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DIETARY SUPPLEMENTS

FDA Officials Accused Of Conspiracy

A unique lawsuit has been brought against the Food and Drug Administration: It provides a basis for the Justice Department to prosecute FDA officials for knowingly causing the FDA to engage in illegal activities. The suit alleges a conspiracy among high-level FDA officials to violate a federal court order that mandated that the FDA adhere to the First Amendment as it relates to health claims on dietary supplements.

The lawsuit accuses specific FDA officials of "flagrantly violating their constitutional duties in order to effectuate an indefinite suppression of the health claims" and further alleges that "those [FDA] officers appear motivated by the illegitimate desire to protect pharmaceutical product claims from competition arising from dietary supplement products."

Further legal basis for these health claims was solidified in a Jan. 15, 1999, federal appellate court order stating that the FDA could not suppress truthful, nonmisleading commercial and scientific speech. FDA officials, the suit alleges, nevertheless continue to deny petitions seeking to disseminate scientific findings to the public. In essence, says the complaint, the FDA is ignoring the 1999 court order, which held that it could not demand conclusive proof—but only "significant scientific agreement"—in order to approve a health claim for a supplement. (See article on Page 4 on lawsuits involving diet supplements.)

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FIFRA

Calif. Supreme Court Repudiates Federal Gov't Position on Pesticide Tort Preemption

By Lawrence S. Ebner

In *Etcheverry v. Tri-Ag Service Inc.*, 993 P.2d 366, 93 Cal. Rptr. 2d 36 (Calif. March 2), the defendants confronted a daunting challenge: convincing the nationally influential Supreme Court of California that a federal statute preempts state law product liability claims, when despite a multitude of favorable cases, the United States, as amicus curiae, suddenly and emphatically disagrees.

The issue presented was whether the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y (1998), preempts failure-to-warn claims in pesticide-related damages suits. Joining "the overwhelming majority of the courts that have considered this question," the court answered affirmatively in a carefully reasoned decision that focuses on the language and intent of FIFRA's preemption provision, 7 U.S.C. § 136v(b). *Etcheverry*, 93 Cal. Rptr. 2d at 37. (Under the court's rules, the decision should become "final" in May.) Most important, four of the court's seven justices, joined by a fifth justice in a separate opinion, squarely rejected the federal government's contention—which it advocated orally before the court, as well as in a lengthy amicus brief—that FIFRA does not preempt tort claims, including those in agricultural crop damage suits. Two justices disagreed.

For a background on FIFRA and *Etcheverry*, see the sidebar on Page 3.

The Government's Belated Litigation Position

Prior to 1996, the government properly refrained from taking any position on the rapidly growing body of FIFRA preemption case law, which applies to personal injury as well as crop damange and other property damage claims. As a result of lobbying by antipesticide advocacy groups and certain California trial lawyers, however, in June 1996 EPA issued Pesticide Registra-

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tion (PR) Notice 96-4. This informal "guidance" document, authored by EPA's Office of General Counsel, asserted that courts that had found FIFRA preemption in crop damage suits, such as the U.S. Court of Appeals for the Ninth Circuit in *Taylor AG Industries v. Pure-Gro*, 54 F.3d 555 (9th Cir. 1995), suffered from a "misunderstanding" regarding EPA's supposedly minimal role in regulating labeling to prevent crop damage due to a product's lack of efficacy in controlling pests.

The PR notice's failure to stem the tide of FIFRA preemption decisions in crop damage cases apparently led EPA's Office of General Counsel to formally request the Environment and Natural Resources Division of the U.S. Department of Justice to file an amicus curiae brief on behalf of the United States in *Etcheverry*. Before it could do so, however, the Environment Division had to obtain the solicitor general's approval. See 28 CFR § 0.20(c) (1999) (providing that the solicitor general shall determine whether an amicus curiae brief will be filed by the government in any appellate court).

Industry attorneys were able to obtain a meeting with the deputy solicitor general to try to dissuade him from authorizing an antipreemption brief. He and his colleagues, along with representatives of EPA's Office of General Counsel, listened to industry's reasons why the government's position, if any, should be in favor of preemption, which is essential for maintaining the national labeling uniformity mandated by Congress. The industry attorneys pointed out that in *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 598, 615 (1991) (holding that FIFRA does not preempt local governments from regulating pesticide use), the solicitor general had filed an amicus curiae brief arguing that "[t]o be sure, an exclusively federal approach is necessary in certain areas of pesticide regulation [and] *[o]ne such area is labeling*" (emphasis added). Nevertheless, the solicitor general's office approved the filing of an antipreemption amicus curiae brief in *Etcheverry*. Several additional amicus briefs were filed, both for

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and against preemption.

