GEORGETOWN UNIVERSITY LAW CENTER
WASHINGTON, D.C. 20001

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10 April 1972

Hearing Clerk
Department of Health, Education and Welfare
Room 6-88
5600 Fishers Lane
Rockville, Md. 20852

This letter constitutes a formal objection to the Commissioner's order in the Matter of Paint Containing Lead, 37 F.R. 5229, March 11, 1972. These objections are legal objections only and do not constitute a request for a hearing. Our decision not to request a hearing, however, should in no way be construed as a waiver of our right to participate and to present evidence and legal argument should a hearing be granted on the objections, legally sufficient to justify the relief sought, of any other person.

I. WE ARE PERSONS ADVERSELY AFFECTED BY THE ORDER

a. Joseph A. Page is an associate professor of law at Georgetown University Law Center. He teaches a course entitled "Regulation of Hazardous Products" and a seminar entitled "Lawyering in the Public Interest Seminar." In this latter role he was the principle proponent of the Page proposal (36 F.R. 20986) which called for a ban (except for minute traces which no reasonable manufacturer could preclude from his product) of lead in paint packaged or intended for household use. He is adversely affected by the Commissioner's order inasmuch as the Page proposal was denied and substituted in its place was an order which only partially effectuates the mandate of the Federal Hazardous Substances Act (hereinafter referred to as the FHSA) in that it obviates the intent of Section 15 of that Act and is therefore contrary to the public interest. He objects as a public citizen who has consistently demonstrated an interest in the proper administration of justice. standing - class -

b. Anthony L. Young is a second-year law student at Georgetown University Law Center and was a fellow petitioner with Joseph A. Page (36 F.R. 20986). He objects for the same reasons as Joseph A. Page and additionally is the owner of one can of paint intended and packaged in a form suitable for use in the household which he submits, upon information and belief, contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film. He objects on behalf of all persons similarly situated. class action

c. Mary-Win O'Brien is a third-year law student at the Georgetown University Law Center and was a fellow petitioner with Joseph A. Page (36 F.R. 20986). She is adversely affected for the same reasons as Joseph A. Page and additionally is the owner of a bicycle which is an article intended for use by children which she submits, upon information and belief, bears paint containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the dried paint film. She objects on behalf of all persons similarly situated..

last
- all children?
- she is not a child
- all toke owners

d. Judith D. Fried is the mother of and legal guardian of Carrie Susan Fried, age two, and Matthew Evan Fried, age four months.. Carrie Susan Fried and Matthew Evan Fried are the possessors of numerous toys and other articles intended for use by children which their mother submits, upon information and belief, bear paint or other surface-coating materials containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the dried paint film. She objects on behalf of all others similarly situated.

II. PROVISIONS OF THE ORDER DEEMED OBJECTIONABLE

a. The provision denominated in the final order as Sec. 191.9 (a) (6) (i) (b).
b. The provision denominated in the final order as Sec. 191.9 (a) (6) (ii) (b).
c. The phrase in Sec. 191.9 (a) (6) (i) (a) reading "Is shipped in interstate commerce after December 31, 1973, and".
d. The phrase in Sec. 191.9 (a) (6) (ii) (a) reading "Is shipped in interstate commerce after December 31, 1973, and".
e. In order to ensure clarity, an order which the undersigned would not deem objectionable would read as follows:
(6) (i) Any paint or other similar surface-coating material intended, or packaged in a form suitable, for use in or around the household that contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film.
(ii) Any toy or other article intended for use by children that bears any paint or other similar surface coating material containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film.

III. GROUNDS FOR OBJECTION

The Commissioner has found that the health hazard from lead in paint for household use will not be effectively limited by cautionary labeling requirements. He has determined that 0.06 percent lead is the maximum level that will provide a margin of safety for children. He has determined that exterior as well as interior paints and surface-coatings must be provided for. By proceeding under the provisions of Sec. 2(q)(1)(B) of the FHSA he has automatically triggered the provisions of Sec. 2(q)(1)(A). Finally, the Commissioner has correctly concluded that the FHSA makes no exception for economic hardship on the affected industry. With these findings we have no quarrel. ?

