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October 13, 1987

Roy T. Gottesman
The Vinyl Institute
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Wayne, NJ 07470

Dear Roy:

Following up on my telephone conversation with Meredith this morning, enclosed herewith is a copy of the Resolution passed by the Polymeric Materials Producers Division at its meeting at Palm Beach, Florida, last week. You might pay special attention to the footnote. Incidentally, I wrote this Resolution at Tom Bohrer's request after I told the PMPD Executive Committee about the Proposition 65 situation.

Also enclosed so that you will be able to see what set the stage for unanimous adoption of the Resolution at the PMPD Plenary Session is a copy of the talk I gave entitled "Proposition 65 and Its Fall Out: How Far Do We Go with States Rights?"

Please give me a call after you look this material over so we can talk about it in terms of the Vinyl Institute and protection of its interests.

With warmest personal regards,

Cordially yours,



Jerome H. Heckman

Enclosures

cc: (w/encl.)
Thomas C. Bohrer
Charles E. O'Connell
Lewis R. Freeman, Jr.
Meredith Scheck

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WHEREAS, it is clear that California's Proposition 65 presents a serious threat that all consumer goods may have to be labelled with severe warnings if they or their packaging contain a chemical listed by California as a carcinogen or reproductive toxin,

AND WHEREAS it has been made known to us that the food industry, among others, is planning litigation to challenge the California law if the Proposition 65 warning provisions are not deemed preempted by the Federal Government promptly (within the next 60 days),

AND WHEREAS it is clear that unless the warning requirements are preempted, they will impact severely on the suppliers of packaging materials components, including especially polymers, since users of packaging are likely to demand excessive warranties or hold harmless clauses from their suppliers, including all of those who supply packaging components.

NOW THEREFORE BE IT RESOLVED that the Polymeric Materials Producers Division shall, if advised to do so by SPI's President and General Counsel, make \$10,000 available to support a suit filed by a suitably constituted and representative food industry litigation group, and will further support a complementary SPI or packaging industry suit with funding of up to \$50,000.

*/ This amount may and should be reduced by contributions from the Vinyl Institute, the American Paper Institute, and any other similar packaging industry organization.

PROPOSITION 65 AND ITS FALL OUT: HOW FAR
DO WE GO WITH STATES RIGHTS?

by

Jerome H. Heckman
Keller and Heckman
Washington, D.C.* /

Two hundred years ago, this country's Revolutionary leaders gathered to consider how the newly united states should be governed. The charter they ultimately created, the Constitution, was the subject of long and sometimes rancorous debate pitting Madison, Hamilton and Washington against such patriots as Patrick Henry and Sam Adams.

The controversy centered on the need to strike a balance between the sovereignty of the several states and those powers which must necessarily be conferred upon the federal government for the good of the nation as a whole. The strategy of Hamilton and Madison was to use the cool reasoning of the Federalist Papers to advocate that the affairs of the nation be managed according to the precepts of the Constitution. Adams and Henry adamantly opposed the Constitution and attempted to convince the people that they should fear any form of national government. Their warning was that adoption of any document like the Constitution could only lead to tyranny. Had the fear tactics of Adams and Henry won the day, America as we know it would not exist. In its stead we might well have 50 separate countries. In the end, however, reason prevailed and the Constitution was ratified.

Today, we are still engaged in constitutional debate on the question of national interests versus states rights. Now, the repercussions are being felt in such diverse areas as airline advertising, insurance risk retention, product safety, labeling and general product liability, right-to-know laws, and the management of solid waste. Paradoxically, the fear tactics are being used by those who arrogate to themselves the title of "federalists"; thus far, reason is taking a back seat because there are few willing to speak out against them.

* / This paper was prepared for presentation to the Polymeric Materials Producers Division of the Society of the Plastics Industry, Inc., on October 8, 1987 in Palm Beach, Florida.

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My intuition is that if Madison and Hamilton were alive today the debate would be taking a different course. Those who cite them for support might well be called the devils who cite the Scripture. The same penchant for reason that led them to advocate a system of government that carefully preserves the rights and liberties of the states would, I feel sure, compel them to recognize that, in today's world of national and international commerce, it does not make sense to have 50 different labeling laws and 50 different standards for product safety, or liability. My notion is that these men of reason would be the first to see that what worked for 13 states trading raw agricultural commodities such as tobacco, cotton and molasses, could completely disable the 20th Century marketplace. Where a vast array of finished manufactured goods moves between 50 states on a scale undreamed of 200 years ago, it is incredible to think that Madison and Hamilton would say "let's do it like we did in 1787."

