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Proposition 65

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G	15	21	6	

Nonprescription Drugs and Proposition 65

1. California's Proposition 65 was designed to assure California residents of safe drinking water and a safe environment, local issues not the subject of NDMA's request.
2. However, Proposition 65 also requires manufacturers of products which contain ingredients determined by the state to be "carcinogens" or "reproductive toxicants" to give "clear and reasonable warning" to consumers.
3. Under the Federal Food, Drug and Cosmetic Act, nonprescription or over-the-counter (OTC) medicines must be safe and effective for their labeled uses. Federal law also requires all nonprescription drugs to be labeled with scientifically based warnings.
4. Nonprescription medicines are the subject of an exhaustive review (OTC Review) by FDA, with the assistance of known scientific experts to assure their safety, effectiveness and scientifically based labeling. Labeling on OTCs informs people what the product is for, how to use it, and warns them when not to use the product -- all in lay language and all needed for safe use of the product. Federal regulations prescribe the precise words used in warnings.
5. Proposition 65 establishes a second regulatory system for OTCs different from FDA's to govern safety and labeling decisions. OTCs in full compliance with federal law after extensive FDA review now must undergo reexamination in California.
6. OTC drugs are contained in relatively small packages, come in a wide range of sizes, are relatively inexpensive, and are sold in over 750,000 retail outlets throughout the nation. Different label warnings for different states would create marketing chaos.
7. A uniform regulatory system for OTC drug labeling and warnings is vital to avoid consumer confusion with differing messages and to keep product costs low.
8. Any concern about the adequacy of current federal regulation of OTC drugs should be addressed by FDA. Human reaction to drugs does not differ depending solely upon the state in which a person lives and one state should not set labeling policy for others. The credibility and effectiveness of FDA to regulate the safety and labeling of OTC drugs for the entire nation must be preserved.
9. The need for uniformity of OTC drug labeling has been recognized in federal regulation three times since 1982: tamper-resistant packaging and labeling, pregnancy/nursing warning requirements, and Reye Syndrome warning requirements. In each case, federal authority was asserted to avoid the possible precedent of local labeling regulations. It should be asserted on Proposition 65.

THE WHITE HOUSE

6/17/89

Dear Mr. O'Keefe -

Thank you for sharing your views
on the impact of California's Proposition 65
with me when you visited the White House.
I welcome your counsel.

Please keep in touch.

Sincerely,
Andy Card

THE WHITE HOUSE
WASHINGTON

Daniel F. O'Keefe, Jr.
Senior Vice President
and General Counsel
Nonprescription Drug Manufacturers
Association
1150 Connecticut Avenue, N.W.
Washington, D.C. 20036



Founded 1881

Better Health
Through Responsible
Self-Medication

NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

Formerly The Proprietary Association

June 13, 1989

By Hand

The Honorable Andrew H. Card, Jr.
Assistant to the President and
Deputy to the Chief of Staff
Executive Office of the President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. Card:

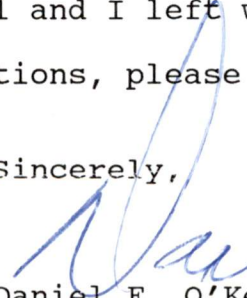
Thank you so much for your kindness in meeting with Neil Chayet and myself today.

I found our visit most productive and appreciate very much your suggestions and thoughts on the very difficult question of the resolution of Proposition 65 insofar as nonprescription drugs are concerned.

On behalf of our industry -- which, as I said, is extremely concerned about the issue -- I appreciate your taking the time to discuss it with us. I attach for your file another copy of the brief position paper which Neil and I left with you.

If you or your staff have any questions, please feel free to contact me.

Sincerely,



Daniel F. O'Keefe, Jr.
Senior Vice President
and General Counsel

Attachment: Nonprescription Drugs and Proposition 65 (6/7/89)

DOK/ska

Nonprescription Drug Manufacturers Association (NDMA)

Nonprescription Drugs and Proposition 65

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4. Nonprescription medicines are the subject of an exhaustive review (OTC Review) by FDA, with the assistance of known scientific experts to assure their safety, effectiveness and scientifically based labeling. Labeling on OTCs informs people what the product is for, how to use it, and warns them when not to use the product -- all in lay language and all needed for safe use of the product. Federal regulations prescribe the precise words used in warnings.
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June 9, 1989

AC:

Call from Rich Williamson

Subject: Proposition 65

He knows you met with Mitch Daniels on this.
He has been working the Hill on behalf of GMA.

He's heard unconfirmed reports that a decision
has been made to shut down a regulatory solution
and that Gov. Sununu sent a letter to Gov.
Deukmejian.

Some urgency in that there's a big meeting
with the Board on Sunday.