Surprisingly, the government's brief went much further than arguing, albeit erroneously, that FIFRA does not preempt failure-to-warn claims in crop damage suits. Instead, the brief took the extreme position that virtually the entire body of FIFRA preemption case law is wrong, and that FIFRA does not preempt state common law damages claims at all. Under the court's rules, the defendants were able to file a brief responding in detail to each of the government's numerous arguments, which were also addressed at the hearing before the court. In its decision, the court adopted much of the defendants' reasoning and sharply criticized the government's position.

The Court's Opinion

The court's majority opinion, authored by Justice Janice Brown, methodically dismantled all the government's major points. The opinion observed that "[e]ven though the question presented in this case has been addressed by nine of the federal circuit courts of appeals, the United States failed to file amicus curiae briefs in any of the cases and permitted those courts to proceed upon a fundamental assumption that it now characterizes as mistaken." *Etcheverry*, 93 Cal. Rptr. 2d at 44. Rebuffing the government's wholesale attempt to write off FIFRA preemption jurisprudence, the opinion explained that "where the decisions of the lower federal courts on a federal question are 'both numerous and consistent,' we should hesitate to reject their authority," and then found that "[t]he federal court decisions holding that FIFRA preempts state law failure-to-warn claims are numerous, consistent, pragmatic and powerfully reasoned." *Id.* at 38 (quoting *Conrad v. Bank of America*, 45 Cal. App. 4th 133, 150 (1996)). Further, the opinion found, "holding that such actions are preempted by FIFRA promotes federalism, rather than undermines it." *Id.* at 37.

Background: FIFRA and *Etcheverry*

FIFRA, the comprehensive federal pesticide regulatory statute, is administered by the U.S. Environmental Protection Agency (EPA). Every pesticide product sold in the United States (e.g., insecticides, herbicides, antimicrobials, repellents) must be registered under FIFRA and accompanied by EPA-approved product labeling. See 7 U.S.C. § 136a. Labeling must contain warnings, directions for use and other information adequate to prevent "unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(C). The term "environment" encompasses air, water, land, plants (including agricultural crops), animals and people. *Id.* § 136(j).

Sec. 136v(b) of FIFRA, titled "Uniformity," declares that a state "shall not impose or continue in effect *any requirements* for labeling or packaging *in addition to or different from* those required under [FIFRA]." 7 U.S.C. § 136v(b) (emphasis added). In effect, this preemption provision vests *EPA alone* with authority to regulate the content of pesticide labeling, including warnings. See *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 598, 615 (1991) (pesticide labeling "fall[s] within an area that FIFRA's 'program' pre-empts").

In *Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 520-21 (1992), the landmark preemption decision involving smoking-related product liability claims, the U.S. Supreme Court held that a federal statute expressly preempting state-imposed "requirement[s]" encompasses requirements imposed by common law claims. An enormous body of federal and state case law holds in light of *Cipollone* that § 136v(b) of FIFRA expressly preempts failure-to-warn claims, and any other state law cause of action, that would have the effect of imposing state law "adequate" labeling requirements that are "in addition to or different from" EPA's requirements under FIFRA. The courts recognizing this FIFRA preemption principle, which applies both in personal injury and property damage suits, include every federal court of appeals and every state supreme court that has considered the issue since *Cipollone*.

Etcheverry is the first California Supreme Court case to address the subject. The plaintiffs, California walnut growers, alleged that their 1993 crop was damaged due to phytotoxicity because they applied a mixture of two insecticides that were distributed with EPA-approved product labeling that did not warn against combining the products. They sued the manufacturer (Bayer Corp.), the retail supplier (Tri-Ag Service) and a state-licensed pest control adviser employed by the supplier (Paul Osterlie). Their state law causes of action included negligence, negligence per se, product liability, breach of implied warranty, misrepresentation, strict liability for ultrahazardous activity, and trespass.

The defendants moved for summary judgment, arguing that all the plaintiffs' causes of action in effect challenged the adequacy of the warnings on the products' EPA-approved labeling, and thus were preempted. The trial court agreed and dismissed the suit. On appeal, the California Court of Appeal, Third Appellate District, reversed in a 2-1 decision, holding, despite all the case law to the contrary, that § 136v(b) does not preempt tort claims. The Supreme Court of California granted review, thereby providing a highly visible forum for the federal government to advocate—for the first time in any court—its position on FIFRA preemption of tort claims.