Thus, it is ironic that the torchbearers of the new federalism have doggedly pledged their allegiance to such anti-commerce absurdities as California's Proposition 65. That they do so in the name of "states' rights" is especially painful. For in so doing they are not echoing the common sense of the first federalists, whom they never fail to cite, but rather the fear tactics of Adams and Henry. If a states' rights movement run amok is the disease, then its most prominent symptom in 1987 is surely California's Proposition 65. I will, therefore, spend my time today acquainting you with Hollywood's new regulatory version of Frankenstein. Once we have met the monster, I'll tell you a few horror stories about who his likely victims will be. Then we'll look at what Proposition 65 means to you as polymer producers, what is being done about it, and what we believe we must do to try to bring the creature to bay. First, the nature of the beast and how it was brought to life.

OVERVIEW OF PROPOSITION 65

Proposition 65 was enacted by voter initiative on November 4, 1986. It is a law designed to limit the public's exposure to known carcinogens and reproductive toxins from drinking water, consumable products and other sources. Sixty-five percent of California voters cast their ballots for Proposition 65, a mandate due in no small measure to the leadership of Tom Hayden and Jane Fonda, and the support of such experienced statesmen as Barbra Streisand, Michael J. Fox, Goldie Hawn, and Tom Cruise.

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The law requires the Governor to publish a list of chemicals "known to the state to cause cancer or reproductive toxicity" and establishes two prohibitions regarding use of these chemicals. First, no person may knowingly discharge or release a listed chemical into drinking water or into or onto land where it will pass into a source of drinking water. Second, no person may knowingly expose^{1/} any individual to a listed chemical without first providing a "clear and reasonable warning" to such individual.

The range of actionable exposures extends far beyond exposure to a chemical from drinking water. Warnings also must be provided for workplace, environmental, and, most significantly, consumer product exposure of an individual to a listed chemical. For consumer product exposures to a listed carcinogen, the offending product must be accompanied by or carry on its label the following statement: "WARNING: This product contains a chemical known to the State of California to cause cancer."

The law's discharge and warning requirements may be enforced by actions for injunctive relief and civil penalties of up to \$2,500 per day for each violation. In addition to enforcement by state officials, Proposition 65 contains a bounty hunter provision that permits private citizens to bring an enforcement action if the state declines to do so. If they succeed they are entitled to 25% of any penalty recovered.

The list of chemicals subject to Proposition 65 presently stands at 81 and is likely to climb to over 200 by 1988. Acrylonitrile, vinyl chloride, benzene, epichlorohydrin, and ethylene dichloride are already on the list, with toluene diisocyanate (TDI), di(2-ethylhexyl) phthalate (DEHP), urethane and formaldehyde due to follow.

^{1/} The Act provides exemptions from the warning requirements for exposures "for which federal law governs warning in a manner that preempts state authority." However, California has given every indication that it will construe this preemption exemption very narrowly. Proposition 65 also provides an exemption for exposures that pose no significant risk. This exemption is of dubious value since the Act nowhere defines "significant risk". Furthermore, guidelines the state has issued to date on the meaning of this term are still disturbingly vague. In any enforcement action, the burden will be on the person responsible for the exposure to prove that it does not pose a significant risk.

IMPACT OF PROPOSITION 65 ON THE PACKAGING MATERIALS MANUFACTURER

What follows is a scenario of what will happen if packaging materials are regulated under Proposition 65 and the long chemical hit list that the Governor is expected to adopt. The typical seller of a food, drug, or cosmetic product, and many others as well, will first try to satisfy himself that his product does not violate the Act. Once he's done that (assuming he can) he will then turn his attention to the packaging materials he uses. In keeping with long standing habit, he will shift the compliance burden to his supplier by asking him to guarantee that there are absolutely no chemical "no-no's" in the material he is buying to package his product. Not many reliable suppliers will be able to provide such assurances, for while there is a wide variety of packaging materials available that can properly be said to be in compliance with the Federal Food, Drug, and Cosmetic Act, there are few, if any, packaging systems totally free of the chemicals on the Governor's list in California.

At this point, the packaging supplier will have several options. If asked, he could comply with a customer's request for a "hold harmless" agreement to insulate the customer from any Proposition 65 liability resulting from the presence of a "known" carcinogen or a reproductive toxin in the food package. Given the broad, ambiguous language of Proposition 65 and the way things are in California, providing such a sweeping guarantee would make about as much sense as insuring the safe passage of a canoe through the Straits of Hormuz. It is something no supplier with integrity and the resources to pay claims can do.

Alternatively, the supplier can, if he knows it, disclose the formulation of all parts of his package to his customer and attempt to convince him that the packaging material's components do not pose a significant risk. Unfortunately, even where this can be done, it is unlikely that the customer will be satisfied to rely on a "no significant risk" conclusion. This is because such a finding is not likely to forestall grotesque bounty hunter court proceedings based on the "zero presence" notion and featuring expensive line-ups of expert witnesses. In such proceedings, science will be on trial in a lay forum where reason is apt to be cast to the winds when exciting nomenclature like acrylonitrile, benzene, and vinyl chloride is tossed at California jurors.

