What effect this letter will have on the officials of California remains to be seen. If California denies all exemption petitions, relief, if any, will come in the form of Interpretive Guidelines and eventually regulations exempting a limited number of substances from Proposition 65 warning requirements.

2. Preemption Petitions

Petitions have been filed with FDA by many of the above-named affiliates and the National Food Processors Association asking that a regulation be implemented preempting California and other states from adopting Proposition 65-type warning requirements. First approaches to FDA on preemption were made in April, 1987.

FDA officials have indicated informally that, because of the Administration's strong views on federalism and state's rights, formal preemption by regulation would be difficult to obtain.

The FDA officials who are sympathetic with preemption efforts have stated that, at best, industry can expect an "incremental approach" to dealing with Proposition 65 by the federal government. The first step in that approach appears to have occurred through the previously mentioned August 28 letter from FDA Commissioner Young to Governor Deukmejian urging California to determine that FDA-regulated products pose no significant risk because of the comprehensive federal regulatory scheme governing safety and warnings. The FDA letter, while useful, does not necessarily mean an FDA preemption regulation is any closer, and, in fact, FDA may now feel that it has done all it can do without a strong signal from the highest levels of the Administration that formal preemption is necessary. No formal action has yet been taken by FDA on any of the preemption petitions.

It is necessary, therefore, that CLU affiliates and their member companies redouble their efforts to obtain federal preemption. To date, we have had numerous meetings with officials at FDA, HHS and OMB and have met with several Congressmen and Senators to seek their help in encouraging the Administration to move on this issue. At least two Senators and several Congressmen have urged FDA/HHS to preempt, and in slightly different terms the

MCO 7647202

member company. CLU should encourage each affiliate to undertake programs to educate its members on the requirements of Proposition 65 so that appropriate steps can be taken if no relief is obtained.

III.
LITIGATION CHALLENGING THE CONSTITUTIONALITY OF PROPOSITION 65

We believe that industry can seriously undermine its formal and informal efforts to obtain preemption through an uncoordinated approach to litigation and, particularly, through the filing of untimely or premature lawsuits. The filing of a preemption lawsuit will give federal agencies an excuse to defer their consideration of the preemption issue, and may deprive us of our strongest case -- a suit filed on the basis of explicit preemption by FDA through a preemption regulation. We, therefore, urge that very careful consideration be given to these factors before any such suit is filed. However, efforts should begin immediately to explore the best approach for filing such lawsuits so that industry is in a position to move quickly at such time that it appears our other efforts to obtain preemption are unlikely to be successful within a sufficient period of time. Timing is extremely critical because of the need to be in compliance with product warning requirements in the State of California on February 27, 1988 or to have the time necessary to obtain a court stay of that effective date.

We recommend that CLU continue to serve as the umbrella industry group for information exchange and assisting in coordination of legal strategies as we approach possible litigation. Although affiliates must obviously do their own preparation as they see fit, there are several economies that can be obtained through coordinated preparation. Such coordination will not in any way restrict the ultimate litigation options of any individual affiliate.

The following is a brief summary in question and answer form of the procedural and substantive issues which must be answered prior to structuring a lawsuit to challenge Proposition 65. Preliminarily, the Legal Committee points out that the process of preparing for litigation must begin immediately. If one accepts that litigation is inevitable, much work will have to be

MCO 7647203

about $500,000 should be created, with a provision that any excess will be refunded pro rata to contributors. It does not appear that trade associations would directly be able to contribute this amount. Therefore the Legal Committee recommends that the major firms in an industry which intends to participate in the lawsuit (e.g., the food industry) should be solicited on as broad a base as possible. Contributions could be solicited on the basis of the total relevant sales of each company so that a company which is a member of several trade associations will still make only one contribution. It is hoped that no company would have to contribute more than $10,000.

7. To whom should the contributions be paid? Any existing CLU affiliate, or CLU itself, could establish a separate bank account for this purpose. If the fund were established for CLU as a whole, some trade associations might feel that they would have to withdraw from CLU since they might not wish to participate in a CLU (or part of CLU) lawsuit. Therefore, the Legal Committee recommends the incorporation of a separate subgroup within CLU, e.g., a CLU Litigation Committee, for this purpose. Checks could be made payable to that group and funds dispensed by that Committee pursuant to prescribed rules. That Committee would be charged with responsibility for selecting counsel, supervising the litigation, etc.

8. How should public relations concerning the litigation be handled? Outstanding public relations expertise is available to CLU through its CLU affiliates. The Legal Committee recommends the establishment of a CLU Public Relations Committee to manage any public relations effort which may be necessary as the result of the initiation of litigation.

IV.
LEGAL ISSUES ON WHICH TO BASE LITIGATION

While enunciation and amplification of the legal issues must await the complaint and memorandum, it now appears that the legal challenge to Proposition 65 might be based on both federal and state constitutional grounds:

1. Potential Bases for Federal Constitutional Challenge:

MCO 7647204

Further investigation may develop additional arguments.

Constitutional challenges to other state labeling requirements in recent years have been successful. General Foods v. Priddle, 569 F. Supp. 1378 (D. Kan. 1983); Grocery Manufacturers of America v. Geraca, 581 F. Supp. 658 (S.D.N.Y. 1984), aff'd in part, rev'd in part, 755 F.2d 993 (2d Cir. 1985), cert. denied, 88 L. Ed.2d 29 (1986); Committee for Accurate Labeling and Marketing v. Jacka, Civil Action No. 86-4296-R (D. Kan. July 9, 1987); Cosmetic, Toiletry & Fragrance Assn. v. Minnesota, 440 F. Supp. 1216 (D. Minn. 1977); American Meat Institute v. Ball, 550 F. Supp. 285 (W.D. Mich. 1982), aff'd on other grounds, 724 F.2d 45 (6th Cir. 1984).

Some or all of the arguments in these cases can also be presented in the Proposition 65 case, but the factual situation may make some arguments stronger and others weaker. Nevertheless, all should be made to give the court a number of options, any one of which would be sufficient to rule Proposition 65 unconstitutional.

V.
SUMMARY

The CLU Legal Committee has been following the developments on Proposition 65 very closely. Efforts by individual affiliate associations at obtaining exemption from coverage of Proposition 65 continue as do efforts on the part of CLU to obtain federal preemption. As time passes, however, it becomes increasingly imperative to consider other options. The Legal Committee recommends that: (1) preparation for litigation begin immediately; (2) a lawsuit not be filed until it becomes clear that efforts for federal preemption have failed; (3) a vehicle be established for companies wishing to join in a unified action; and (4) an equitable funding system be established to support this vehicle. This will allow other affiliates and their member companies to continue to participate in CLU activities and to pursue litigation on their own if they so choose.

Questions concerning this memorandum can be addressed to any member of the Legal Committee (an open committee whose meetings have been attended by lawyers

MCO 7647205