Want to know if they should keep harassing
the Administration or pursue other remedies
with Congress???

*I called
6/9/89*

LG

THE WHITE HOUSE

WASHINGTON

June 5, 1989

Dear Frank,

Thank you for your letter regarding a possible federal response to California's Proposition 65.

The Administration has been closely monitoring the impact of California's Proposition 65 on the nation's economy. We are paying particular attention to developments in the courts and actions by the state of California. As these activities proceed, we will look for significant effects on interstate commerce and consider what would constitute appropriate federal action.

While we believe we have an accurate understanding of where implementation now stands, please let us know of any changes in the situation that may come to your attention.

Thank you for sharing your concern. You may rest assured that we will be watching with interest the course of events relating to the implementation of Proposition 65.

Regards,

John H. Sununu
Chief of Staff

Mr. Frank Visco
Chairman
California Republican Party
Post Office Box 2659
Lancaster, California 93534

JEFFREY NEDELMAN
Vice President, Public Affairs



AC has seen ✓
No reply necessary

202/337-9400
FAX: 202/337-4508

May 31, 1989

Andrew Card
Assistant to the President and
Deputy Chief of Staff
The White House
Washington, D.C. 20500

Dear Andy:

No, this is not another plea to push federal pre-emption.
Rather, it is well-deserved "thank you."

You have been instrumental in pushing the most important
public policy issue before the food industry to the
forefront of the Administration's attention. For this we
are truly grateful.

Despite recent setbacks (see enclosed articles), we will
continue our efforts to obtain a uniform national standard
for health safety warnings on food and hope that we may
count on your support in the future.

Sincerely,

Jeffrey Nedelman

White House's Stand

State Toxics Law To Be Left Alone

Another round of industry lobbying aimed at overturning Proposition 65, California's tough disclosure law for toxic chemicals, has been flatly rejected by the White House.

The Bush administration's position was spelled out in a directive last week from the Office of Management and Budget, which said that unless there is a "significant change" in the way the measure is being carried out, "no federal preemptive action ... is warranted."

"We're going to continue to monitor it," federal Food and Drug Commissioner Frank Young said yesterday. "But this brings it to an absolute close for the moment."

The budget office's edict was the latest response to the high-level politicking surrounding Proposition 65, which requires companies to warn consumers about chemical exposures posing a "significant risk" of cancer or reproductive harm. The law was passed by California voters in 1986. The food industry, which tried to win an exemption before President Reagan left office, had been vigorously pressing its case in recent weeks.

"There's been a lot of lobbying and it was heaviest at the very high levels," said an official at the Department of Health and Human Services, where Secretary Louis Sullivan reportedly heard pleas from trade groups and food company executives.

The decree was intended to stop the arm-twisting.

"Conflicting signals about the Administration's position ... can create false hopes and encourage counterproductive efforts to undermine this carefully considered policy," the letter warned. "They can

also be a source of potential embarrassment to the President."

The agency said the White House is sticking by the findings of a high-level policy group that examined the law during the Reagan administration and found no basis for industry's claim that the measure was causing havoc in the marketplace.

Industry has argued that the food supply is adequately guarded by federal laws and that manufacturers cannot cope with a proliferation of state measures setting different food-safety standards.

Spokesmen for the Grocery Manufacturers of America, which has led the industry lobbying, could not be reached yesterday for comment.

In trying to fend off the latest round of lobbying, supporters of Proposition 65 found a strong ally in Environmental Protection Agency chief William Reilly, who defended the law in a letter to Secretary Sullivan.

"The law simply warns people about their exposure," Reilly wrote. "It is hard to argue with providing information to the public."

Reilly also noted that the measure's use of market forces to control toxics "is consistent with the president's call for more economically oriented regulatory programs," and that Californians approved the law by a ratio of nearly 2 to 1.

"Overturning the will of the voters," he said, "will have a cost."

Reilly's strong stance, and the administration's rebuke to industry, were applauded by environmentalists.

The Washington Post

MAY 30, 1989

HEALTH SECTION PAGE 5

White House Keeping Hands Off Toxics Law

Despite an intense industry lobbying campaign, the Bush administration is taking a hands-off approach toward a controversial California chemical warning law called Proposition 65.

In recent weeks, representatives of the influential food, drug and cosmetics industries have blitzed top officials in the Food and Drug Administration and its parent Department of Health and Human Services, seeking federal relief from the California law.

The law is drawing national attention because it requires warnings on products containing levels of chemicals that pose a significant risk of cancer or reproductive harm.