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Finally, the supplier, also following tradition, can turn to his suppliers, the resin and adjuvants manufacturers, and request essentially the same guarantees and assurances he is being asked to provide to the consumer product producer. And where will you be? Holding this complete bag because you are the end of the line -- in most cases, you have no suppliers to turn to.

To summarize, fear of the bounty hunter will compel buyers to adopt their own zero presence standard and turn the Governor's list into a blacklist. Scientific risk assessment -- FDA style -- will be discarded and the idea that substances can only be evaluated sensibly by taking into account their intended conditions of use will be pushed aside again. Thus, in practical effect Proposition 65 will out-Delaney Delaney. The misbegotten law will disrupt the federal regulatory process, which is, with all its frailties, and they are many, marginally workable and improving slowly. In so doing, Tom and Jane will have defeated the progress FDA has made in evolving a world renowned scientific approach to the evaluation of substances.^{2/}

While no other state legislature has yet passed a Proposition 65-type bill, such proposals can be expected to proliferate in the legislatures next year. Furthermore, environmental groups are reportedly pushing for Proposition 65-type voter initiatives in many jurisdictions throughout the nation. Meanwhile, the Massachusetts legislature is considering a harsh antichemical measure (H. 4277) that would place restrictions on the use of many substances and ultimately ban certain chemicals outright. Although the bill is not expected to pass, it will probably be reincarnated as a referendum on Massachusetts ballots next year.

^{2/} For an illustration of the havoc Proposition 65 will wreak, one need look no farther than yesterday's headlines. Consider for example, this September 25 headline in the Washington Post: "Dioxin Found in Some Paper Products." The subheading says "Concentrations Reported in EPA Study Seen as No Threat to Health." But seen by whom as no threat? Not by California. Regardless of the fact that federal scientists say the dioxin levels do not pose a public health concern, or that the assistant administrator of EPA says the risks from the levels detected "get down to negligible", California's rules, as presently proposed, will go the other way. As a result, paper companies could soon be beset by a myriad of state regulatory compliance headaches over dioxin levels that federal authorities say are totally insignificant.

FEDERAL PREEMPTION OF PROPOSITION 65

So we have met the monster. The next question is what is being done to try to drive a stake through his heart. I can tell you that an unprecedented coalition of FDA-regulated industries has banded together for the sole purpose of stopping Proposition 65. I can also tell you that this group, in which SPI has taken a leading role, has worked diligently over the last six months to persuade FDA to preempt the application of Proposition 65 to FDA-regulated products, including packaging materials.

Unfortunately, I cannot tell you that our best efforts to date have been enough to slay the creature or even wound him. More must be done right now to try to stop the California law. But before considering what steps should be taken, and what you can do to aid the cause, let me bring you up to date on the uphill struggle.

On April 10, 1987 the Inter-Industry Group (IIG), an alliance of FDA-regulated industries, was formed to try to gain relief from the warning requirements of Proposition 65. The IIG was an offspring of the Food Industry Safety Committee, a coalition of food companies originally established to deal with the regulatory status of ethylene dibromide. As instructed by your President, Chuck O'Connell, we participated in that first strategy session of the IIG on behalf of SPI and have been deeply involved in the activities of the group ever since.

Up to this point, the primary focus of IIG, which was subsequently renamed the Council for Labeling Uniformity (CLU), has been on persuading the Food and Drug Administration to preempt the application of Proposition 65's warning requirements to FDA-regulated products.^{3/} This effort has taken many forms, from petitioning FDA, to lobbying the Agency's federalist overlords, to mounting a congressional letter writing campaign.

3/ SPI has also participated in efforts to persuade California to grant a categorical exemption from Proposition 65 for FDA-regulated products. On June 15, 1987 SPI submitted comments supporting a Grocery Manufacturers of America (GMA) petition seeking exemption from the warning requirements of Proposition 65 for food products and packaging already in compliance with the Federal Food, Drug, and Cosmetic Act and FDA regulations promulgated thereunder. California has repeatedly postponed a decision on the GMA exemption petition and other similar petitions. At this time it appears that denial of the petitions is all but certain.

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In April, for instance, the National Food Processors Association (NFPA), a CLU affiliate, petitioned FDA to adopt a regulation preempting state and local food warning requirements of the kind mandated by Proposition 65. On July 16, 1987, SPI filed comments supporting the NFPA petition. Our comments urged FDA to explicitly preempt Proposition 65-type warnings for food, drug, or cosmetic packaging materials used in compliance with the Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations.

Unfortunately, soon after the filing of the NFPA petition, it became clear that FDA was helpless to act on Proposition 65 because of "political concerns" -- read "states rights" -- emanating from the White House. Throughout the summer CLU worked to override these "concerns" and convince the powers that be to free FDA's hand and permit the Agency to preempt Proposition 65.