A. The Commissioner Has Disregarded Section 15 of the FHSA

Section 15 of the FHSA provides for the repurchase of banned hazardous articles or substances. The final order of the Commissioner is written in such a way as to obviate the thrust of that provision and is therefore contrary to the intent of the Congress. The plain import of the order is that repurchase would only apply to those banned hazardous substances "shipped in interstate commerce after" the dates provided. This means that consumers, such as those objecting herein, are denied their right to refund under Section 15 (a)(3) of the FHSA.

The preface "Is shipped in interstate commerce" is unnecessary to the proper operation of the FHSA. Section 4(a) and (c) are automatically operative upon completion of the rule making. Shipment of a banned hazardous substance after an order has become effective is punishable as a misdemeanor under Section 5(a) of the FHSA. conclusion

facts The Commissioner has found that "paints and other surface-coating materials do not present an imminent hazard to the public health." When 29 percent of the children tested in the District of Columbia in 1971 were found to have elevated blood-lead levels and when those blood-lead levels can be correlated directly to the ingestion of peeling and flaking paint in housing, the Commissioner's finding is, at best, questionable. Perhaps the mother of a young child who is now permanently institutionalized in a mental hospital could shed some reality on the situation. Section 15 of the FHSA, however, makes no distinction between banned hazardous substances which are proceeded against under Section 2(q)(2) and those proceeded against under Section 2(q)(1).. The Commissioner's mistaken finding of a lack of imminent hazard is therefore irrelevant to the matter at issue.

Section 15 of the FHSA provides the consumer, the dealer and the distributor a means by which he can dispose of banned hazardous articles or substances. The statute specifically grants the right of refund for an article or substance which has been banned whether or not it was such at the time of its sale. The Food and Drug Administration has consistently made efforts to obfuscate Section 15 of the FHSA. The prime example of the commitment to obfuscate is the priority which the Bureau of Product Safety has given to publishing implementing regulations under Section 15. Another example is Malcolm Jensen, paraphrased in Fortune, February 1972, at 146, as wanting repurchase to apply only if the consumer purchased the toy after November, 1969, when that section of the Act was passed. This interpretation is plainly contrary to the clear language of the statute. Finally, Bureau of Product Safety's news release, HEW News Release #72-16, on proposed regulations concerning garments containing asbestos fibres, indicates recall of the offensive garments is not anticipated. No mention is made of the right granted to the consumer by Section 15 of the FHSA, and in that latter case alone the potential loss to consumers is approximately 24 million dollars.

It is quite apparent that either legal error has toys ? been made in interpreting a difference between imminently banned hazardous substances and banned hazardous substances, or there is concern over threats of protracted litigation, or that someone has engrafted upon the FHSA a perverted policy of protecting small business at the expense of the nation's children. The industry at issue here, however has a poor track record to receive favored treatment by the Food and Drug Administration for any reason. This industry is perhaps second only to the pharmaceutical industry in wrecking havoc on America's young. The human cost does not appear on their books, but if one looks closely it is apparent that there is blood on their balance sheets.

William Hart, mayor of East Orange, New Jersey, pinpointed the problem in decision-making when he testified before the Senate Subcommittee on Health on extension of the Lead-Based Paint Poisoning Prevention Act. After listening to the Lead Industries Association poormouth the findings of the American Academy of Pediatrics, the Environmental Protection Agency, the Bureau of Community and Environmental Management, and the DHEW Ad Hoc Committee (of which Associate Commissioner for Science Lloyd Tepper was a member) and bemoan the impact on the paint industry of a 0.06 percent lead level, Mayor Hart noted that there was a manufacturer of soup in his community that placed several poisonous cans of soup into interstate commerce, resulting in the death and injury of two persons. That company was bankrupted due to the Food and Drug Administrations aggressive enforcement policies against adulterated food. But Mayor Hart's main point was this; Bon Vivant's soups were primarily consumed by the wealthy, the poor did not buy it. He then noted that the children who have died from lead-based paint poisoning have almost universally been poor and predominantly, Black.

vindictive

We submit that the time has come for the paint industry to pay the piper. The FDA did not hesitate to bankrupt Bon-Vivant or to destroy the swordfish industry in the United States. There was little hesitation with cyclamates, DMSO, or Panalba; (these latter cases in the face of tremendous political pressure). But in the area of product safety, the Food and Drug Administration seems to see its mandate as one of protecting industry. <u>See</u> disregarded memorandum dated November 25, 1969, from Hearing Examiner William E. Brennan to Commissioner Ley, <u>In the Matter of Carbon Tetrachloride</u>; Docket No. FDC-FS-1.