Last week S. Jay Plager, administrator of the Office of Information and Regulatory Affairs in the White House Office of Management and Budget, sent a terse letter to FDA chief Frank Young, rebuffing industry efforts. Plager said the administration "has determined that, until there is a significant change in the situation in California . . . no federal preemptive action—either by regulation or otherwise—is warranted," according to sources who had seen the letter.

Plager, whose office is responsible for

monitoring the law, warned that "conflicting signals about the administration position by departmental or agency officials can create false hopes" and "be a source of potential embarrassment to the president."

"This is the administration's position at this time," said FDA's Young. "The position is no different than it was at the end of the Reagan administration."

Another letter sent May 17 to HHS head Louis W. Sullivan by Environmental Protection Agency administrator William K. Reilly also warned against precipitous federal action against the California law. "The law simply warns people about their exposure to carcinogenic or reproductively toxic chemicals at levels exceeding 'no significant risk.' It is hard to argue with providing information to the public," he wrote.

Prop 65 proponent David Roe, an Environmental Defense Fund attorney, said, "this should put the preemption issue to bed."

"We're reloading. We will continue presenting our case," responded Grocery Manufacturers Association vice president Jeffrey Nedelman.

—Cristine Russell

May 23, 1989

Andrew Card
Assistant to the President and
Deputy Chief of Staff
The White House
Washington, D.C. 20500

Dear Andy:

For once the Post got it right in today's Health section cover story on Proposition 65. Will FDA determine what is safe for the nation or will the land of "fruits, nuts and sunshine?"

Also, the enclosed letter from the immediate past Chairman of the California Republican Party, Mr. Bob Naylor, should arrive at the White House today. We would welcome the opportunity to briefly visit with you to determine what, if any, additional information is required before the Administration makes a final decision on this most important issue.

Sincerely,



Jeffrey Nedelman

Enclosures (2)

no meeting!
Andy 5/23/89



California Republican Party

1903 West Magnolia Blvd. • Burbank, California 91506 • (818) 841-3210

May 22, 1989

The Honorable John Sununu
Chief of Staff
The White House
Washington, D.C. 20500

Dear Governor Sununu:

As immediate past Chairman of the California Republican Party (you may recall our joint press conference in San Diego last September), I am writing to urge that you authorize the Department of Health and Human Services to preempt the food labeling requirements of California's Proposition 65.

Unfortunately, because of frustration of legislative efforts to make Proposition 65 workable, its implementation raises the specter of a maze of state-by-state regulations requiring warnings about cancer and birth defects on food, drugs, cosmetics and medical devices which have already been deemed safe by the Food and Drug Administration.

As ridiculous as it may sound, almost all chemicals will be classified as reproductive toxicants when subjected to the standards of Proposition 65, resulting in the absurdity of requiring warning labels on perfectly safe food items.

State legislation to correct this most objectionable provision was gutted last week in a move led by Assemblymen Tom Hayden and Lloyd Connelly.

The national interest requires a uniform policy on warning requirements and risk assessment procedures because a state-by-state approach:

(a) will lead to great public confusion about the differences in warnings and concern about why "unsafe" products are being marketed, as well as public cynicism about the judgments underlying the warnings,

The Honorable John Sununu
May 22, 1989
Page 2

(b) will lead other states to impose stringent requirements based on inadequate information (states do not have the scientific resources to do adequate risk assessments), and

(c) will place a huge burden on interstate commerce through a multiplicity of labeling requirements imposing excessive costs on producers and marketers throughout the nation.

FDA regulations provide fully adequate public health protection and have assured the basic safety of the nation's food, drug and cosmetic supply for 80 years. Indeed, Proposition 65 was never intended by California voters to conflict with such regulations, but rather to regulate environmental (air, water, workplace) conditions.

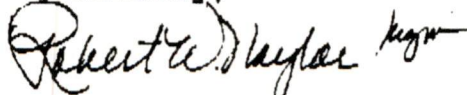
Laws like Proposition 65 undermine the goals of the entire federal regulatory framework and undermine the confidence which that system has earned from the American public.

Therefore, as a matter of national policy, FDA regulation of food should preempt local regulations, whether in the form of Proposition 65 or otherwise.

One further observation: this issue, unless preempted, will only get worse, given the power which the radical left has in the California Legislature and efforts to push similar laws in other states. Moving early to solve this problem will prove much easier than waiting until next year or the year after.

Thank you for your leadership on this vital matter.

Sincerely,



ROBERT W. NAYLOR

RWN:rgm

THE WHITE HOUSE

5/22/89

JH-

Thanks for the latest on
Prop. 65. The bell is ringing!