Since August, however, it has become increasingly apparent that both Congress and the Administration are unwilling to move on the preemption of Proposition 65. The sole fruit of some six months of intensive lobbying at FDA and above was a letter from Commissioner Frank Young to Governor Deukmejian. The letter, sent in late August, did not assert FDA's preemptive authority. Instead, it urged the Governor to consider exempting FDA-regulated products from Proposition 65's warning requirements. California has not responded.

So here's where we stand. FDA, Congress and the White House have all but washed their hands of the matter. California apparently has no intention of granting any categorical exemption from Proposition 65. In fact, it looks as though the state will not even have comprehensive implementing regulations which will exempt some chemicals in place by February. Meanwhile, the Governor's List continues to grow and letters from customers demanding hold harmless agreements have begun to arrive. We think it is essential that unusual measures be considered to try to prevent the application of Proposition 65 to food, drug, and cosmetic packaging materials.

In the final analysis, as always, the only avenue available to attempt to achieve the timely preemption of Proposition 65 is the courts. The CLU organization has reached the same conclusion. Various industry associations within CLU are even now preparing to challenge Proposition 65's warning requirements on constitutional grounds. The food-related associations in

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CLU, namely NFPA and the Grocery Manufacturers Association (GMA), are planning their own suit to block the warning rules. They have invited SPI and other packaging associations to participate.

My recommendation is that we first support and contribute to the food industry umbrella suit if there is one. The food companies have a strong argument that FDA's regulation of the safety and labeling of food products is comprehensive and leaves no room for state regulation such as Proposition 65. Clearly, the more closely we can link FDA regulation of packaging materials with its regulation of food, the stronger our case will be. However, it must be borne in mind that any food industry-sponsored suit will focus primarily on food product concerns. In such a suit the arguments for preemption relief for packaging materials might well get lost.

Therefore, it is my further recommendation that SPI file its own suit challenging the constitutionality of the application of Proposition 65's warning requirements to plastic food, drug, and cosmetic packaging materials. This is the only way I know of to be reasonably certain that the concerns and interests of the plastics packaging industry (30% of the polymer business) are adequately represented.

Such a suit would be based principally on the following legal theories. First, that the warning requirements of Proposition 65 are invalid and unenforceable vis-a-vis FDA-regulated packaging materials because they are inconsistent with the objectives of federal law, i.e., the Federal Food, Drug and Cosmetic (FD&C) Act. Second, that the warning requirements are preempted with regard to packaging materials because the FD&C Act and such revisions as the Food Additives Amendment of 1958 and the Color Additives Amendment of 1962 are and were intended by Congress to be a comprehensive regulatory scheme for such products. Third, that the warnings are preempted because they would apply to nationally merchandised products that need not bear such warnings in other states, thus placing an unconstitutional burden on interstate commerce.

What we would seek is a Declaratory Judgment that any warnings required under Proposition 65 are preempted if the particular product at issue can properly be said to be in compliance with the Food, Drug, and Cosmetic Act and all applicable regulations. We would also ask the Court to issue an injunction

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prohibiting enforcement of the law when the product complies with the Federal Act. Such relief would not eliminate the possibility of "bounty-hunting" lawsuits raising the issue of whether a particular product is, in fact, in compliance with federal law, but it could lead to prompt dismissal of such suits if the defendant were able to demonstrate federal compliance. This is a far easier burden for the industry than a series of full blown trials to deal with such vagaries as whether or not a given product presents a "significant risk."

The warning requirements of Proposition 65 are a cause for immediate concern and demand immediate action. However, stopping Proposition 65 per se will not lay the states rights issue to rest. As I noted at the outset, Proposition 65 and the activities it has spawned in other states are but a symptom of a disorder afflicting nearly all parts of the body politic. They are only the most flagrant examples of a trend on the part of the states to adopt measures challenging federal regulation in virtually all areas.

Adding fuel to the fire, the Reagan Administration has decided to make explicit its heretofore tacit approval of such states' rights monstrosities as Proposition 65. Later this month, the President is expected to sign an Executive Order entitled "Federalism" calling on federal agencies to defer to state standards "whenever possible." The proposed order will give further impetus to a policy already out of control.

Interestingly enough, however, even this neo-federalist set of commandments condones federal agency preemption of state law in certain special circumstances. According to a draft version of the Executive Order, federal preemption is appropriate when "there is . . . firm and palpable evidence compelling the conclusion that Congress intended preemption of State law, or when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute."4/

I submit that if ever there were a clear case of a palpable conflict between state and federal authority, Proposition 65 is it.

4/ Letter from Charles J. Cooper, Assistant Attorney General, Office of Legal Counsel, to President Reagan (September 4, 1987) transmitting proposed Executive Order entitled "Federalism."

