A Corrosive Fight Over California's Toxics Law

Proponents call Proposition 65 innovative; industry calls it a nightmare. The White House may ultimately decide

"CHICKEN LITTLE WAS WRONG, the sky is not falling," says Tom Warriner, who for the past 2 years has occupied one of the hottest seats in California—that of implementing the state's tough new antitoxics law, the Safe Drinking Water and Toxic Enforcement Act, better known as Proposition 65.

When the ballot initiative passed in 1986, after a multimillion dollar campaign that will not be remembered for its veracity, there was talk of warning labels on thousands of consumer products, from vanilla ice cream to motor oil. Opponents predicted a deluge of citizen lawsuits against food manufacturers and computer chip makers alike, and a mass exodus of industry from the state.

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Jane Fonda and friends *championed Proposition 65, while industry spent $5 million in an unsuccessful bid to stop it.*

But nearly 1 year after Proposition 65 went into effect, none of the horror stories has come true, in no small part because of the efforts of Warriner and his staff in translating the vaguely worded proposition into regulations that both environmentalists and industry can live with, if reluctantly. In fact, though the full effect of the law has yet to be felt, what seems to be shaping up is an innovative new approach to toxics regulation that could be the harbinger of what's to come around the country.

And that may explain why industry continues to fight the law 2 years after its passage. Although companies in California are adjusting to Proposition 65, industry is waging a nationwide campaign to prevent its spread to other states. In the past few months industry groups have carried their complaints all the way to the White House, where they have petitioned President Reagan's Domestic Policy Council to preempt the California statute. A decision is believed to be imminent.

Although industry's arguments revolve around the purported costs of compliance, other opponents, including Bruce Ames, a University of California biochemist and member of the advisory panel guiding implementation of the law, complain that it is diverting public attention and money from real risks like smoking and diet to nonexistent problems. Says Ames: "It is a thoroughly silly law, with an enormous cost and no gain in public health." But that is an old fight, pertinent not just to Proposition 65 but to federal regulation in general (see box).

At the heart of the debate is a bold new law that turns toxics regulation on its head. The initiative, remarkable for its brevity, simply says that business must warn the public if it knowingly exposes them to a substance that poses a significant risk of cancer or birth defects.

The state was charged with coming up with a list of known carcinogens and reproductive toxins, and then took upon itself the task of defining "significant risk," which was unspecified in the law. Warriner's office settled on 10^{-5}, or one excess cancer per 100,000 people with a reasonable lifetime exposure. Under the law, no warning is required unless a chemical is present in an amount that exceeds this significant risk threshold. The state has now listed some 250 chemicals and is setting standards, or allowable doses, for 50 widely used ones.

Substances on the state's list include alcoholic beverages (in abusive amounts), tobacco smoke, and a host of familiar and not-so-familiar chemicals, some of which are found in everyday products like plastic and gasoline, including benzene, arsenic, lead, asbestos, vinyl chloride, chromium, and ethylene oxide. The state has listed urethane, found in red wine; a nitroso compound commonly found in bacon and other cured meats; and formaldehyde, found in a range of consumer products from toothpaste to mobile homes.

Once the state has listed a chemical, industry has 12 months before it must provide a "clear and reasonable" warning—package or shelf labels, signs, and the like. (The warning provision, which went into effect for the first 29 chemicals on the list in February 1988, applies to occupational exposures and ambient exposures in air or water as well as to consumer products.) And 20 months after a chemical is listed, the second part of the law kicks in: no company can knowingly discharge it into an actual or potential source of drinking water at a level that would pose a significant risk.

While the discharge provision of the law, which went into force last October, would appear to be more onerous for industry—it is an actual prohibition, not just a warning statute—almost all the debate has focused on the warning provision, which represents the most dramatic departure from current regulatory practices.

What sets this law apart from other state and federal laws—and what has aroused such industry ire—is that it shifts the burden of proof from the regulator to industry. If industry chooses to use a carcinogen or teratogen identified by the state, it bears the responsibility for determining whether the chemical poses a significant risk.

"It seems a reasonable thing to ask," says David Roe of the Environmental Defense Fund, the bill's principal author. "If you are going to use a known carcinogen, you should know the safe limit."

And the company may have to defend its scientific judgment in court, because as an enforcement measure the law provides for citizen suits—known derisively as the law's "bounty hunter" provisions because the citizen can keep 25% of the fines, which could be as high as $2500 a day. The state, however, has 60 days to decide whether to take on the suit itself, in which case the citizen cannot sue.

