

CLEARY, GOTTlieb, STEEN &amp; HAMILTON

September 15, 1978

MEMORANDUM TO ROBERT C. BARNARD, ESQ.

Re: Proof of Irreparable Harm  
Arising From Issuance of  
the OSHA Generic Regulations

Proof of irreparable harm as the basis for a motion for stay or preliminary injunction of OSHA's generic carcinogen regulations, and for supporting affidavits, can be derived from the following subject matter areas:

1. The need to make capital investment and other business decisions as a result of the possibility of classification in Category I

It would be useful if it could be demonstrated that the possibility that a substance will ultimately be classified as a Category I carcinogen will force a company producing or using it to make irreparable, and potentially injurious, business decisions once the generic regulations are issued in final form.

For example, a company may suspect that a substance it produces or uses will ultimately be classified as a Category I carcinogen under the criteria specified in the generic proposal, even though it disagrees with the appropriateness of such classification. Such a company might then face a number of alternatives. It could begin to set aside the funds which would be required to comply with OSHA regulations, assuming Category I classification in a subsequent individual rulemaking. It could actually invest in the installation of required engineering or work practice controls, or in the research and develop-

ment generated by the suitable substitute provisions. Such investment at the present time, i.e. at the time the generic regulations are issued in final form, may be deemed necessary to avoid a slowdown or halt in operations at the time of individual substance classification, or to allow a more long-term distribution of capital expenditures. Alternatively, the company could decide to wait until the actual categorization is made before investing any of its funds in achieving compliance. Even if this alternative is pursued, however, it might still be necessary to allocate funds in the event that substantial investments are required at a later date.

In the event that the substance is not ultimately classified as a Category I carcinogen, unnecessary investments might have been made, or investment in other desirable projects might have been foregone. In short, the uncertainty arising from the possibility of classification in Category I will have immediate, concrete, and irreparable effects upon the operation of one's business. Cf. Abbott Laboratories v. Gardner, 387 U.S. 136, 152-53 (1967); U.S. v. Storer Broadcasting Co., 351 U.S. 192, 200 (1956); Frozen Food Express v. United States, 351 U.S. 40, 43-44 (1956).

2. Other uncertainties pending final classification of individual substances

The uncertainties arising from the possibility of ultimate Category I classification could have other immediate and irreparable harmful effects upon a business. The possibility that a substance will be classified in Category I, especially if it is a substance on the Clement Associates list, could generate a great deal of adverse publicity for producers or users of that substance. If the substance

is later determined not to be a Category I carcinogen, unjustifiable and irreparable harm will have been done to the business.

The results of such adverse publicity could include cancellation of or failure to renew contracts for the use of a suspect substance, a rise in business insurance premiums (e.g. product liability insurance), difficulties in arranging for transport of the substance or imposition of extra packaging precautions as a prerequisite for such transport, a decline in investment in a business heavily dependent upon a suspect Category I carcinogen, and adverse effects on relations with employees, thus impairing the efficiency of operations, due to fear of working with a particular substance. Proof of adverse effects such as these, which would seriously disrupt business operations, might furnish the required showing of irreparable harm. Cf. Columbia Broadcasting System, Inc. v. U.S., 316 U.S. 407 (1942); A. O. Smith Corp. v. FTC, 530 F.2d 515, 524 (3d Cir. 1976).

3. Inability to contest policy determinations foreclosed in the generic rulemaking proceedings in subsequent individual rulemakings

OSHA stated in the preamble to its proposed regulations that it "will not . . . modify its policies in actions taken subsequent to the promulgation of, and pursuant to, these regulations." 42 Fed. Reg. 54149 n.2 (October 4, 1977).

"OSHA's policy and factual judgments, based mainly 'on the frontiers of scientific knowledge' with a 'command to act,' will be established after opportunity for full public participation in this rule-making, and any future amendments thereto, and will not be allowed to be relitigated in the 'standard-by-standard or substance-by-substance process.'" 42 Fed. Reg. at 54155 (emphasis added).

Among the policy determinations which have been reached in the proposed generic regulations, and which, if included in the final

regulations, could not be contested in subsequent proceedings, are the following: (1) workplace exposure limits must be set at the lowest feasible level; (2) there is no threshold or no effect level; and (3) the requirement that "suitable substitutes" be used for Category I carcinogens.

Because policy determinations such as these will be definitively resolved in the generic rulemaking proceeding, those subject to regulation will be irreparably injured if they do not have an opportunity to seek judicial review of those policy determinations and a stay of the generic regulations pending such judicial review. Absent such a stay, both OSHA and other federal agencies will begin implementing and relying upon the policy determinations made in the generic rulemaking in a manner which immediately and irreparably injures manufacturers and users of chemicals (as described more fully above) which could eventually be classified in Category I.

4. The absence of an adequate draft or final environmental or economic impact statement with respect to the generic regulations

OSHA has asserted that it is not possible to adequately assess either the environmental or economic impact at the generic rulemaking stage. These assessments, according to OSHA, will be made in subsequent rulemakings on individual substances.

However, as the draft AIHC brief points out, there is substantial support for the proposition that a thorough environmental (and economic) impact assessment must be made at the outset of a generic or programmatic government action which will result in a series of environmental impacts. See, Natural Resources Defense Council,

Inc. v. Nuclear Regulatory Commission, 539 F.2d 824, 7839 (2d Cir. 1976).

Thus, unless a stay is granted with respect to the generic regulations pending completion and circulation of an adequate EIS and economic impact assessment, the plaintiffs seeking the stay will be deprived of their opportunity to submit the critical commentary and objective data which OSHA is required to consider prior to taking action at the generic stage.

Opportunity to submit such materials during individual rule-making proceedings will not compensate for the loss of an opportunity to participate in the evaluation process at the generic stage. First, certain policy determinations will be foreclosed in the generic proceedings, and will therefore not be the proper focus of assessments in individual rulemakings. Second, the assessments during individual rulemakings will not address the impact of the generic program as a whole. Third, OSHA will continue to make, as it has done to this point, irretrievable commitments of resources to the generic proposal and its underlying policy determinations and classification criteria.

5. The effect of the generic proposal on the actions of other federal agencies

It is clear that the policy determinations, classification criteria, and criteria for animal test adequacy developed in the course of the generic rulemaking will have a substantial effect on the regulatory programs of agencies other than OSHA. Thus, CPSC has already begun to implement its carcinogen program, and has applied it to at least one individual substance. The CPSC policy demonstrated marked similarities to OSHA's proposal, and reliance thereon seems apparent.

A similar "snowballing" effect can be expected with respect to the work of FDA, EPA, IRLG, and other agencies. Thus, even though there will be an opportunity to seek judicial review of some of OSHA's determinations in subsequent individual rulemakings, other agencies will begin (indeed, have already begun) to implement the determinations made in the generic proceeding prior to such individual rulemakings. Though obviously attenuated, the growing bias and commitment on the part of other agencies toward OSHA's questionable policies and factual determinations may furnish an element of irreparable harm.

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