CONCLUSION

Teddy Roosevelt, one of Ronald Reagan's personal heros, was a staunch supporter of the original Food, Drug, and Cosmetic Act. In his 1905 State of the Union address, Roosevelt urged Congress to pass the original Food, Drug, and Cosmetic Act to "protect legitimate manufacture and commerce . . . [and] secure the health and welfare of the consuming public."^{5/} During his address, Roosevelt made the point that as commerce and industry become national in scope, so too must government regulation of business activities:

"The makers of our National Constitution provided especially that the regulation of interstate commerce should come within the sphere of the General Government. The arguments in favor of their taking this stand were even then overwhelming. But they are far stronger today, in view of the enormous development of great business agencies, usually corporate in form. Experience has shown conclusively that it is useless to try to get any adequate regulation and supervision of these great corporations by State action. Such regulation and supervision can only be effectively exercised by a sovereign whose jurisdiction is coextensive with the field of work of the corporations -- that is, by the National Government."^{6/}

What was true at the dawn of the 20th Century is even more true today.

Responsible businessmen must keep an eye on the federalist movement. While it might have some wonderful features, it shouldn't be permitted to continue to make the much desired competitiveness in commerce a virtual impossibility. With due apologies to Mr. Henry: "If this be treason, make the most of it."

^{5/} Roosevelt, Fifth Annual Message, reprinted in The State of the Union Messages of the Presidents, 1790-1966, Vol. III, at 2183 (F. Israel ed. 1966).

^{6/} Id. at 2145.

SLIDES USED IN THE PRESENTATION

CTL028796

Insurance Law Needs Changes, Commerce Says

By Nancy L. Ross
Washington Post Staff Writer

A federal law designed to make liability insurance more available and more affordable "is not working as well as intended" and should be modified, according to a Commerce Department report released yesterday.

Conflicting state interpretations are at the heart of the confusion about the Risk Retention Amendments of 1986 that were passed in the wake of the 1984-85 liability crisis. During those years physicians, child care services, municipalities, truckers, waste disposal companies, midwives and corporate directors and officers were among the many for whom coverage was either unavailable or available only at premi-

ums double or triple what they had been paying.

Twenty-six states have adopted laws allowing members of these categories to form risk retention groups—self-insured pools—or to purchase group insurance, according to the report. The report counted 63 purchasing groups, 20 of which are in the health field. Six are in the recreation area, including two previously uninsured parks with large water slides.

Despite the rapid growth of these groups, the federal law is not accomplishing its intended purpose because each state interprets the law differently, the federal government said. (The insurance industry is regulated by the 50 states, not the federal government.)

The result for carriers trying to sell insurance in many states is "regulatory redundancy" and a "severe and costly paperwork burden," the report said.

For example, nurses in Fairfax lost their liability insurance coverage

See LIABILITY, C2, Col 1

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FTC Opposes Guidelines on Airline Ads

■ The Federal Trade Commission yesterday objected to proposed state guidelines for airline advertising, saying they might inhibit "effective price competition among airlines." The National Association of Attorneys General has been drafting rules governing fare advertising that are reported to include requirements for disclosure of restrictions. "We are unaware of any evidence indicating that airline fare advertising, frequent flier programs or overbooking compensation policies are generally unfair or deceptive," the FTC said.

Earlier this year, during congressional hearings, the Department of Transportation testified that some airlines had advertised fares that were not available, but that the department had been able to get the airlines to correct such ads.

PANEL RECOMMENDS 34 COMPOUND
TO BE ADDED TO PROPOSITION 65 LIST

stars storm governor's office

The Yes on 65 campaign

An inside look at how Hollywood beat Big Oil

JUDGE ORDERS CALIFORNIA GOVERNOR TO EXPAND
LIST OF CHEMICALS SUBJECT TO PROPOSITION 65

The people have spoken:
It's time to get tough
on toxics.

Proposition 65 May Spread
to Other States

Pennsylvania Debates Solid Waste Recycling

CTL028798

Reagan Weighs Trimming U.S. Role on Standards

Raising a potential preemption battle
NE STATES PROPOSE VOLATILITY PROGRAM MORE STRINGENT THAN EPA PLAN

From USA Today

Stars storm governor's office

Hollywood won't get off the California clean-water bandwagon.

Jane Fonda, Jeff Bridges and Veronica Hamel joined a delegation of angry celebrities Monday in Sacramento, Calif., seeking a meeting with Gov. George Deukmejian.

The stars — who were unable to get an audience with the governor — are upset about his reaction to Proposition 65, a toxic-waste cleanup law spearheaded by state legislator Tom Hayden and passed by voters in November.

The law requires that the governor publish a list of toxic chemicals to be banned from drinking water. But Deukmejian's list includes only 29 chemicals, not the 250 experts

warn about, say the stars, who also included Donna Mills, Ed Begley Jr., Demi Moore, Hart Bochner and Stephen Bishop.

