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ECONOMIC ANALYSIS OF PROPOSITION 65

Submitted by the Working Group on the Economic Costs of Proposition 65 to the Working Group on Federal Preemption

Summary of Analysis

This Working Group has attempted to assess the magnitude of the economic costs that have been or are likely to be imposed upon persons outside of California by that state's Proposition 65. 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. Unfortunately, there is not yet sufficient data available to offer an accurate estimate of the magnitude of those costs.

The implementation of this law is in a relatively early stage, and it is possible that over time, as the structure of implementing regulations is more fully articulated, and as affected companies make the adjustments needed for compliance, more substantial burdens on interstate commerce will result, perhaps in quite sudden fashion. We therefore recommend that the conclusions of this Working Group be periodically reassessed by Federal officials as more information becomes available, and that the Federal Government take steps to determine how quickly it could act to preempt the Proposition 65 warning requirements should it become advisable to do so.

Discussion

I. Introduction

Claims have been made by representatives of the food industry, the cosmetics industry, the over-the-counter drug industry, and others that the portions of California's Proposition 65 that relate to the exposure of consumers to carcinogens and reproductive toxins impose a substantial burden on interstate commerce which justifies Federal preemption. This Working Group has attempted to assist in evaluating these claims by ascertaining the economic costs that these provisions of Proposition 65 have imposed on persons outside of California, and by identifying the circumstances under which the law may in the future impose substantial costs upon non-California persons.

Proposition 65 imposes separate and distinct warning requirements for products containing chemicals listed by the state of California as known carcinogens, and for those containing chemicals listed as known reproductive toxins. This analysis will therefore consider separately the economic effects of each of those two requirements.

The Working Group has met with various trade associations, a representative of the Environmental Defense Fund, and representatives of over half a dozen companies. The industry organizations have expressed strong concern as to the impact of Proposition 65. The company representatives almost unanimously asserted that faced with a listed chemical that was unavoidably contained in a product in sufficient concentration, they would choose to label for California alone rather than either label nationally or withdraw from the California market. The California market was viewed by them as too important to abandon.

Given that under those circumstances they would choose to label only a portion of their output, their major concern stemmed from the costs of having to segregate products intended for California distribution from those intended for distribution in the rest of the country. In most cases, their existing distribution systems could not achieve the segregation. They claim, undoubtedly accurately, that their inventory costs would rise as well.

The companies also expressed concern about keeping unlabeled products from being transferred to California, opening them up to potential liability, as well as about the effect on sales of having products labeled for California turn up on the shelves in other states. They were concerned as well with the impact that future law suits claiming their products contained substances causing cancer or reproductive harm would have on their sales.

It should be noted that a potentially significant cost that might result from labeling is that consumers could be mislead about risk. Existing products meet Federal standards, and the Proposition 65 labels could lead consumers to believe they are less safe than is in fact the case. If labeled products are sold outside of California, then consumers may switch to unlabeled products which might contain more of the specified chemical than the labeled product. We have not tried to quantify the cost of any misinformation that Proposition 65 may provide, but it could be significant, especially in California. If California's labels interfere with consumers' understanding of Federally required labels describing true risks, preemption may be required. Since no Proposition 65 labels are now being provided, it is premature to consider this issue.

II. Economic Costs Imposed Upon Non-California Persons by the Carcinogen Warning Requirement.

A. Existing economic costs.

The economic costs imposed thus far upon non-California persons by the carcinogen warning requirement appear to be relatively minimal. Interim California regulations exempt all FDA-regulated products from those requirements, and allow the alcoholic beverage warning requirements to be satisfied through the posting of signs on the sale premises. Additional protection is also provided many producers through their participation in a toll-free telephone information system, although this regulation-endorsed system is now subject to court challenge which may well result in its invalidation as a means of sufficient warning. While at least two major California retailers (Safeway and Von's) have publicly announced that they will not post shelf signs for consumer products, and will instead require producers to provide product labels or certification of product compliance, we are not aware of any producer (with the exception of the tobacco companies discussed below) who has either labeled its products with carcinogen warnings, or has withdrawn those products from the California market.

A Proposition 65 lawsuit filed against the cigar and tobacco manufacturers has been recently settled on terms that will require such manufacturers to label all of their California products with carcinogen and reproductive toxin warnings. Indications are that the primarily national-scale producers of such tobacco products intend to incorporate Proposition 65-conforming labels nationwide, so as to avoid incurring substantial segregation of products distribution costs, and thus are likely to incur only minor added label redesign costs.[1]

B. Potential future economic costs.

While Proposition 65 has of yet only had minimal impact, it is likely that its impact over time will be more substantial. Several foreseeable future events, if they come to pass, will potentially increase the impact of the carcinogen warning requirements on out-of-state producers. First, the toll-free telephone information system could be judicially determined in pending litigation to provide inadequate warning, an outcome we regard as likely. Second, the interim exemption now available for FDA-regulated products could be superceded by numerical standards for exposure levels for individual chemicals, also a likely prospect. Third, California is likely, over time, to add new chemicals to the carcinogen list, possibly including some commercially important pesticides.