Whether the people of California actually knew what they were voting for is the subject of considerable debate. The bill, written by a consortium of environmental and consumer groups, was championed by Assemblyman Tom Hayden and his wife Jane Fonda, who enlisted the help of other celebrities—and a few million dollars—to sell their case, sometimes not on the surest

scientific footing. Industry countered with a $5-million advertising blitz.

Both sides served up a "parade of horribles," with epidemics of cancer and birth defects from pollutants on the one hand, and the loss of Silicon Valley on the other. Notes Warriner: "The campaign was not conducted under penalty of perjury."

But the bill's underlying message was clear. "The people of California find that hazardous chemicals pose a serious potential threat to their health and well-being, [and] that state government agencies have failed to provide them with adequate protection," reads the preamble to the law. The initiative passed by an overwhelming margin of 2 to 1, despite vociferous opposition from the governor, industry, and most of the state's newspapers.

The idea behind Proposition 65, says Roe of the Environmental Defense Fund, is to give industry a compelling incentive to remove nonessential carcinogens and reproductive toxins from its products and processes. And it does so with very little arm twisting. If the choice is warning or finding a new chemical, explains Roe, most companies will opt for the latter.

It is, says Tom McGarrity of the University of Texas Law School, who was consulted during the drafting of the proposition, Adam Smith's invisible hand at work. "The free market economy is predicated on the informed consumer. It is the fundamental assumption about how markets work. The most conservative of theoreticians should love this approach."

In addition, says Roe, Proposition 65 provides a way around the roadblock that has stymied federal toxics regulation for years. "It gives both the regulators and the regulated an incentive to make decisions."

In 1976 Congress passed the Toxic Substances Control Act, or TSCA, designed to protect the public from hazardous chemicals. But in the past 12 years, says Roe, the Environmental Protection Agency has set regulatory limits—in essence, telling manufacturers how much is too much—for just 15 existing chemicals under TSCA. As Roe describes it, federal statutes like TSCA fail because they instruct EPA to regulate, but until the numbers are set, the law is not enforced. The result is endless wrangling over how much is too much, and endless debate over risk assessment techniques. "Prop. 65 takes effect anyway," says Roe, "so if government hasn't figured it out, industry must."

Not surprisingly, industry is clamoring for the state to set standards—"bright lines," as Roe calls them—so it will know whether it is in compliance. "Industry is saying I wish you would draw the line more leniently, but for God's sakes, draw it." As a result, "California has decided how much is too much. In 1 year, California has drawn lines for more than 40 chemicals, not because California is better scientifically but because suddenly there is a reason to do it."

Industry is far less enamored of the law, which they say will require warnings on thousands of products the federal government considers safe, thus diluting the effects of legitimate warnings. And, industry spokesmen say, companies will be held hostage by bounty hunters and their fates will be decided by lay juries uninformed about the intricacies of risk assessment and low dose extrapolation. They call the law duplicative, unnecessary, expensive, and a nightmare to comply with.

"How many regulatory systems are needed in this country to decide which products are safe and how to enforce it?" asks Sherwin Gardner, a former Food and Drug Administration official now with the Grocery Manufacturers of America, which has led the fight against the law. "Our view is that FDA has been doing just fine for over 80 years."

Industry spokesmen also maintain, as they have in a lobbying blitz before Reagan's Domestic Policy Council, that the costs of labeling and then separating products, making sure the labeled ones go to California and not Oregon, will be vast. And they warn that these costs will be passed on to consumers throughout the nation.

According to one creative economic analysis, which assumes that 90,000 products will require labels, the law is tantamount to a 2% tax on the food dollar of every person in the United States, posing an intolerable burden on interstate commerce. Thus, the case for preemption, along with the fact that Proposition 65 duplicates federal laws such as the Food, Drug, and Cosmetic Act.

Rubbish, says Warriner. At the 1:100,000 threshold the state set, very few products will require warnings. "If we had a food product that was that risky we would have taken it off the market." He predicts that perhaps 20 consumer products will require warnings and that no food products will—a far cry from industry's 14,000 or 90,000. He concedes that "there are lots of warnings in occupational settings, but those were needed."

As for the bounty hunter suits, instead of the predicted onslaught, only seven suits have been filed to date. And most of those, according to Craig Thompson in the attorney general's office, are not the glamorous, big-buck suits predicted. In one, for example, employees at a nursery sued the owner for leaving a pile of asbestos on the grounds. Environmental groups have brought only one action, which the state took over, suing 25 tobacco companies and eight retailers for providing inadequate warnings on noncigarette tobacco.