The group presented a letter signed by more than 200 other stars, including Michael J. Fox, Tom Cruise, Barbra Streisand, Bruce Willis, John Forsythe, Gregory Peck, Chevy Chase, Linda Evans, Victoria Principal and Goldie Hawn.

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PROPOSITION 65

No person in the course of doing business shall knowingly discharge or release a chemical known to the state to cause cancer or reproductive toxicity into water or onto land where such chemical passes or probably will pass into any source of drinking water, notwithstanding any other provision or authorization of law...

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual...

On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity.. and he shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter

SCIENCE

25 SEPTEMBER 1987
VOLUME 237
NUMBER 4822

California's Proposition 65

Impending implementation of the recently enacted California law entitled Safe Drinking Water and Toxic Enforcement Act of 1986 is causing concern among a substantial fraction of companies doing business in California. The groups affected include grocery manufacturers, producers of alcoholic beverages, the chemical industry, and restaurants. Anxiety is mounting because part of the law will become effective 1 March 1988, and there is uncertainty about what must be done to comply with it. Beyond that, the law contains a "bounty hunter" clause that is likely to lead to an enormous amount of litigation. Individuals can file suits against alleged violators of the law and share 25 percent of any fines. It costs only a few hundred dollars to file a suit. Defending against one may involve millions of dollars.

The new law has two major parts—one dealing with drinking water, the other requiring a warning before exposure to chemicals known to cause cancer or reproductive toxicity. It is the second part that becomes applicable on 1 March. This part of the law states, "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual. . . ."

The Grocery Manufacturers of America pointed out that virtually all food naturally contains arsenic and other trace elements known to be carcinogenic. Thus they estimate that 15,000 items on a supermarket's shelves may have to be identified as carcinogenic. The law does provide an exemption: "An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity. . . . [T]he burden of proof that an exposure meets the criteria of this subdivision shall be on the defendant."

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PROPOSITION 65 WARNINGS

Under the regulations currently proposed by the California Health and Welfare Agency, consumable products containing a carcinogen or reproductive toxin placed on the Governor's List at a level which cannot be said to present an insignificant risk must be made the subject of some form of warning (labels, placards or perhaps ads) which set forth the statement that:

WARNING: This product contains a chemical known to the State of California to cause cancer. [or which is a reproductive toxin]

Products containing chemicals that demand the warning treatment must meet the requirements within 12 months after the chemical is added to the Governor's List.

(A VERY SERIOUS CONSIDERATION FOR MANUFACTURER'S OF ANY PRODUCT DEEMED TO REQUIRE A WARNING LABEL OR PLACARD IN CALIFORNIA IS WHETHER OR NOT THIS WILL GREATLY INCREASE THEIR LIABILITY EXPOSURE IN OTHER AREAS WHERE THEY DO BUSINESS BUT DO NOT ATTEMPT TO WARN CONSUMERS THAT THEIR PRODUCT CONTAINS A CARCINOGEN OR REPRODUCTIVE TOXIN.)

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PENALTIES

Any person violating or threatening to violate [Proposition 65] may be enjoined in any court of competent jurisdiction.

Any person who has violated [Proposition 65] shall be liable for a civil penalty not to exceed \$2,500 per day for each such violation in addition to any other penalty established by law.

Actions...may be brought by any person in the public interest...

CTL028803

Governor's List of Chemicals Known
to the State to Cause Cancer
of Reproductive Toxicity

CARCINOGENS

<u>Chemical</u>	<u>CAS Number</u>	<u>Date</u>
2-Acetylaminofluorene	53963	07/01/87
Acrylonitrile	107131	07/01/87
Adriamycin	23214928	07/01/87
AF-2; [2-(2-furyl)-3-(5-nitro-2-furyl)] acrylamide	3688537	07/01/87
ortho-Aminoazotoluene	97563	07/01/87
4-Aminobiphenyl (4-Aminodiphenyl)	92671	02/27/87
2 Amino-5-(5-nitro-2-furyl)-1,3,4-thiadiazole	712685	07/01/87
Amitrole	61825	07/01/87
ortho-Anisidine and ortho-Anisidine hydrochloride	90040	07/01/87
Analgesic mixtures containing phenacetin	---	02/27/87
Aramite	140578	07/01/87
Arsenic (inorganic arsenic compounds)	---	02/27/87
Asbestos	1332214	02/27/87
Auramine	492808	07/01/87
Azaserine	115026	07/01/87
Azathioprine	446866	02/27/87
Benz[a]anthracene	56553	07/01/87
Benzene	71432	02/27/87
B n zidine [and its salts]	92875	02/27/87
Benzo[b]fluoranthene	205992	07/01/87
Benzo[j]fluoranthene	205823	07/01/87
Benzo[k]fluoranthene	207089	07/01/87
Benzo[a]pyrene	50328	07/01/87
Benzotrichloride	98077	07/01/87
Benzyl violet 4B	1694093	07/01/87
N,N-Bis(2-chloroethyl)-2-naphthylamine (Chlornapazine)	494031	02/27/87
Bischloroethyl nitrosourea (BCNU)	154938	07/01/87
Bis(chloromethyl)ether	542881	02/27/87
1,4-Butanediol dimethane-sufonate (Myleran)	55981	02/27/87
beta-Butyrolactone	3068880	07/01/87