Assuming for the sake of argument that all of the above events occur, the economic impact upon non-California persons will depend upon the producer responses. Assuming further, as

seems reasonable, that most or all producers would choose not to withdraw their products from the significant California market if this can be avoided, they would be forced to choose from among the following options:

1. Implementation of quality control procedures sufficient to assure that all products sold in California do not contain concentrations of any listed carcinogenic chemicals sufficient to require warning labels. This may include monitoring suppliers or even switching sources of supply;

2. Labeling of all products sold anywhere in the U.S. that contain sufficient concentrations of listed carcinogenic chemicals with Proposition 65-conforming warnings; or

3. Labeling of only those products intended for distribution in California, and that contain sufficient concentrations of carcinogenic listed chemicals, and segregation of those products during distribution from those to be distributed elsewhere.

On the basis of discussions with a number of representatives of producer firms or their trade associations, it appears to us that very few products (tobacco excepted) contain levels of listed carcinogens sufficient to require warnings under the numerical exposure standards likely to be imposed by California once the interim exemption for FDA-regulated products is lifted. However, food industry representatives claim that the level set for Dieldrin, a pesticide no longer in use, would require labeling for virtually all products containing fruits and vegetables, as well as for raw produce. Standards for other pesticide compounds may be set quite close to the persistent "background" levels stemming from prior use. Whether the "naturally occurring" exemption is interpreted to cover concentrations resulting from earlier human activity may have a major impact on the burden. The current definition specifies that only chemicals that do not result "from any known human activity other than ordinary cultivation practices" are considered to be "naturally occurring."

California's final exposure standards may well be no more restrictive than current FDA requirements, and may be more lenient than those existing FDA standards by roughly an order of magnitude, although this claim has been strongly disputed by some industry representatives who have argued that issuance by California of exposure standards more stringent than those of Federal law is almost inevitable. The costs imposed by the cancer-warning provisions of the law may be primarily of the nature of product testing and quality control expenditures, rather than what appears to be the more substantial labeling and product segregation outlays.[2] However, if very stringent exposure standards are in the future applied by California,

particularly to any newly-listed and commercially important pesticides, cancer warning labels may be required for a large number of products, rather than only quality control measures.

These quality control expenditures may prove to be fairly substantial, given the need to test individual product batches for a large number of low-concentration chemicals,[3] and given the problems faced by manufacturers of controlling the quality of inputs received from numerous raw material suppliers. As an example of these type of costs, one company has told us that to meet the standard for aflatoxin, a naturally occurring carcinogen, they have given up using certain kinds of peanuts and are spending more on screening the peanuts after purchase. This company asserts that they cannot separate their peanut butter produced for California from that sold elsewhere. That company has spent $1.2 million in the last few months on ensuring that only peanuts with less aflatoxin are used. They estimate that their ongoing annual costs to meet this California standard will be $3.5 million. If other companies follow this lead and purchase only peanuts with low levels of aflatoxin, the price of such peanuts will rise while the price of other peanuts fall.

It must be kept in mind that firms now have in place extensive quality control and testing procedures designed to assure compliance with Federal standards. Only the marginal added costs of more comprehensive and/or sensitive procedures sufficient to comply with the Proposition 65 standards are probably attributable to that statute. Even if these marginal added quality control costs are substantial, much or even most of these costs are likely to ultimately be borne by California consumers rather than by either the producers or the non-California consumers of those products. The precise allocation of the costs among these groups depends upon the elasticities of supply and demand in the relevant California product markets,[4] and upon the degree of competition from producers who do not sell in California that faces national producers in their non-California markets. At this time, there is insufficient information available concerning those parameters to accurately estimate either the total amount of likely marginal added quality control expenditures, or the portion of those expenses that will be borne by non-California persons.[5]

Any quality control measures undertaken are unlikely to be 100 percent effective, and some products sold may subsequently be determined (in litigation) to have contained sufficient levels of carcinogens to require warnings.[6] Some penalties may consequently have to be paid by producers, and adverse publicity resulting from those lawsuits may injure sales.