Andy

Andy Card
THE WHITE HOUSE
WASHINGTON

Jeffrey Nedelman
Vice President
Grocery Manufacturers of America
1010 Wisconsin Avenue, N.W.
Washington, D.C. 20007

JEFFREY NEDELMAN
Vice President, Public Affairs



202/337-9400
FAX: 202/337-4508

To Roger Porter -
FYI
Andy

May 19, 1989

Andrew Card
Assistant to the President and
Deputy Chief of Staff
The White House
Washington, D.C. 20500

Dear Andy:

Enclosed are copies of letters mailed last night to President Bush from an overwhelming majority of the GOP members of the California State Senate and Assembly. Via the wonders of technology we are able to provide you with an advance copy.

As the letters from Assemblyman Jones and Senator Doolittle state, "the national interest requires a uniform policy on warning requirements."

This week's efforts by California Assemblymen Tom Hayden and Lloyd Connelly succeeded in gutting legislation which would have corrected the most objectionable provision of Proposition 65--the standard for reproductive toxicity. As a result, "...industry efforts to lessen the effects of overwarning have been frustrated." We have reached the critical point on this issue and action is needed now, further study is not warranted by the facts.

These letters underscore the urgency to act now to ensure that the FDA retains the control it has had for the past 80 years as the agency charged with protecting the public health.

Sincerely,

Jeffrey Nedelman

THE WHITE HOUSE
WASHINGTON

5/18 Per Katie -
JH's reply already
sent - Sumner
has seen this.
5/16 LK

TO:

John Sumner

FROM:

FRED McCLURE
Assistant to the President
for Legislative Affairs

- ☒ FYI
☐ Comment
☐ Action

John Paul Hammerschmidt
wanted to make sure you
saw the attached letter.

JOHN PAUL HAMMERSCHMIDT

THIRD DISTRICT, ARKANSAS

HOME ADDRESS:
HARRISON, ARKANSASWASHINGTON ADDRESS:
2110 RAYBURN BUILDING
WASHINGTON, DC 20515
PHONE: 225-4301

Congress of the United States
House of Representatives
Washington, DC 20515

April 20, 1989

The Honorable John Sununu
 Chief of Staff
 The White House
 Washington, D.C. 20500

Dear John:

Recently, two members of your staff, Mr. Andy Card and Mr. Ed Rogers, were briefed on California Proposition 65. The issue at hand is whether food products produced anywhere in the United States should be required to post cancer and/or birth defect warnings. The warnings would be required because of the possibility that the products may be sold in California.

As you probably know, in January the Food and Drug Administration (FDA) submitted a draft regulation to the Office of Management and Budget (OMB). Historically the FDA has held the philosophy that the federal government should be the only entity empowered to place cancer and birth defect warnings on food, drugs, cosmetics and medical devices. I believe this is the correct philosophy.

Unfortunately, to date, no action has been taken by OMB on the FDA draft. There are a great many Arkansas products which are threatened by Proposition 65. I, therefore, believe it is essential that OMB respond to the FDA.

Will you look into this matter and see if it is possible for OMB to act in an expeditious manner?

Thank you for your consideration.

With kind regards,

Sincerely,

(Signed) John Paul Hammerschmidt

JOHN PAUL HAMMERSCHMIDT
 Member of Congress

JPH:rf

COMMITTEE:

PUBLIC WORKS AND
 TRANSPORTATION—
 RANKING MEMBER

SUBCOMMITTEES:

(EX OFFICIO WITH VOTE)
 AVIATION
 ECONOMIC DEVELOPMENT
 INVESTIGATIONS AND OVERSIGHT
 PUBLIC BUILDINGS AND GROUNDS
 SURFACE TRANSPORTATION
 WATER RESOURCES

VETERANS' AFFAIRS—

SENIOR REPUBLICAN
 SUBCOMMITTEE

HOSPITALS AND HEALTH CARE—
 RANKING MEMBER

SELECT COMMITTEE ON AGING
 SENIOR REPUBLICAN

SUBCOMMITTEE

HOUSING AND CONSUMER
 INTERESTS—RANKING MEMBER

THE WHITE HOUSE

WASHINGTON

May 10, 1989

MEMORANDUM FOR GOVERNOR SUNUNU

FROM: ROGER B. PORTER *RBP*

SUBJECT: Possible Federal Preemption of California
Proposition 65

An issue that continues before the Federal government is whether the Food and Drug Administration (FDA) should preempt California's Proposition 65, which requires that products containing carcinogens or reproductive toxins bear a warning. This is an issue that was extensively debated in late 1988 and early 1989 in the waning days of the Reagan Administration. Recently, questions have been raised about what is Bush Administration policy with respect to possible Federal preemption of Proposition 65.