CTL028804

THE PROPOSITION 65 CRITICAL PATHS

The Food, Drug or Cosmetic Manufacturer

Does my product contain a chemical on the Governor's List?

yes, must label even if product complies with FD&C Act, e.g. decaffeinated coffee, because CA standard is absolute and FDA risk assessment too "liberal" for CA.

If no, food producer will ask supplier re package compliance; likely to request warranty that package contains nothing on Governor's List, hold harmless protection; or, as a minimum, package composition and formulas

Package Supplier

Provide Warranty of nothing on List; unlikely to have enough information

Provide Hold Harmless; will subject him to virtually unlimited liability with special danger from "Bounty Hunters"

Somehow obtain formula, data, etc. and provide it to customer to show no problem; virtually no likelihood of this possibility

Insist his resin and component suppliers handle the problem "in some way;" this is easiest and most customary fabricator approach

RESIN SUPPLIERS, COLOR COMPOUNDERS, OTHER ADJUVANT SELLERS

Provide Guaranty that far exceeds assurance of compliance with FD&C Act and guarantees product contains no chemicals on Governor's List? Provide "Hold Harmless" clauses and run risk of paying off Bounty Hunters at rate of \$25,000 per day? Reveal product formulations if customers will take the risk with your products from there? Refuse the business if any type of California style guaranty is demanded?

COUNCIL FOR LABELING UNIFORMITY

FOR FOOD, DRUGS, COSMETICS, AND DEVICES

FOOD INDUSTRY -

American Bakers Association
American Butter Institute
American Dairy Products Institute
Frozen Food Institute
Meat Institute
Association for Dressings and Sauces
Biscuit and Cracker Manufacturers Association

Association
Alone Control Council
Chocolate Manufacturers Association of the U.S.A.

Committee for Accurate Labeling and Marketing

Concord Grape Association
Federal Nutrition Council

Enzyme Technical Association
Food Industry Salary Council

Food Marketing Institute
Instant Formula Council

Institute of Shortening and Edible Oils, Inc.

International Food Additives Council
International Hydrolyzed Protein Council

International Ice Cream Association
International Jelly & Preserves Association

Association
All Industry Foundation

Killers' National Federation

National-American Wholesale Grocers' Association

National Association of Margarine Manufacturers

National Bakery Suppliers Association
National Cheese Institute

National Coffee Association of the U.S.A.

National Confectioners Association of the U.S.A.

National Food Processors Association
National Juice Products Association

National Kraut Packers Association
National Pecan Shellers Association

National Potato Council
National Restaurant Association

National Single Service Food Association

National Soft Drink Association
Tobacco Packers International

Processed Apples Institute
Produce Marketing Association

Rack Food Association
The Tea Association of the U.S.A.

The Vinegar Institute

United Fresh Fruit & Vegetable Association

Western States Meat Association

DESCRIPTION DRUG INDUSTRY

National Association of Pharmaceutical Manufacturers

National Pharmaceutical Alliance
Pharmaceutical Manufacturers Association

The Oral Contraceptive Council

OVER-THE-COUNTER

DRUG INDUSTRY

The Proprietary Association

COSMETIC INDUSTRY

Cosmetic, Toilet and Fragrance Association

Independent Cosmetic Manufacturers and Distributors

NIMAL DRUG INDUSTRY

National Health Institute

PACKAGING INDUSTRY

American Paper Institute
Paper Manufacturers Institute

Flexible Packaging Association
Society of the Plastics Industry

Glass Packaging Institute

EVIC INDUSTRY

Health Industry Manufacturers Association

BIOTECHNOLOGY INDUSTRY

Association of Biotechnology Companies

PROPOSITION 65 BACKGROUND PAPER

The Council for Labeling Uniformity (CLU) is a growing coalition of over sixty food, drug, cosmetic, and packaging trade associations opposed to the consumer product warnings provisions of California's new law, Proposition 65.

Background

Proposition 65, "The Safe Drinking Water and Toxic Enforcement Act," was adopted in November 1986 pursuant to California's initiative process and provides for extensive state regulation of chemical substances. CLU and its members do not object to the main purposes of Proposition 65, the regulation of safe drinking water, but oppose the law's consumer product warning requirements.

Under Proposition 65, any chemical "known to the state" to cause cancer or reproductive toxicity is considered a health hazard, and persons exposed to the chemical must be warned. These warnings would be required by the state despite the fact that the various consumer products have already been accepted as safe by the FDA and other federal regulatory agencies.