To the extent producers instead choose to label products on a nationwide basis--a course of action that appears to us unlikely outside of the tobacco industry, given the realities of marketplace competition with unlabeled products outside of

California--the costs are likely to be minor, consisting only of a one-time label redesign outlay.[7] If, however, some producers choose to label only those units of products destined for California, and not those destined for sale elsewhere, they may incur substantial added distribution and inventory costs. However, a major portion of those costs are likely to be borne by California consumers, given the relevant California price elasticities, and given the effect of competition in non-California markets in restraining price increases in these markets. Again, the precise allocation of these costs between producers and California consumers depends upon the elasticities of supply and demand in the relevant California markets.

If national producers choose the labeling and segregation option, this will provide a slight advantage for producers who produce only for the California market, and who thus need not incur segregation expenses. However, this cost advantage is likely to be relatively small in magnitude and benefit only a small proportion of the producers.

We have been provided with an economic analysis of the costs of Proposition 65 that was prepared by (research group) for a national grocery group. That study estimates the total cost of out-of-state food producer compliance with Proposition 65 to be approximately $200 million per year, and that between 35 percent and 70 percent of that cost will not be shifted forward to California consumers in higher prices, but will instead come out of producer profits.

However, for a number of reasons this estimate appears to us to vastly overstate the potential impact on producers. First, and most importantly, the study assumes that all processed food items will be labeled and segregated from production not destined for California, when in fact many items (for example, meats and shipments to food service establishments) which may total 45 percent of more of all shipments are not even governed by the retail product labeling requirements of Proposition 65. Second, for those products potentially covered by the Proposition 65 labeling requirements, as discussed above most do not contain carcinogen levels sufficient to justify warnings. Third, for those products which may contain sufficient carcinogen levels to require warnings, producers will likely, if it is possible at reasonable cost, utilize better quality control measures rather than more costly labeling and product segregation. Fourth, the demand elasticities estimated by (res. gp.) are presented in misleading fashion so as to suggest higher demand elasticities and less shifting of costs to California consumers than would likely be the case.[8] Finally, the study attaches undue weight to regression coefficients that suggest only partial cost shifting, when those coefficients are in fact not significantly different (even at the 90 percent significance level) from coefficients which would imply that all costs were shifted to California

consumers. On the whole, the Lexecon study must be taken as an unlikely worst-case scenario.

We were also provided with a similar study done by the Research Group B. That study estimated the added costs of Proposition 65 at $95 million annually. However, that study utilized many of the same unrealistic assumptions used by the Lexecon study regarding the scope of the coverage of Proposition 65, and the likely producer responses. The RG B study did not address the allocation of the cost burden between producers and California consumers.

In estimating the potential cost of Proposition 65 on the rest of the economy under the pessimistic assumption that substantial labeling will be required, it is critically important to accurately estimate the relevant elasticities of demand and supply. The relevant demand elasticity is not that facing an individual producer or seller in California, which may be quite high, but is the generally smaller elasticity of demand facing the importers of the product viewed as a group. Thus, if all the product is produced entirely outside of California, coffee being such an example, the relevant demand elasticity is the industry elasticity, which is estimated by USDA for coffee to be only -.19. In such a case, given a reasonable estimate of the industry supply elasticity, say 2 (to be conservative), less than 10 percent of the cost imposed by Proposition 65 would be borne by the suppliers; the remainder would be passed on to California consumers.

In summary, we are of the view that the future costs for food products of the Proposition 65 carcinogen warning requirements are likely to be primarily of the nature of additional quality control expenditures, rather than labeling expenditures, and consequently are likely to be smaller in magnitude, and in any event will be borne in large part by California consumers through higher prices. This conclusion presumes, however, that California does not subsequently list as carcinogens and adopt highly stringent exposure standards for any widely used pesticides.

However, the over-the-counter industry may face more substantial problems. It seems likely that California may list ethanol, aspirin, and saccharin as either carcinogenic or causing reproductive harm. If so, many if not most over-the-counter drugs may be required to be listed. Since many of these preparations come in a multitude of sizes and different forms, labeling and segregation could become quite expensive.

Even if one assumes that substantial numbers of products will require labeling and segregated distribution systems, the costs of Proposition 65 that will be borne by out-of-state producers will only amount to a very small percentage of their

California sales revenues. For example, accepting as accurate (res. gp.) estimates that California annually imports $8.8 billion of processed foods, and that labeling and segregation costs for labeled products will amount to between one and six percent of their sales values, if one arbitrarily assumes that 10 percent of such foods will have to be labeled (probably a high estimate even for the worst case), the total annual cost of labeling and segregation will be between $8.8 million and $52.8 million. If on average the elasticity of demand for imported foods is -1, and the elasticity of supply is 2, then one-third of this cost will be borne by out-of-state producers, or roughly $2.9 million to $17.6 million, a "tax" on the industry of only about 0.03 percent to 0.2 percent of the value of California sales.