Background

In November 1986, California enacted by popular referendum Proposition 65. In addition to less controversial provisions regarding the discharge of certain effluents into water resources, this law requires that any product that contains a chemical known to the State to be either a carcinogen or a reproductive toxin must be so labeled. An exception is allowed when the level poses "no significant risk," defined as 1/1000th of the level that causes no observable effect. The practical effect of this California requirement is unknown.

However, it has generated widespread fears that special warning labels for consumer products sold in California could confuse consumers, obscure needed health warnings, and interfere with the flow of interstate commerce.

Reagan Administration Discussions

In July 1988, the Domestic Policy Council discussed this issue for the first time and decided to establish a working group to consider it. The group's mission was to assess possible conflicts with Federal law and regulatory authority proposed by California's implementation of Proposition 65.

At meetings during the fall of 1988 the consensus of the working group was that California's implementation of Prop 65 had not yet created conflict with federal law. The state had not yet implemented the new law, and, until actual harm could be demonstrated, Federal preemption of a state law would be premature. However, the Interior Department, under Secretary Hodel, argued strongly for immediate preemption.

A number of private sector groups, for example, the Grocery Manufacturers Association, pressed for promulgation of a national rule giving FDA sole regulatory authority in setting standards for food, drugs, and related products -- an option known as "occupying the field." In early 1989, the Justice Department rendered an opinion that FDA does have the legal authority to issue such a national rule and that the decision on whether to promulgate a national rule is a policy decision for the Secretary of Health and Human Services.

Thereafter, FDA prepared a draft notice of proposed rule making to establish a national rule occupying the field of safety warnings, including a specific statement that Prop 65 would be thereby preempted. After extensive discussions, as of the end of the Reagan Administration, HHS still had not officially submitted this draft NPRM to OMB for Administration clearance, and therefore, Federal preemption of Prop 65 did not occur.

Bush Administration Policy on Prop 65

Thus far during the Bush Administration, the policy has been to continue monitoring the implementation of California's Proposition 65 but not to go forward with preemption. The Office of Information and Regulatory Affairs of the Office of Management and Budget is leading this monitoring effort. The industry, however, continues to pursue Federal preemption.

FDA is still in favor of preemption, but the current position of Secretary Sullivan is not yet clear.

Discussion

Surely there are aspects of Proposition 65 that are wholly mistaken from a scientific standpoint. Putting aside the merits, however, the political costs of preemption, without compelling justification, could be enormous. The environmental groups would be outraged, and would label such preemption as an effort by this Administration to protect big business at the cost of environmental and health and safety considerations.

Furthermore, such a preemption would be difficult to justify in the face of our principles of federalism. A further difficulty of preemption would be that it would mean a major growth in Federal regulatory activity to fill the void left by the former state action.

Conclusion

The recently established Domestic Policy Council Working Group on Health Policy, chaired by Bill Roper, is discussing food safety issues, in the wake of the apples and Alar controversy. The Prop 65 issues could be referred to this Domestic Policy Council Working Group.

Before taking this step, however, we would like to discuss this with you. We need to be clear about where we are headed before we begin.

copy - Handle

March 24, 1989

The Honorable John Sununu
Chief of Staff
The White House
Washington, D.C. 20500

Dear Governor:

When we spoke last week I mentioned a very serious problem regarding a California State Law known as Proposition 65.

I have enclosed all the pertinent information relating to this law and would greatly appreciate any assistance you may be able to offer.

Let me take this opportunity to thank you in advance for your valuable time.

With warm regards,

Sincerely,

Don Sundquist, M.C.

(vit. "A")

FDA

THE WHITE HOUSE

5/12/89

Jff -

Thanks for the Proposition 65 information. I'll make sure others here are aware of the Tom Hayden letter.

Keep in touch.

Andy Card

THE WHITE HOUSE
WASHINGTON

Jeffrey Nedelman
Vice President
Grocery Manufacturers of America
1010 Wisconsin Avenue
Washington, DC 20007

Suit 800

Proposition 65

JEFFREY NEDELMAN
Vice President, Public Affairs



202/337-9400
FAX: 202/337-4508

Re: Labor and Employment
Subcommittee on
Higher Education

Dir
and Long Term Care
ation
Environmental Safety and
ic Materials
Research Management

To Rose Porter
FY2
Andy

May 10, 1989

Andrew Card
Assistant to the President
The White House
Washington, D.C. 20500

Dear Andy:

You might be interested in the enclosed letter from Tom Hayden.
It will intensify the pressure being brought upon the
Administration to make a decision.

