of a popular line of weight-loss products sold under the Hydroxycut brand.

The case was built in part on examples of side-effects and other health issues that the manufacturer, Iovate Health Sciences, had disclosed to the agency under a new federal reporting law, including the case of a 20-year-old man who died after taking the company's pills. Iovate disclosed the death case to the agency earlier this year before the recall was official.

Relying on another section of the new law, the FDA was also able to conduct an inspection of company records that led to the discovery of hundreds of other cases of health problems associated with Hydroxycut that Iovate had not previously reported to the agency.

FDA officials declined to say how those findings influenced their decision to press for the recall. Iovate officials told the FDA that they did not believe those unreported cases – totaling more than 2,100 between December 2007 and March 2009 – were "serious."

Photo by Lori Shepler calishep@yahoo.com

An Iovate spokesperson declined to comment. The company has previously said that it believed the concerns over its products were overblown, and that it agreed to the recall "out of an abundance of caution and because consumer safety is our top priority."

The case is the most high-profile against a supplement maker since a nationwide flap over the stimulant ephedra, and appears to signal a new aggressiveness on the part of the FDA.

Some legal and public health experts said the early action by the agency in the Hydroxycut case may have headed off the possibility of widespread public harm, unlike the case with ephedra, which took years to pull off the market even while it was contributing to more than 100 deaths, including the 2003 death of a top Baltimore Orioles pitching prospect.

Since January, the agency has identified more than 70 supplement brands that have been illegally spiked with prescription drugs, including seizure medications and anti-depressants. In a related case, several officials with a Georgia-based supplement maker were sentenced to federal prison in January, for importing into the U.S. illegal knockoffs of several popular prescription drugs, from a warehouse in Belize.

"It seems to me they are making up for lost time," says Paul D. Rheingold, a New York plaintiffs' attorney, who specializes in drug and medical device litigation.

Anne Andrews, an attorney in Irvine who has litigated against supplement manufacturers for years, senses a political shift under the Obama Administration.

"They have acted very quickly on early data," Andrews said. "My sense is that the FDA has looked at these products and just been agog."

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Obama is not new to the issue. As an Illinois state senator in 2003, he authored legislation banning ephedra. That effort came in the wake of the deaths of Northwestern football player Rashidi Wheeler and a 16-year-old high school football player in Illinois.

The president has promised an increase in the FDA budget to address chronic staff shortages and other problems. While not addressing supplements directly, the agency's new commissioner, Margaret Hamburg, has spoken of the need to make food safety generally a priority.

Susan Cruzan, an FDA spokesperson said the agency was not singling out supplement makers but rather responding to public health threats as they arise. At the same time, some agency officials have acknowledged that they have benefited from new powers from Congress.

"I think given our new authority we're able to collect information much more quickly and to act more quickly," Vasilios Frankos, the director of the FDA division of dietary supplements, said at the time of the Hydroxycut recall.

Dietary supplements have long been a sore point for critics of the agency because, unlike prescription drugs, they can be marketed to the public without any showing of safety or efficacy. Boosters say the approach, embodied in the Dietary Supplement Health & Education Act of 1994, enhances consumer choice.

Critics say the approach has threatened public health by putting untested, and in some cases dangerous, products readily on the market. Making matters worse has been the fact that manufacturers of the supplements have had no duty to advise the FDA of cases in which their products have hurt people.

With millions of Americans taking weight-loss products, and polls showing most believing, incorrectly, that the government had found them safe, public health experts saw a recipe for disaster.

Finally, in December 2006, Congress acted, in the wake of the decade-long battle over ephedra, during which the industry was found to have concealed deadly and widespread evidence that supplements containing the ingredient caused heart attacks and other cardiovascular problems. The new law – the Dietary Supplement and Nonprescription Drug Consumer Protection Act – became effective in December 2007, and requires supplement companies to begin reporting "serious" health problems to regulators, within 15 days after becoming aware of them. The law also gave the FDA the authority to examine the records of supplement manufacturers. It mandated that companies maintain those records for six years.

The new rules have led to a tripling of the number of adverse health reports received by the agency, the Government Accountability Office found this January. For regulators, that is a potentially powerful weapon, although the GAO found that the agency still lacks the resources to adequately monitor the reports.

The GAO also found that the FDA continues to be hindered from effectively protecting the public from dangerous supplements in other ways.