The Act's warning requirements are enforceable by injunctive relief and civil fines up to \$2,500 per day per violation. If state officials do not take action, any person may sue for enforcement "in the public interest" and is entitled to one-fourth of the penalties assessed--the so-called "bounty hunter" provision. This provision not only removes enforcement of this law from federal regulatory authorities, but also from any state regulatory authority. Thus in addition to facing state warnings where none are required at the federal level, companies also will have to defend enforcement suits in the various courts in California.

All this arises due to a law for which there were no hearings--it was a proposition on a ballot--and it was not clear that voters knew they were voting for warnings on literally thousands of consumer products.

CTL028806

PROPOSITION 65 LAWSUIT STRATEGY

Basic premises for suits will be that the California Law is unconstitutional because (1) it will undermine the Federal law which empowers the Food and Drug Administration to prescribe suitable labelling for Foods, Drugs, Cosmetics, and Devices, (2) the Federal government has at least implicitly occupied this area thus precluding conflicting State laws, and (3) Proposition 65's labelling or warning provisions will impose an intolerable and illegal burden on interstate commerce.

The most directly and impacted parties, probably represented by their trade associations will file suits focusing on the impact of the Proposition and Law on, for example, the marketing of drugs, cosmetics, and foods. One suit will be filed on behalf of a coalition of food industry companies. SPI and others have been asked to support this suit with some financial aid.

OUR RECOMMENDATION: Support the food industry suit with a maximum contribution of \$10,000 if and when requested. After the other suits are filed, follow immediately with an SPI suit to try to make certain packaging interests are fully considered in the court decision on constitutionality--estimated cost about \$50,000.

OBJECTIVE: A JUDGEMENT THAT WOULD MAKE IT CLEAR THAT NO WARNINGS WILL BE REQUIRED IN CALIFORNIA FOR ANY PRODUCT WHERE IT CAN PROPERLY BE SAID THAT THE PRODUCT AND ITS PACKAGING ARE IN COMPLIANCE WITH THE FEDERAL FOOD, DRUG AND COSMETICS ACT AND ALL APPLICABLE REGULATIONS PROMULGATED THEREUNDER. THIS SHOULD MAKE IT REASONABLY EASY TO FEND OFF OR DEFEND EVEN BOUNTY HUNTER SUITS IF THEY ARE PREMISED ON THE PRESENCE OF CARCINOGENS OR REPRODUCTIVE TOXINS AT LOW LEVELS IN ANY PACKAGING.

CTL028807

EXCERPTS FROM PROPOSED EXECUTIVE ORDER ON FEDERALISM

By the authority vested in me as President by the Constitution and laws of the United States of America, and in order to restore the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution and to ensure that the principles of federalism established by the Framers guide the Executive departments and agencies in the formulation and implementation of policies, it is hereby ordered as follows:

Sec. 3. Federalism Policymaking Criteria

(b) Federal action limiting the policymaking discretion of the States should be taken only where constitutional authority for the action is clear and certain and the national activity is necessitated by the presence of a problem of national scope.

(d) When undertaking to formulate and implement policies that have federalism implications, Executive departments and agencies shall:

(2) Refrain, to the maximum extent possible, from establishing uniform, national standards for programs and, when possible, defer to the State to establish standards.

Sec. 4. Special Requirements for Preemption. (a) To the extent permitted by law, Executive departments and agencies shall: construe, in regulations and otherwise, a Federal statute to preempt State law only when the statute contains an express preemption provision or there is some other firm and palpable evidence compelling the conclusion that Congress intended preemption of State law, or when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.

CTL028808

SPE EASTERN SECTION ECON LOCATION SURVEY

- 1) Are you a: _____ Supplier ☒ Processor _____ Other _____
 (please identify)
- 2) Have you attended past ECONs? ☒ no _____ yes. If so, which years?

- 3) Please check factors which would encourage you to attend:
☒ peer contact and interactions _____ social functions
_____ previous attendance ☒ location
☒ program content _____ other _____
_____ recreational functions _____
- 4) If you have not attended past ECONs, indicate why:
_____ location _____ time of year
☒ travel cost ☒ busy schedule
- Comments: _____

- 5) Please rate your location preferences (1=top, 3=last)
2 South (FL, GA, SC) in October 1 Northeast (NJ, PA; NY) in September
3 Mid South (VA, NC) in October
- Comments: _____

- 6) Suggested locations and/or resort complexes _____

- 7) Please give region where you live: _____ South _____ Mid South
 ☒ Northeast
- 8) Optional: Name _____
Company CertainTeed

THANK YOU FOR YOUR HELP. PLEASE RETURN BY NOVEMBER 16 TO: **CTL028809**

SANDY HEYDT
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