Sincerely,

Jeffrey Nedelman

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Sacramento Office
State Capitol
P.O. Box 942846
Sacramento, CA 94293-0001
(916) 445-1876

District Office
1337 Santa Monica Mall
Suite 313
Santa Monica, CA 90401
(213) 393-2717

Assembly California Legislature



TOM HAYDEN
Member, California State Assembly
44th District

Committees:
Chair, Labor and Employment
Chair, Subcommittee on
Higher Education

Member
Aging and Long Term Care
Education
Environmental Safety and
Toxic Materials
Policy Research Management

May 5, 1989

Honorable Tony Coelho
Member of Congress
403 Cannon
Washington, DC 20515-0505

Dear Congressman Coelho:

It has come to our attention that an informal poll is being conducted by staff at the Department of Health and Human Services regarding the possibility of a federal preemption of Proposition 65. Apparently DHHS is contemplating preemption by the publication of a regulation in the Federal Register.

Since its passage, the opponents of Proposition 65 have tried several tactics to weaken Proposition 65. We have been in court to defend Proposition 65 several times, and no judge has overturned any of its provisions. The tactic of federal preemption was attempted in the final days of the Reagan Administration to no avail. The Reagan administration saw a conflict between preemption and the subscription to the "New Federalism."

The "Economic Analysis of Proposition 65" from the Executive Office of the President, Council of Economic Advisors, December 5, 1988, concluded that, "Only if significant costs are borne by non-Californians can we justify recommending preemption. Our conclusion is that the law to date has imposed only relatively minor costs upon non-California persons." And for decades, states have had the authority, under the FDCA, to set tougher standards on pesticide regulations.

As you know, Proposition 65 is the Safe Drinking Water and Toxic Enforcement Act of 1986. It received 63% of the vote in November 1986, and received consistent support in every region of California. Assemblyman Lloyd Connelly and I were co-chairs of the Proposition 65 campaign. Our campaign theme of "Yes, Get Tough on Toxics" obviously struck a responsive chord with the voters.

Proposition 65 requires businesses to provide warnings if their chemicals pose a significant risk of cancer, birth defects or other reproductive harm. It also prohibits chemicals that pose a significant risk from being discharged into drinking water. The law requires the state to identify what chemicals cause cancer or birth defects.

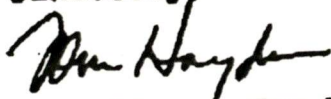
In the two-and-a-half years since its passage, Proposition 65 has moved California ahead of the Federal Government in many areas. California's Health and Welfare Agency has established more significant risk guidelines (50) than the E.P.A. had in fifteen years, and not one of those guidelines has been challenged. Proposition 65 is creating clarity in exposure assessments that the E.P.A. has not provided.

Proposition 65 is also ahead of the Federal Government in the areas of alcohol warnings for birth defects, warnings of non-cigarette tobacco products, and posting cancer warnings for secondhand tobacco smoke.

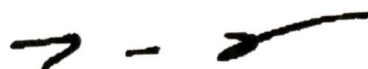
We hope you will continue to resist the misguided efforts to pre-empt Proposition 65 by the federal government and let California move forward providing a safer and more healthful state.

Thank you for your continuing help.

Sincerely,



Assemblyman Tom Hayden



Assemblyman Lloyd Connolly

JEFFREY NEDELMAN
Vice President, Public Affairs



202/337-9400
FAX: 202/337-4508

fil

April 7, 1989

Mr. Andrew Card
Deputy Chief of Staff
The White House
Washington, D.C. 20500

Dear Mr. Card:

Thank you for taking time out of your very busy schedule to visit with us this morning regarding Proposition 65. It was good to put a face with a name--Mitch has sung your praises loudly and widely.

The FDA proposed regulation will continue to remain stuck in OMB unless and until the West Wing instructs them to allow FDA to publish. Can you help us?

Sincerely,

Jeffrey Nedelman



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

Prop 65

April 19, 1989

NOTE TO BILL ROPER
ANDY CARD
JOHN SCHMITZ

FROM: JAY PLAGER

A handwritten signature in black ink, appearing to be "JP" or "J. Plager", written over the "FROM:" line.

FYI: Current status of the food industry's challenges to Proposition 65. They seem to be pursuing all available routes. We will continue to monitor closely, and advise if there is any significant change in the situation that appears to warrant Federal involvement.