For one thing, supplement makers are not required to disclose all the ingredients in their products; they are deemed "proprietary," like the closely held trade secret for Coca-Cola. But that makes it hard to isolate harms when regulators suspect supplements are causing medical problems.

In the Hydroxycut case, for example, the FDA was unable to pinpoint which ingredient was causing harm to the public so it pressed for a recall of the whole line of products. But that has left the company free to reformulate the product, without having to tell the FDA about what new ingredients were put in or old ones taken out.

Iovate pulled 14 products, marketed with such names as "Hydroxycut Hardcore" and "Hydroxycut Max Aqua Shed." But since the recall it has come out with another line based on "new" and "advanced" formulas. Like other weight-loss products, they promise to boost your metabolism, and like others, often include caffeine as a key ingredient.

Some experts say consumers could still be at risk.

"The recall was a good first step. But it is product specific rather than ingredient specific," said Ano Lobb, a public health consultant in Barre, Vt. "The fear I have is that it sends the message that this harm has now been resolved and taken care of."

The FDA told Iovate in April that it should conduct a "rigorous safety review" if it intended to use any of the old ingredients in the new products, and to share the evaluation with the FDA. The company declined to say whether it had given the requested information to the regulator.

Indeed, while saying the FDA has made progress, some say it is way too early to conclude whether any changes are anything but incremental, at best.

Without some sort of pre-market approval process, they say, the current system covering diet supplements makes guinea pigs out of unwitting consumers.

"Given the scant resources they have, and given the scant legal authority they have, I am not sure doing something once every three or four years raises any evidence they are being more aggressive," said Sidney M. Wolfe, the founder and director of the Health Research Group arm of the Washington advocacy group Public Citizen, and a long-time FDA critic. "They are picking their way at it, very slowly and minimally."

Hydroxycut made a name for itself, and its corporate owners, during the heyday of ephedra.

A profile of the company in the National Post in 2006 said it grossed as much as $350 million a year, and made a multimillionaire out of its 30-something owner, Paul Gardiner, a body building enthusiast who used to pose in company ads. A 2005 Los Angeles Times article reported that the firm spent $10 million a year on advertising and marketing, including TV spots and placement with such retailers as Wal-Mart and GNC.

Andrews said the firm was one of the few companies that aggressively sold ephedra-based products right up until the FDA banned the substance in 2004. Then known as MuscleTech Research and Development, the company sought bankruptcy-law protection after it was hit with a number of personal injury lawsuits by people who had gotten sick taking its pills.

According to the National Post, MuscleTech reformulated itself, transferring most of its assets to Iovate Health Sciences, which is now based in Ontario, Can., and which continues to use the MuscleTech brand on some of its products.

Today, Iovate, which is privately owned, distributes 750 different weight-loss and muscle-building products, and operates in 70 countries, the company says. It touts Hydroxycut as "America's No. 1 weight-loss supplement." It sold about nine million packages in 2008.

In announcing the recall, the FDA cited a risk of severe liver injury associated with the pills, based on evidence it found in reports to the agency, medical journals and discussions with leading liver specialists.

Besides the one death, the pills were associated with at least one liver transplant, and other acute liver injuries. Several of the injured were members of the U.S. military including a soldier deployed to Iraq.

Officials said it had identified other conditions associated with the supplements, including people who had suffered seizures and cardiovascular disorders. Among others, an otherwise healthy woman contracted hepatitis, while taking six Hydroxycut pills a day in preparation for a body-building competition.

A flurry of lawsuits has followed. A Wisconsin man has sued Iovate claiming that he developed necrosis of the liver after taking Hydroxycut for three weeks.

Andrews says she has been retained by a former Army sergeant in Germany who had an acute form of heat stroke and was subsequently discharged after taking Hydroxycut.

Several lawsuits seeking class action status have also been filed, including one in Los Angeles accusing Iovate and Hydroxycut of fraud and misrepresenting the safety and effectiveness of their products.

"My whole body was cramping," says Tony Noyola, 23, who took Hydroxycut for a few days, and ended up in the hospital for a week. "It started in my legs and then started gradually moving up into my upper body." His urine turned brown. Eventually, Noyola says he was diagnosed with rhabdomyolysis, a condition that involves the breakdown of muscles, more often found in victims of earthquakes and bombings.

