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August 14, 2001

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RQ-0414-08

OPINION COMMITTEE

The Honorable John Cornyn
Attorney General of Texas
Attn: Ms. Susan Gusky
Chair, Opinion Committee
P.O. Box 12548
Capitol Station
Austin, TX 78711-2548

FILE # ML-42100-01
I.D. # 42100

Re: Request for Attorney General Opinion

Question Presented: Does the Texas Department of Health exceed its statutory and regulatory authority in mandating the use of a federal reporting system, which system was not operationally designed or intended by United States Congress or the Texas Legislature for use by or for state agencies, state purposes or state consumers?

Dear General Cornyn,

The Texas Department of Health (TDH), in a rule with the effective date of September 1, 2001, mandates that all dietary supplements sold in Texas that contain ephedrine alkaloids include the toll-free Federal Drug Administration's (FDA) "MedWatch" number on the label (TDH Rule 229.462 Product Labels for Dietary Supplements Containing Ephedrine) (hereinafter, "TDH Rule").

The toll-free FDA "MedWatch" number is intended to be part of the FDA's Special Nutritionals Adverse Events Monitoring System. Upon information and belief, the FDA designed and represents the toll-free number as a resource for health professionals, principally doctors and pharmacists. The legislative history and limited purpose of the FDA "MedWatch" System and its inability to respond to this unauthorized state mandate are well documented. In the case of ephedrine, appropriate utilization of the toll-free number is clearly intended for health professionals. Since that time, Congressional and General Accounting Office reports confirm no expansion in the FDA "MedWatch's" mission, capabilities, or funding.

Clearly, the mandate by the TDH will encourage consumers to utilize a federal toll-free number in a fashion that is not part of its current public purpose. In the absence of an FDA directive enabling a state agency to utilize its federal resource, and in light of Congressional and legislative intent to the contrary, I welcome your Opinion concerning what appears to be an unlawful exercise of a state agency's limited rulemaking authority.

The Honorable John Cornyn
Attorney General of Texas
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Should additional information be needed from my staff or me, please do not hesitate to call.

Sincerely,

A handwritten signature in black ink that reads "David Cain". The signature is written in a cursive, slightly slanted style.

David Cain
Chair, Senate Committee on Administration

cc: Mr. Don Gilbert, Commissioner of Health, Texas Department of Health

DHC/ir