We cannot sit idly by and watch the public trust abused. There can be no more carbon tetrachloride fiascos. The FHSA requires repurchase of banned hazardous articles or substances. That mandate must be executed. In an opinion dealing with the lack of implementation of the National Environmental Policy Act by the Atomic Energy Commission, Judge J. Skelly Wright pinpointed the problem at issue here, "It seems an unfortunate affliction of large organizations to resist new procedures and to envision massive roadblocks to their adoption." <u>Calvert Cliffs' Coord. Com. v. United States A.E.C.</u>, 449 F.2d 1109, 1121 (D.C. Cir. 1971).

B. <u>The Staggering of the Effective Date of the Order by the Commissioner Is Arbitrary and Capricious and Based Upon Irrelevant Considerations</u>

There is no section of the FHSA giving the Commissioner discretion as to the effective date of the regulation based upon grounds of alleged technical incapacity or economic hardship on small businessman. Nor could the Commissioner grant an extension of time as to the effective date of the order in order to allow retailers time to dispose by sale of existing inventories of the hazardous products at issue. Congress provided amply for the retailer with Section 15 of the FHSA. The retailer is fully protected from economic injury by the statutory scheme.

Sections 2(f), (q)(1) and (q)(2) of the FHSA and Sections 701(e), (f) and (g) of the Federal Food, Drug and Cosmetic Act provide procedures for effectuating the ban of a household substance. Section 701 (e) gives the Commissioner discretion as to the effective date of the regulations issued under that section. Discretion may be exercised, however, only within the standards dictated by the substantive statutory grant.

The degree of the hazard from lead in paint is great. Assuming, arguendo, that paints marketed today do not have as high a lead content as paints marketed before 1960, the degree of the hazard remains the same due to the presence of elevated blood-lead levels in a substantial portion of the population at risk. Eight percent of the children tested in Boston have blood-lead concentrations above 50 micrograms per 100 ml. of blood. The figure is much higher in New York City. In the District of Columbia, 29 percent of the surveyed children had elevated blood-lead levels. This means that any additional environmental insult from lead that is added can bring the child closer to a medical emergency and permanent brain damage. We will assume the risk is not so great in Potomac, Maryland. Tests?

The nature of the hazard is that of an insidious poison. Once the paint is on the wall or the toy, warning labels become irrelevant. A label on the can of paint is no longer efficacious after application; a label on a toy can't be read by the population at risk.

Medical evidence and opinion have shown that paint containing lead in quantities greater than 0.06 percent is toxic. It is reasonably foreseeable that children with pica (50 percent of the nation's children) will ingest chips or flakes of paint. If that paint contains lead in an amount greater than 0.06 percent it may cause substantial personal injury or substantial illness as a result of reasonably foreseeable continued ingestion by children. This latter factor is especially true if the child ingesting the paint is already suffering from an elevated blood-lead level due to other environmental insults from lead, as many children are.

The above is a complete recitation of the considerations relevant to the ban of a hazardous household article or substance. The Commissioner, however, has added a new consideration; "each manufacturer, prior to marketing consumer products, must take steps to determine that any substitute for lead has been adequately tested for safety and shown to be safe." We concur in that statement as a moral principle. It is the least that one would ask of an industry that has been responsible for the deaths of so many children. We would submit, however, that this statement is being utilized as a dodge to give the paint industry time to comply with the regulation and to give retailers of toys and paints time to dispose of existing stocks of hazardous articles or substances. The effective dates of the regulation have been staggered in order to protect the paints, coatings and toy industries from economic insult, a consequence which the FHSA, by its clear terms, does not call into consideration. In so doing the Commissioner has disregarded the environmental insult that is endangering the lives and well being of the nation's children by the continued presence on the marketplace of hazardous articles and substances.