But the relatively early intervention by the FDA suggests it may not turn out to be the public health catastrophe that some had originally foreseen. Lawyers said many people who took Hydroxycut and got sick appear to have recovered once they stopped taking the supplements.

That stands in sharp contrast to ephedra where lawsuits and injuries proliferated while the industry and government battled over whether the stimulant was truly dangerous.

This new dynamic could be good for public health.

"This time around, the FDA acted obviously much quicker than the former FDA did in the days of ephedra. They wanted to eliminate the risk sooner rather than later," says Tom Anapol, a plaintiffs' attorney in Philadelphia. "We have a different administration now. My speculation would be that they are out in front of this."

Mark Zamora, an attorney in Atlanta, says only a small percentage of the calls he has been getting from Hydroxycut users involve people who may have been seriously injured. The majority mainly are interested in getting their money refunded, he says.

"Honestly, I think that is good. It shows that people were not severely hurt by it," he says. Zamora says he has been no fan of the FDA over the years but senses a change may be afoot. "Maybe that is a function of a new day at the FDA," he says. ■

AAJ Report

By Ingrid M. Evans

San Francisco welcomed attendees to the American Association for Justice (formerly the Association of Trial Lawyers of America) Annual Convention this past July for a full week of activities including educational seminars, meetings and numerous social events. The convention had a number of programs, including business and informational meetings on various areas of law, exhibit sponsor booths, and CLE programs with well-known speakers such as David Ball, Mark Lanier, Elizabeth Cabraser, Joe Cotchett, Tim Blood, Chris Spagnoli and Brian Kabateck to name a few. Of course, each night was capped off with multiple social networking events, a critical part of the convention and one of the best ways to meet attorneys in other jurisdictions where you may need local counsel or that may refer you a case.

On Saturday evening, we were honored to have Speaker of the House, Nancy Pelosi, address the convention attendees at the opening plenary session, followed by a private party at the newly renovated California Academy of Sciences in Golden Gate Park. Also present during the convention were Senator Barbara Boxer (CA), Congressman Bruce Braley (Iowa), Congresswoman Mary Jo Kilroy (Ohio), Senator Clair McCaskill (Missouri) and Congressman Henry Waxman (CA), among many others.

On Sunday night of the conference, Consumer Attorneys of California and the local associations throughout California welcomed over 300 attendees to the Asian Art Museum. This elegant fete was sponsored by the following law firms: Mary Alexander and Associates; Casey Gerry Schenk Francavilla Blatt & Penfield LLP; Coughlin, Stoia, Geller, Rudman & Robbins; Ernst & Mattison, APC; Girard Gibbs, LLP; Goldstein, Gellman, Melbostad, Gibson & Harris, LLP; Greene, Broillet & Wheeler LLP; Khorrami Pollard & Abir, LLP; DiMarco, Araujo & Montevideo, APC; Jones Clifford Johnson & Johnson; Robinson, Calcagnie & Robinson; Rose, Klein & Marias LLP; Schneider Wallace Cottrell Brayton Konecky, LLP and Waters Kraus Paul.

Lastly, AAJ recently created a Class Action Litigation Group which now has an active list server, a substantive newsletter, an objector database (so you can determine if objectors to your suits have objected in other lawsuits), a document repository and exceptional education, that it intends to also partner with Consumer Attorneys of CA. To join this litigation group, you must join AAJ at www.justice.org. ■

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UCI's New Law School Opens

California's first new public law school in 40 years held its first classes in August, thanks in part to the efforts of consumer attorneys Mark Robinson, Joe Dunn and Anne Andrews. They're pictured here at the dedication of the UC Irvine School of Law library August 23, the day before classes began. All three are significant donors to the school and are members of the Dean's Campaign Cabinet. Dunn is the cabinet chair, and Robinson chairs the Dean's Advisory Council.

"Without their support and their help in raising funds, we could not have opened our doors," said Dean Erwin Chemerinsky.

The school was ranked among the nation's top 20 law schools even before the first class was held, on the strength of the qualifications of its faculty and first class of students. The idea for the school was set in motion a decade ago by Dunn, then a state senator representing Orange County.

Robinson was his law partner at the time and hosted an initial meeting with the university's provost. Robinson went on to donate $1 million to the law school, while Dunn and Andrews each made a six-figure contribution. "The simple fact is the plaintiffs' trial bar was a significant player in making this dream a reality," Dunn said.