A Risk Worth Worrying About?

"Proposition 65 has nothing to do with public health," says Bruce Ames, a member of the governor's scientific advisory panel and one of the law's most outspoken critics. "Proposition 65 is based on the assumption that these chemicals are dangerous, but all science points against pollutants having much to do with public health." He calls the commonly accepted view that 3 to 4% of all cancers in the United States are due to environmental exposures "wildly exaggerated." Occupational exposures may account for some, he says; pollution, probably for none.

When half the chemicals tested, natural as well as synthetic, turn up as carcinogens, either the tests are measuring the wrong thing, which Ames thinks is a strong possibility, or carcinogens at these doses just are not that dangerous.

Moreover, says Ames, the significant risk threshold the state has set for Proposition 65 is incredibly low, and given the uncertainties of low dose extrapolation, it could actually be far lower. Chemicals are tested at high doses, often the maximum tolerated dose, he points out, and then effects are extrapolated to a dose 100,000 times smaller. This means, in essence, that a risk of 1:100,000 may in fact be as low as zero.

On the basis of his arguments, the scientific advisory panel attaches the "Ames caveat" to every chemical it recommends listing. In light of those uncertainties, reads the caveat, it is important to set a "de minimis" level below which one simply does not worry about a chemical. And the panel sets that level at a risk of 1:10,000, the logic being that EPA has decided that this is an acceptable risk for chloroform, an animal carcinogen used to chlorinate drinking water. The state, however, opted for a threshold ten times lower.

Ames' common refrain is to ignore pollution, which he considers a red herring, and focus on the real culprits like diet, sunlight, and tobacco. ■ **L.R.**

This is not to say that compliance with Proposition 65 does not have its costs. It clearly does, as companies review their products and perform risk assessments. And under the new law, occupational standards are in many cases more stringent than federal standards. But most of Warriner's time in the past 2 years has been taken up by trying to ensure that industry's worst fears do not materialize. He has done so in a remarkably open process, circulating draft regulations and inviting industry and environmentalists in to talk. That he has succeeded is evident from the praise, and a few gripes, he has earned from both camps.

And in the process, Warriner, the lead man in a Republican administration that fought the initiative, has become something of a convert. Says Warriner: "There is nothing inherently wrong in telling people if you expose them to chemicals at high levels."

As Warriner sees it, the intent of the law is to focus on chemicals that might pose a major risk and "not to drag in the whole world." That is why the state set the threshold for a significant risk at 1:100,000, more lenient than many federal regulations and halfway between what the environmentalists and industry representatives wanted.

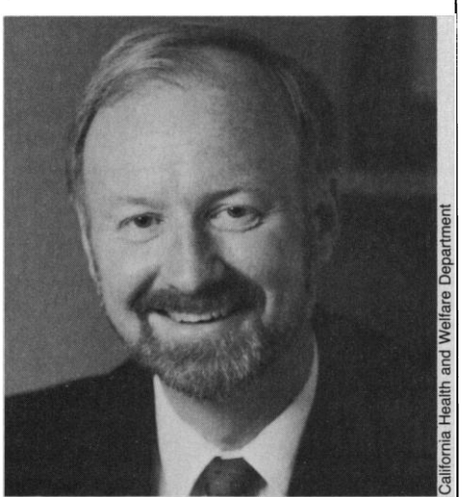
Similarly, the state has exempted naturally occurring substances, like arsenic in carrots, assuming that the law meant to focus on chemicals that industry can do something about. And to provide some certainty to industry as it performs risk assessments on 50 widely used chemicals, the state temporarily adopted FDA standards for foods, drugs, cosmetics, and medical devices.

To his credit, Governor Deukmejian, who campaigned vigorously against the law, has turned over the scientific decisions to scientists, appointing an advisory panel of 12 eminent scientists to recommend which chemicals the state should list as carcinogens and reproductive toxins. While many on the panel agree with Ames' criticism that the law is focusing on trivial problems, at least to some extent, they have taken their task seriously, logging long hours and pouring through file cabinets full of risk assessments. The panel started first with those carcinogens identified by the International Agency for Research on Cancer and the federal National Toxicology Program, and have been adding to the list as they see fit.