Even if, however, economic considerations are brought into play, and we make no concession in that regard, the comments of the affected industry clearly indicate that a substantial portion of existing inventory meets the 0.06 percent standard. The Enterprise Paint Manufacturing Co. in a letter to the FDA dated February 17, 1972, indicates that 76 percent of its interior and 73 percent of its exterior paints meet that standard. The Sherwin-Williams Company in a February 17, 1972, letter indicates 87 percent of its interior paints and 40 percent of its exterior paints meet the standard. DeSoto, Inc. in a letter dated February 16, 1972, indicates that 91.8 percent of its interior paints and 77.5 of its exterior paints meet the standard. We would submit that the staggering of the effective date of the regulations protects those companies which, under the broad classification of calling themselves small businessmen at risk, are the companies that have taken the least interest in the welfare of children and have in fact been responsible for a substantial part of the death and destruction that lead in paint has wrought.

We also believe the Commissioner is naive to think that the industry affected by his order will test replacements for lead for safety. This industry is concerned that replacements for lead will be less effective and less durable. See Conchemco Coatings letter to the Hearing Clerk dated January 3, 1972. This is the general theme that pervades most of industry's comments to the regulations. One comment even goes so far as to allege "that the chrome yellow paint on pencils has been eaten and enjoyed by several generations of school children as they merrily chewed the bright yellow lacquer off their wooden yellow pencils. See Essex Chemical Corp. letter to the Hearing Clerk dated December 28, 1971. (Emphasis added).

To allow the marketing of paint containing 0.5 percent lead for one more year is a gross abuse of discretion. The difference between that standard, if it can be so called, and the 0.06 percent standard is 833 percent. Only one purpose is served by the one year interim standard; industry is given time to reformulate their products in order to ensure their quality.

C. Rewriting the Regulation so as to Effectuate Section 15 of the Federal Hazardous Substances Act is Not Beyond the Scope of the Regulations Proposed at 36 F.R. 20986 (November 2, 1971)

We note that the Commissioner has recently concluded in several final orders that comments raised on proposed regulations "go beyond the scope of the proposal". We would like to note that the Page proposal, by invoking procedures under Section 2(q)(1)(B) of the FHSA, automatically brought Section 15 of the statute into play. The National Paints and Coatings Association acknowledged this provision in a letter to the Commissioner dated February 16, 1972. The Toy Manufacturer's Association, the National Association of Children's Home Playground Manufacturers, Inc., the National Association of Doll Manufacturers and the Stuffed Toy Manufacturer's Association also acknowledged this provision and its operation in a letter dated March 2, 1972. In the latter joint comment, Mr. Aaron Locker, Counsel for the above made the following statement; "Retroactivity would raise serious issues of procedural due process and violation of other constitutional safeguards and would undoubtedly lead to protracted litigation between industry and government." Because the Commissioner found that it was necessary for him to proceed with "voluntary" regulation of the cosmetic industry due to a similar potential of lengthy litigation, thus erroneously making the threat of litigation a consideration in rule making, we believe it is necessary to make the following observations on Mr. Locker's threat:

-no

taking of property

a. Failure to make Section 15 of the FHSA operative in the rule making at issue would raise grave questions of administrative abdication and moral bankruptcy.

b. While we do not believe that there has been any violation of constitutional safeguards in the rule making at issue, we would point out that the Commissioner's duty is to effectuate the mandate of the Congress. In any event, there is no criminal sanction for failing to repurchase under the mandate of the statute.

But the statute (15) does

Section 15 of the FHSA envisions civil remedies only, and there is no prohibition of retroactive civil obligations or penalties. The regulation does not make an action done before its effective date criminal. The regulation does not aggravate a crime, or make it greater than it was when committed. The regulation does not change the punishment, and inflict a greater punishment, than the law annexed to a crime when committed. The law does not alter the rules of evidence which the law required at the time of the commission of the offense, in order to convict the offender. Mr. Justice Chase made the following observation; "Every ex post facto law must necessarily be retrospective; but every retrospective law is not an ex post facto law: the former only are prohibited. Every law that takes away or impairs rights vested, agreeable to existing laws, is retrospective, and is generally unjust, and may be oppressive; and it is a good rule, that a law should have no retrospect: but there are cases in which laws may justly, and for the benefit of the community, and also of individuals, relate to a time antecedent to their commencement; as statutes of oblivion or pardon." Calder v. Bull, 2 U.S. (Dallas) 385, 390 (1798). The Federal Hazardous Substances Act is such a case.

c. The courts are open to everyone. When administrators abdicate, the people will litigate..

Objections filed,

Joseph A. Page

Anthony L. Young

Mary-Win O'Brien

Judith D. Fried