BURDITT, BOWLES & RADZIUS, CHARTERED

WASHINGTON OFFICE
1029 VERMONT AVENUE, N.W.
SUITE 200
WASHINGTON, D.C. 20005
G3 FAX: (202) 628-0532
TELEPHONE: (202) 638-3833

SAN FRANCISCO OFFICE
201 SPEAR STREET
SUITE 1111
SAN FRANCISCO, CA 94105
G3 FAX: (415) 957-5905
TELEPHONE: (415) 957-0101

MILAN OFFICE
BURDITT, BOWLES, RADZIUS
& BRUNO
10, VIA P. VERRI
20121 MILAN, ITALY
TELEX: 316089 BRUNOS I
CABLES: BRUNOLEX-MILAN
FAX: 011392701473
TELEPHONE: (02) 798609

LAW OFFICES

333 WEST WACKER DRIVE
SUITE 2500
CHICAGO, ILLINOIS 60606-1218
TELEX #350188
G3 FAX: (312) 781-6630
TELEPHONE: (312) 781-6633

WRITER'S DIRECT LINE

March 30, 1989

S. Jay Plager
Room 246
Old Executive Office Building
Washington, D.C. 20503

Dear Mr. Plager:

Thank you very much for asking about CURL v. Allenby on Wednesday. Here are some bullets on it:

-- CURL consists of about eighty food manufacturers and related companies and trade associations.

-- The complaint alleged violations of the Commerce, Supremacy, Due Process, Equal Protection and Free Speech Clauses of the Federal Constitution, and Clear Title and Single Purpose provisions of the California Constitution.

-- Judge Lynch, in the federal court in San Francisco, denied the state's motion to dismiss on venue.

-- The defendants then filed motions to dismiss based on Federal Rule 12(b)(6) (failure to state a claim). Judge Lynch declined to take pendent jurisdiction of the state constitutional issues, dismissed the Equal Protection and Free Speech counts, and denied the motion on the Commerce, Supremacy and Due Process Clauses.

-- We filed a motion for partial summary judgment based on the express preemption provisions of the Federal Meat Inspection Act and Federal Poultry Products Inspection Act. After briefing and a hearing, Judge Lynch did not rule on the motion but said he wanted more information on standing and on case or controversy.

-- Both sides are involved in pretrial discovery.

-- No hearing is set, but I anticipate that both sides will be filing additional documents, possibly including motions for summary judgment, over the next few months.

S. Jay Plager
March 30, 1989
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In the 1989 sessions of state legislatures, Proposition 65-like bills have been introduced in Hawaii, Illinois, Massachusetts and New York. While the bills are quite similar to Prop. 65, they have significant differences. For example, the Massachusetts bill increases the fine to \$25,000 per violation, and the Illinois bill makes a violation a felony. The Illinois bill is particularly dangerous this year because, for the first time, one of its sponsors is a Democratic leader in the house.

I am also putting together a list of the cases which Prop. 65 has spawned. All of this proposed state legislation and existing litigation could be obviated by a simple stroke of the pen in Washington! I will of course continue to keep you posted on developments on all fronts, but I don't see the lessening of pressure for federal preemption as a possible scenario.

Thanks again for your time on Wednesday.

Sincerely,


George M. Burditt

GMB/cbj

Chairman
of Heinz

(Jane Eberle) 331-7700

The Gov. does not
want to do this.

Should you suggest

I will - although I

just met w/ GMA about
this.

Andy

Document Originally
Attached to
Following Page

TIMMONS AND COMPANY, INCORPORATED
1850 K STREET, N.W. WASHINGTON, D.C. 20006 (202) 331-1760

Ok if
before trip
to NJ.
No

April 3, 1989

WILLIAM E. TIMMONS
*Chairman, Executive
Committee*

TOM C. KOROLOGOS
President

HOWARD G. PASTER
Executive Vice President

WILLIAM H. CABLE
Vice President

MARY A. SIDLEY
Vice President

MICHAEL J. BATES
Vice President

Dear Andy:

I will be grateful if you would see if Governor Sununu would be willing to meet on Thursday, April 13th, with the Chairman of the H.J. Heinz Company, Tony O'Reilly; the President of the Grocery Manufacturers Association, George Koch; and me to discuss briefly a proposed rule for the Federal government to preempt California State's Proposition 65.

I understand you are familiar with this issue, so I will not go into the merits except to point out preemption is critical for many industries, especially the food business. FDA submitted a proposed preemption rule to OMB for clearance late in President Reagan's term.

Thanks, Andy, for your consideration of this request.

Sincerely,

Bill

William E. Timmons

The Honorable Andrew H. Card, Jr.
Deputy Chief of Staff
The White House
Washington, D.C. 20500

Prop. 65 file

THE WHITE HOUSE

WASHINGTON

April 12, 1989

MEMORANDUM FOR ANDREW H. CARD, JR.

FROM: ROGER B. PORTER *RBP*

SUBJECT: Possible Federal Preemption of California
Proposition 65

Recently, questions have been raised about what is Bush Administration policy with respect to possible federal preemption of California Proposition 65.

As you know, this matter was thoroughly discussed during the latter half of 1988 in the previous administration. The attached paper explains this history.

The decision on promulgating a national rule preempting Proposition 65 is a policy decision for the Secretary of Health and Human Services. To date, Secretary Sullivan has not submitted such a notice of proposed rule making to the Office of Management and Budget for administration clearance.