— Lawrence S. Ebner

One of the government's principal arguments—that state law claims for inadequate labeling or warnings do not impose "requirements," and hence are not preempted by § 136v(b) of FIFRA—mimicked the conclusion in an old, pre-*Cipollone* case, *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984). The court's majority opinion explained, however, that "[r]eliance upon *Ferebee* is misplaced because it is no longer good law…[its] fundamental thesis…has been rejected by the federal courts since *Cipollone* as 'sophistry' and 'silly.'" *Etcheverry*, 93 Cal. Rptr. 2d at 42.

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The opinion also rejected another major argument raised by the government—that *Medtronic Inc. v. Lohr,* 518 U.S. 470 (1996), a medical device preemption case, erodes FIFRA preemption case law relying on *Cipollone.* As the *Etcheverry* opinion explains, "*Medtronic* does not undermine the conclusion that FIFRA preempts state failure-to-warn claims....*Medtronic* is distinguishable on the ground Congress gave the federal Food and Drug Administration a unique role in determining the scope of preemption under the [federal medical device statute]....Congress did not give EPA an analogous role in implementing FIFRA." *Etcheverry,* 93 Cal. Rptr. 2d at 43, 44.

In addition, the majority opinion extensively criticized the government's fall-back position that FIFRA preemption of tort claims does not extend to crop damage suits. The court explained that PR Notice 96-4 notwithstanding, EPA does regulate labeling to prevent crop damage when and if problems develop. See *id.* at 44-47. Further, under FIFRA § 136v(a), a state can prohibit or restrict use of a pesticide that it determines causes crop damage. As the court cautioned, "[t]his does not mean, however, that the regulation may be accomplished through the back door by means of tort suits that effectively require changes in EPA-approved labeling." *Id.* at 47.

Court Rejects Government's Position

The court's ruling in *Etcheverry* is a resounding repudiation of the Justice Department's attempt, initiated at the request of EPA, to influence the outcome of private product liability litigation involving pesticides. Moreover, it is an excellent example of why appellate courts owe no special deference to a federal agency's advocacy views regarding the scope of a statutory preemption provision that Congress gave the agency no authority to implement or interpret.

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PREVENTION

Dietary Supplement Makers, Sellers: Guard Against an Increase in Liability Suits

By Ray Aragon, Will O'Brien and Suzan Onel

When the Phoenix Suns' starting forward Tom Gugliotta suffered near-fatal seizures in December and blamed it on a dietary supplement he took to help him sleep, yet another manufacturer seemed on the brink of a multimillion-dollar product liability lawsuit. Mr. Gugliotta claimed he did not know the extent of the risks of taking this supplement, which contains gamma butyrolactone (GBL) and is sold in health food stores under different brand names.

This was just one more example in a long line of incidents with dietary supplements. In the past few years, the industry has boomed, but this growth has been tempered by a slew of recent claims that these products have caused injury and death. Furthermore, given that supplement companies now rake in more than an estimated $13 billion annually,[1] it comes as no surprise that aggressive lawyers have filed huge lawsuits claiming that makers and sellers of supplements overpromoted their products, failed to warn of their dangers and failed to test their products before putting them on the market.

Unfortunately, fighting these lawsuits may be more difficult for supplement makers and sellers than for prescription pharmaceutical manufacturers, because the typical defenses used by the pharmaceutical companies against negligence claims may not apply. For instance, the "learned intermediary" defense—which, in many jurisdictions, protects a manufacturer from liability when a trained professional, such as a doctor, prescribes a drug—may not be available when people self-administer over-the-counter dietary supplements. Moreover, people taking supplements may not disclose this fact to their doctors, creating a risk of drug-supplement interactions. Complicating matters, the Food and Drug Administration (FDA) has not actively regulated dietary supplements and has provided little practical guidance on what constitutes a "dietary supplement" as distinguished from an unapproved drug, or what warnings and claims are appropriate for these products. This has been good for sales, but has left many manufacturers and sellers in the dark about what claims to make or warnings to issue. The lack of regulation also makes it hard for supplement manufacturers to assert regulatory compliance defenses. As a result, many companies are essentially unprotected from lawsuits alleging failure to warn.

This situation may only grow more complex: On Jan. 6, the FDA surprised consumer and industry groups alike by issuing regulations that effectively allow dietary supplement manufacturers to make broader claims about the health benefits of their products. 21 CFR § 101.93. Again, while this may be good for sales, it also invites more lawsuits against manufacturers that push the envelope too far when making health benefit claims. Moreover, in spite of its new rule, FDA continues to challenge companies it believes are making unwarranted product claims. Thus, before rushing to promote new uses or make new claims, supplement makers and sellers should take care to

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