

## COVINGTON &amp; BURLING

1201 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004-2401  
TEL 202.662.6000  
FAX 202.662.6291  
WWW.COV.COM

WASHINGTON  
NEW YORK  
SAN FRANCISCO  
LONDON  
BRUSSELS

August 12, 2004

Daniel E. Troy, Esq.  
Chief Counsel  
Food & Drug Administration  
5600 Fishers Lane  
Room 605  
Rockville, MD 20850

Re: California Proposition 65 Warnings on Canned Tuna

Dear Mr. Troy:

As you are aware, the Attorney General of the State of California has filed suit under that state's Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") against distributors of canned and packaged tuna, alleging that they failed to warn consumers that these products expose them to chemicals (mercury, mercury compounds, methyl mercury and methylmercury compounds) known to the state to cause birth defects or reproductive harm. The state seeks injunctive relief as well as civil penalties.

As we discussed, I am submitting the attached memorandum, which describes in detail our conclusion that a Proposition 65-compliant warning on canned tuna would be preempted by federal law, provided that FDA's Acting Commissioner issues an appropriately-worded letter to California officials expressing the agency's preemptive intent.

We believe a Proposition 65 warning would be preempted on three grounds. First, such warnings on canned tuna would be misleading in light of the recently revised joint FDA/EPA consumer advisory entitled "What You Need to Know About Mercury in Fish and Shellfish" ("Consumer Advisory"), because such warnings would considerably overstate the risk of eating canned tuna while failing to state the substantial health benefits of tuna consumption. Such warnings would therefore render the tuna misbranded under sections 403(a) and 201(n) of the Federal Food, Drug and Cosmetic Act (FDCA). Consequently, it would be impossible for tuna manufacturers to comply with both federal and state labeling law.

Second, Proposition 65 warnings on tuna would frustrate the federal objectives of the carefully-considered Consumer Advisory, which is expressly intended to encourage consumption of healthful amounts of canned tuna and other beneficial fish so that the population to which the Advisory is addressed will receive the benefits of fish consumption while minimizing any risk. Third, FDA has the authority to require mercury warnings on tuna but chose not to do so and has

DC: 1498044-2

COVINGTON & BURLING

Daniel E. Troy, Esq.  
August 12, 2004  
Page 2

determined that no such warnings are appropriate. Accordingly, Proposition 65 warnings on tuna should be deemed preempted under the doctrine of negative preemption.

While the above-mentioned statutory provisions and expressions of federal policy, standing alone, are likely to be held insufficient to preempt state law on this subject, FDA could assert its authority and intent to preempt state-imposed warnings for mercury in tuna in a manner that a court would likely accept and defer to the agency's determination of preemption. Accordingly, we urge FDA to present such an expression of preemptive intent in a letter from the Acting Commissioner to appropriate California officials responsible for administering Proposition 65.

We would be happy to meet with you to discuss this matter in greater detail.

Sincerely,

Clausen Ely, Jr.

Attachment