Federal preemption of a state regulatory law is a serious matter. While the concerns of those urging federal preemption are important, I believe that we should consider carefully the issues involved before undertaking a Domestic Policy Council or other appropriate policy review of this matter. Appearing to reopen the issue at this time will surely engender very forceful lobbying efforts on the part of those seeking preemption of Proposition 65.

I believe that it would be worthwhile for you, me and Richard Darman to meet with Governor Sununu to discuss these issues before we commit to reopening the debate about Proposition 65.

I would be happy to discuss this with you further.

Attachment

cc: Richard G. Darman

FEDERAL PREEMPTION OF CALIFORNIA PROPOSITION 65

ISSUE:

Whether and on what theory the Food and Drug Administration (FDA) should preempt California's Proposition 65, which requires that products containing carcinogens or reproductive toxins should bear a warning, even if the products have been found safe by the FDA.

BACKGROUND:

In November 1986, California enacted by popular referendum Proposition 65. In addition to less-controversial provisions regarding the discharge of certain effluents into water resources, this law requires that any product that contains a chemical known to the state to be either a carcinogen or a reproductive toxin must be so labelled. An exemption is allowed when the level poses "no significant risk," defined as 1/1000th of the level that causes no observable effect. The practical effect of the California requirement is unknown. However, it has generated fears that special warning labels for consumer products sold in California could confuse consumers, obscure needed health warnings, and interfere with the flow of interstate commerce.

DISCUSSION:

On July 27, 1988, the DPC discussed this issue for the first time, and decided to establish a Working Group on Federal Preemption. The chairman of the DPC directed the Working Group to "identify any conflicts ... between [state] laws and federal programs, that could warrant federal preemption of state laws." The group's mission was to assess possible conflicts with federal law and regulatory authority posed by California's implementation of Prop 65.

At meetings during the fall of 1988, the consensus of the Working Group was that California's implementation of Prop 65 had not yet created a conflict with federal law. The state had not yet implemented the new law, and, until actual conflict could be demonstrated, federal preemption of a state law would be premature. At the December 15th meeting, the Working Group's subgroup on the economic effects of Prop 65 reported that it had arrived at the same conclusion. However, at the same meeting, the Interior Department argued strongly for immediate preemption. A subgroup was then established to prepare an options paper.

On December 13th, the Justice Department's Office of Legal Counsel (OLC) submitted to the Cabinet Secretary a memorandum commenting on the options developed by the subgroup, stating the position that as a matter of law it was premature to preempt Prop 65. OLC recommended that FDA solicit public comments in order to develop the factual record necessary for a preemption

determination on conflict grounds. Industry, perhaps in response to the economic and legal challenges which were being raised to preemption by the Working Group, began to press for promulgation of a national rule giving FDA sole regulatory authority in setting standards for food, drugs and related products--an option known as "occupying the field." The option went beyond the original charter of the Working Group because it proposed a preemption of all state regulatory efforts in the area, not just Prop 65.

This approach was reflected in a December 28th letter from the Secretary of Interior to the Attorney General requesting the views of the Justice Department on whether FDA has the legal authority to preempt all state health warning requirements on food and drugs. The Attorney General having recused himself, the Deputy Attorney General, on January 4, 1989, responded stating the Justice Department position (1) that FDA does, if it chooses to do so, have legal authority to issue a national rule occupying the field, and (2) that a decision on promulgating a national rule is a policy decision for the Secretary of Health and Human Services.

Thereafter, FDA prepared a draft notice of proposed rule-making to establish a national rule occupying the field of safety warnings, including a specific statement that Prop 65 is currently preempted. As of January 20, 1989, HHS still had not officially submitted this draft Notice of Proposed Rule Making (NPRM) to OMB for Administration clearance. There is no deadline on this (unofficial) draft NPRM, and the matter now awaits the direction of President Bush and his Administration.

IMPLICATIONS:

The action proposed in the draft NPRM goes well beyond the original charter of the Working Group on Federal Preemption. It is also likely that creation of the draft NPRM was strongly influenced by a desire to complete some kind of action before the end of the outgoing Administration. It appears that options requiring more time were not given equal attention. Whether requirements imposed by Prop 65 are a serious barrier to interstate commerce cannot be known until the State of California actually begins putting the requirements of the new labelling law into effect.

Federal preemption of a state regulatory law is a serious matter. In the case of Prop 65, the state law was passed with the approval of a 70 percent majority of California voters, and the Executive Order on Federalism requires self-restraint to be placed on the use of federal power in overriding state laws. The price of taking what may be premature preemptive action must be carefully weighed against the anticipated benefits of intervention.