Just how many products now have warnings, almost 1 year after the provision took effect, is for some reason a closely guarded secret. John Gray of the Ingredient Communication Council, an offshoot of the Grocery Manufacturers of America, declines to say how many consumer products now carry warnings or if those warnings are required by law, though he is in an excellent position to know. The ICC runs a hotly contested toll-free telephone system in California set up to provide consumer warnings under Proposition 65. Some 45 companies use the 800 number in lieu of product or shelf labels to provide information on about 10,000 consumer products.

The question is not simply how many products will require warnings, but whether industry will slap warnings on products that don't need them. Michele Corash, former general counsel for the U.S. Environmental Protection Agency and now an attorney for the well-heeled Environmental Working Group, an industry lobbying group set up to deal with Proposition 65, insists that the only way companies can protect themselves from suits is to provide a warning on any product that contains even a trace amount of a listed chemical, whether or not it exceeds the state's threshold. Despite Warriner's assurances to the contrary, the Environmental Working Group and several other trade groups have counseled their members to do just that, a move that Tom McGarrity, for one, sees as a deliberate attempt to sabotage the law.

Not all companies are buying this approach, however. Chevron Chemical Co., for example, decided early on that it would provide warnings for only those products that pose a significant risk, says Nancy Reyda, who has been coordinating the company's response to the new law.



Tom Warriner. *Making sure the horror stories do not materialize.*

To Warriner, it is tough to see what all the grumbling is about. If industry is complying with existing laws, he says, then Proposition 65 makes little difference.

Roe thinks he knows why industry continues to rail against the law. It is not where the line is being drawn; rather, it is that lines are being drawn at all. "10^{-5} is one order of magnitude more lenient than what FDA and EPA purport to do, but it is far more stringent than what they actually do. And that is what makes Prop. 65 threatening: it closes the gap between theory and practice."

Food manufacturers, for example, assert that federal regulations protect the public adequately, but for some of the carcinogens California has listed, including vinyl chloride, benzene, chromium, and arsenic, FDA has no standards.

Some of industry's complaints, however, are clearly legitimate—namely, that the exposures allowed under the law for reproductive toxins are unworkable. The law sets the allowable dose for reproductive toxins at 1000 times lower than the "no observable effect level." And unlike the provisions for carcinogens, which allow the state some flexibility, the 1000-fold safety factor, as it is called, is inscribed in stone and can only be changed by a two-thirds vote of the state assembly. This might mean that vitamin D in milk, for example, would exceed the allowable limit, and a plethora of consumer products and over-the-counter drugs would likely require warnings.

Roe now concedes that the standard is too stringent and too inflexible, and negotiations are under way to amend the law, perhaps as early as this month, an example of the reasonableness that has characterized the implementation process.

Despite extensive lobbying, industry spokesmen failed to convince White House economists that the law has caused any significant economic disruption. "We could not find a clear case where industry had suffered any marketing problem because of Proposition 65," says Al Jennings of EPA, speaking for the White House Council of Economic Advisers, which in December completed an analysis of the law's economic cost for the Domestic Policy Council.

This is not to minimize the potential economic impact, says Jennings. "So much depends on how California issues the implementing regulations. It is too soon to tell what it will look like. We agree, if the state does certain things, it could be expensive. But those are a lot of 'ifs.' From what we have seen so far, rationality still prevails among the environmentalists and within state government." For the time being, the CEA recommended that the situation warrants watching but nothing more.

"If it ain't broke, don't fix it," is the view of Jack Moore, EPA's representative on the Domestic Policy Council's task group. The domestic council, however, is examining more than the costs of the law. As *Science* went to press, it was not clear whether the Reagan Administration, in its last days, would make a decision—there is reportedly considerable pressure for preemption—or pass the buck to President-elect Bush.

But is the law actually doing anything to protect public health? Without question, says Warriner, citing the fact that California now requires warnings on alcohol and noncigarette tobacco, filling two loopholes in the federal regulatory system. "The law is reaching where we couldn't otherwise," says Warriner.

Alcoholic beverages are a major cause of birth defects in the United States, but bills to require warnings had repeatedly died in the U.S. Congress. In October warning signs went up in stores, bars, and restaurants throughout California. A few months later Congress enacted a law requiring warning labels on all bottles of alcoholic beverages.

For tobacco, although warnings on cigarettes have been mandatory since 1965, roll-your-own tobacco, pipes, and cigars have escaped such federal scrutiny. "That was a conspicuous federal loophole for 25 years," says Roe. "Prop. 65 closed it in 3 weeks, over the objections of one of the most powerful lobbying groups in the country."