III. Economic Costs for Non-California Persons of the Reproductive Toxin Warning Requirement

A. Existing economic costs.

The economic costs imposed thus far upon non-California persons by the reproductive toxin warning requirement also appear to be relatively minimal. We are not aware of any product that has been labeled with such a warning, or that has been withdrawn from the California market to avoid having to give such a warning. (Although, as discussed above, cigar and pipe tobacco will shortly carry such a warning label.)

B. Potential future economic costs.

There is a potential for substantial economic costs to ultimately result from the reproductive toxin warning requirement. The warning-triggering levels of such toxins are statutorily set at a low level equal to 1/1000 of the "no observable effect level," and no interim exemption is available for FDA-regulated products. The application of this standard to the listed reproductive toxin lead poses special concern, since the warning level standard is so low as to approach "background" environmental levels. The California regulations do provide an exemption for that portion of toxin concentration which was "naturally occurring" in the raw materials, but that exemption is of uncertain scope, may be difficult to establish in practice, and is inapplicable to cosmetics or over-the-counter drug products. An additional potential concern is that aspirin or vitamin A could conceivably be added to the reproductive toxin list.[9] If so, labels would be required for a number of items, since those chemicals' concentrations in products that utilize them far exceed the level requiring a warning label. The addition of certain commercially important pesticides to the list could also lead to labeling of significant numbers of products.

Legislative efforts to amend this statute to introduce flexibility into the application of the reproductive toxin warning requirements have thus far proven unsuccessful, but are

ongoing and have some support from Proposition 65's major environmental group advocates. If those efforts continue to be unsuccessful, it could well be that significant numbers of products would have to be labeled with reproductive toxin warnings on account of their lead concentrations, and perhaps also because of pesticide concentrations. If so, substantial labeling and segregation costs would result. However, again, such costs would be borne to a large extent by California consumers.

V. Conclusions

The Proposition 65 carcinogen and reproductive toxin warning requirements have to date imposed relatively minor costs upon non-California persons. There is a potential, however, for the future costs of those requirements to be substantially higher, the level depending primarily upon the stringency of the numerical carcinogen standards ultimately adopted by California, the nature of any new carcinogens or reproductive toxins subsequently listed, and upon the ability of producers to meet whatever reproductive warning standards are finally imposed upon lead or pesticide concentrations in products. We thus recommend that the application by California of Proposition 65 be monitored by Federal officials on an ongoing basis, and that the conclusions of this Working Group be periodically reassessed as that experience dictates.

In meeting with industry and environmentalists we are hearing conflicting testimony as to the reasonableness of California's risk assessment methods. We were told by some persons that the resulting standards for carcinogens would be less strict than Federal standards, and by other persons that they would be more strict. California has completed about six such risk assessments. We recommend that FDA and EPA examine these risk assessments to determine how reasonable their methodology is, and how their outcomes compare to Federal standards.

We also recommend that the FDA and other relevant agencies determine how quickly they could act to preempt the Proposition 65 warning requirements, should the costs imposed by that statute on non-California persons increase to a level sufficient to justify such action, so that Federal officials can better determine what preemptive action would be necessary when they were presented with certain and sufficiently large harms that clearly call for such action.

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Footnotes

1. The FDA has estimated such costs to range from $100 to $570 (in 1984 dollars) per product label, depending on the nature of the packages.

2. The Working Group has undertaken a questionnaire survey of approximately 100 major producers of foods, cosmetics, or over-the-counter drugs for the California market concerning their responses to Proposition 65. No results are as yet available from this survey.

3. Hazelton Laboratories, in a study done for The Proprietary Association, estimated that the cost of a full test of a product sample for all listed chemicals, using currently available analytical techniques, would be approximately $6,000.

4. The higher the elasticity of demand, the smaller the proportion of producer costs that can be passed on to California consumers. Similarly, the lower the elasticity of supply, the smaller the proportion of producer costs that can be passed on to California consumers.

5. A preliminary analysis of Proposition 65 conducted by the Department of Agriculture estimated that only 11 percent of the cost burden of that law will be borne by out-of-state producers rather than California consumers.

6. It seems possible, however, that the courts may rule that quality control measures need only be reasonably effective, rather than perfect, for manufacturers to avoid being found to have "knowingly and intentionally" caused exposures to carcinogens. If so, manufacturers may not be found liable for isolated non-labeled exposures.

7. See Footnote 1, Supra.

8. A preliminary analysis of Proposition 65 conducted by the Department of Agriculture has concluded that only about 11 percent of the cost burden of Proposition 65 will be borne by out-of-state producers, rather than the 35 to 70 percent estimated by Lexecon.

9. There is some question whether the FDA pregnancy nursing warning rules would preempt the application of the reproductive toxin warning requirements to aspirin products.