The other effect of the law, which is harder to quantify but is perhaps just as significant, is what Roe calls industry's "quiet compliance," which he says far outweighs the vocal grumblings about the law. Without fanfare, businesses in California have been reviewing their products and processes to see if they can reduce or replace toxic chemicals. And that, says Roe, was the true intent of the law—not to provide warning but to provide products that don't need warnings. Chevron, for example, is reviewing its entire product line. The company is perhaps exemplary, but it is also very visible. Of the 50 or more Ortho consumer products and agricultural chemicals Chevron has checked to date, none requires a warning, says Reyda, bolstering Warriner's claim that few products, in fact, will.

None of this addresses the larger question of whether it is in society's best interest to spend its time and money chasing the last microgram of a toxic chemical (see box). But California has clearly decided that it is, and society does not necessarily make these decisions on purely scientific grounds. The people of California did not ban products that contain toxic chemicals. They simply said, "Give us the information and let us decide if we want to accept the risk."

"Whether it will produce a safer environment, a reduction in cancer, I don't know," says Warriner. "There have been warnings on cigarettes for a long time. People are entitled to make bad choices."

Just what Proposition 65 will mean for California will probably not be clear for a few years. The drinking water regulations are not out in final form, and the state is still wrangling with industry and environmental groups on such details as where to measure discharge. For many listed chemicals, the grace period has not yet expired, and only industry knows how many will ultimately require warnings. The state has not lifted the temporary exemption for food products, and until it does, manufacturers will continue to worry that the new law will be more restrictive than FDA regulations.

But judging from the state's past performance, few surprises should be expected. Although there were some bumps in the road during the first year, even industry representatives concede that implementation has been smoother than they anticipated and that their worst case scenarios have not materialized. "I have no doubt we will get through this and people will understand risk better," says John Hunter of the Environmental Working Group. "David Roe is getting his bright lines, whether we like it or not."

■ LESLIE ROBERTS

Watkins Named Energy Secretary

Retired Admiral James D. Watkins will succeed John S. Herrington as secretary of the Department of Energy. Watkins, 61, takes over the department at a time when its nuclear weapons manufacturing complex is deteriorating and when there is mounting pressure on DOE to clean up sites contaminated by these operations.

President-elect George Bush acknowledged that he selected Watkins for the job in part because of his background in nuclear energy. Watkins served under Admiral Hyman Rickover, who guided the Navy's development of nuclear propulsion, in the early 1960s. He trained at the Navy's reactor school at West Milton, New York, and is a graduate of Oak Ridge National Laboratory's reactor training program. In addition, Watkins has commanded a nuclear attack submarine and nuclear cruiser. Watkins served as chief of naval operations between 1982 and 1986, before retiring.

James D. Watkins. *Will head energy department.*

It is expected that the operation and modernization of DOE's defense production program and related cleanup problems will be a top priority for Watkins. One pressing issue Watkins will have to deal with is restarting one or more of DOE's heavy water reactors at Savannah River to produce tritium, which is needed for the nation's nuclear warheads. Watkins has said that he will not compromise on safety in the operation of defense production plants.

Watkins, who also holds a master's degree in mechanical engineering, may have the strongest technical background of any top DOE administrator to date. But his administrative skills may have been a larger factor in his selection than his technical experience. He is regarded as a sensible, get-the-job-done administrator, according to knowledgeable executive branch officials.

Most recently, he headed the Presidential Commission on the Human Immunodeficiency Virus and he is credited with rescuing the panel's effort, which had been mired in internal strife.

The nomination of Watkins to the energy post has been praised by electric utility executives and the nuclear power industry. Watkins has pledged to try to revitalize nuclear power as an energy supply option for the United States. He serves on the board of the Philadelphia Electric Company.

Petroleum industry officials had hoped Bush would pick someone who understood the needs of American oil and gas producers. Bush stated publicly that he has urged Watkins to hire a deputy secretary with a strong background in fossil fuels, particularly oil and gas—an area where Watkins says he has little knowledge.

Environmental groups are responding coolly to Watkins' nomination. "From all accounts, he is a very fair and scrupulous man," says Dan W. Reicher, an attorney at the Natural Resources Defense Council. "We are concerned, however, about his military orientation. We are worried that under Admiral Watkins the cleanup of nuclear wastes is going to continue to take a back seat to nuclear weapons production."

■ MARK CRAWFORD