VOL. 22, NO. 9 SEPTEMBER 1967

Food Drug Cosmetic Law JOURNAL

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD AND DRUG LAW INSTITUTE, INC.

THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $20; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

September, 1967
Volume 22 • Number 9

Second-class postage paid at Chicago, Illinois and at additional mailing offices.

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TO THE READER

An Ombudsman for Industry.—The drug industry must police itself, and it can best do so by employing the concept of the ombudsman. This is the contention of *Vincent A. Kleinfeld,* whose article on this subject begins on page 472. Mr. Kleinfeld, who is a Washington, D. C. attorney, first presented these remarks in an address before the Division of Food, Drug and Cosmetic Law, American Bar Association, in Honolulu, Hawaii.

New Developments in Food and Drug Legislation in Hawaii. — *Mr. George H. Akau,* Food Commissioner and Analyst of the Hawaii State Department of Health, discusses the latest Hawaiian legislation concerning food and drugs. He places special emphasis on the Drug Abuse Control Act as compared to the "Model Act" prepared by the Federal Food and Drug Administration, the Milk Control Act, concerning the production and distribution of milk and milk products, and the new State Food, Drug and Cosmetic Act. The address was given before the Division of Food, Drug and Cosmetic Law of the American Bar Association and begins on page 478.

Products Liability Today: Whither Thou Goest, I Will Go (A Modern Tale of Biblical Ruth and Naomi).— *Warren Freedman,* counsel to the Bristol-Myers Company, presented the article beginning on page 486 before the American Bar Association Section of Corporation Banking and Business Law in Honolulu, Hawaii. Mr. Freedman compares the Ruth-Naomi epigram, "Whither Thou Goest, I Will Go," and the field of products liability today by examining the areas of privity of contract, strict liability in tort, liability without fault, "defect" in the product, and the Uniform Commercial Code and products liability.

Good Manufacturing Practices Regulations in the Food Industry. — This was the topic of a paper presented by *Alfred Barnard* at the Annual Meeting of the Association of Food and Drug Officials of the United States at St. Paul, Minnesota on June 21, 1967. Mr. Barnard, the Director of the Bureau of Regulatory Compliance of the Food and Drug Administration, traces the history of current Good Manufacturing Practices regulations in the food industry and the Food and Drug Administration. The article begins on page 511.

Does the Term "Special Dietary Use" Apply to All Baby Foods?—The authors of a recent article in the *New England Journal of Medicine* state that baby foods should not necessarily be considered special dietary foods. Is this position legally sound? This is the question asked by *Franklin M. Depew,* President of the Food and Drug Law Institute, in his article which begins on page 518. After examining the regulations on special dietary foods adopted in 1941 by the FDA and the legislative history of the Federal Food, Drug and Cosmetic Act of 1938 he comes to the conclusion that the position is correct.

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Journal

An Ombudsman for Industry

By VINCENT A. KLEINFELD

The Following Article Was Presented Before the Division of Food, Drug and Cosmetic Law, American Bar Association, in Honolulu, Hawaii. Mr. Kleinfeld Is a Washington, D. C. Attorney.

A LONG TIME AGO, when I was spending some halcyon years with various agencies of the federal government, I concluded, only half in jest, that every government employee (including myself) should be required to change his position within the government, or at least within his agency, at least once every five years. It seemed to me that the average human being, after spending too many years in performing the same duties as a government official, particularly as a prosecutor or regulator, almost inevitably lost his sense of proportion and his ability to view a problem reasonably and dispassionately.

After too much time in one position, the ordinary human being seems bound to acquire limited and narrow horizons: he can think only of the specific functions he is performing and the particular law which he is administering or enforcing. Excessive and continuous power produces in him a corrupting arrogance. After the passage of time, anyone who disagrees with a position taken by the bureau or agency in which the official is employed is seen by him as obviously a miscreant, a rascal, a moneymaker, or something else equally nasty.

It was perhaps because of this not overly-serious thought on my part that I came to the conclusion, years ago, that the Swedish idea of having an Ombudsman is excellent, and is one which has a strong potential for good from the viewpoint of both the consumer and industry. To put it in a somewhat negative way, this watchman would perform no disservice to the government, but rather would contribute

to efficient, but discriminating, administration, and to enforcement of our laws.

At first I was going to write a paper on "Who Will Watch the Ombudsman," but I do not believe this would present a real problem. Our system of checks and balances (I know of no better one) would be strengthened by an Ombudsman to whom a citizen or member of industry could go with a complaint of unjustified, over-aggressive or arbitrary action by a government official. During the past few years, many have come to the same opinion, and I feel that Congress should give serious consideration to the Ombudsman device of establishing another and most effective check on the occasional government official who abuses the powers vested in him by Congress. The continued violation of the wire tapping statute by, of all people, many government agencies and officials, which is a flagrant violation of the letter as well as the spirit of the law, points up most forcefully the merit of having a watchman. Not so strikingly perhaps, but equally clearly, some of the governmental acts of omission or commission during the last few years in the food and drug arena (I use the term advisedly) highlight the advantage of—in fact the necessity for—the Ombudsman.

A complete and detailed article should be written on the advisability of the Ombudsman in the food and drug area. This paper, however, discusses an entirely different facet of the philosophy of the watchman. I have come to the conclusion that the average company in the drug industry could well employ the concept of Ombudsman, although his title, of course, would be something much more mundane. I have criticized and shall continue to criticize many of the actions taken by governmental agencies in the food and drug and other fields. These criticisms, I feel, have been well taken. It is trite, but true, to say that power corrupts, although I do not use the term in any venal sense. On the other hand, I believe that the drug industry still has not faced up to a vital fact of life. This is that this industry, because it deals with the drugs which all of us must consume and which have such potentialities for harm as well as good, is different from and cannot be treated the same as any other industry. This was pointed out most forcefully by the Supreme Court in *Dotterweich*,* in 1943. It is safe to say that this concept has not changed in the Thalidomide-Kefauver-Goddard era. Certainly if the philosophy of *caveat emptor* is no longer applicable in other industries, it never did, and does not now, properly belong in the field of foods and drugs.

* *United States v. Dotterweich*, 320 U. S. 277, 64 S. Ct. 134.

The consumer, being the amateur he is, must have strong governmental protection, and if the industry does not perform strong self-policing, we are inevitably going to have complete governmental licensing.

The Drug Industry Must Police Itself

If we are to avoid this dubious blessing, we must face the simple fact of life that the drug industry is *sui generis*, and that a different philosophy and dissimilar concepts must apply. The drug industry must police itself, and pious policy statements and declarations will not do the trick; nor will the public relations man. Winston Churchill is supposed to have said that war is too important to be left in the hands of the generals. Certainly drugs are too vital to be left to the tender mercy of the pitchman. And so to the industry Ombudsman.

Mythology has it that Apollo, at Delphi, was a link between the gods and man, guiding him to know the divine will, and showing him how to make peace with the gods. In the drug area it is the Food and Drug Administration which has the power of the gods, and especially in the sense that the gods of old were by no means infallible, and that the Delphic oracle, was famous for its ambiguity. Who then will be the drug manufacturer's Apollo, his Ombudsman, to whom complaints within a company may be taken and who must commune with the gods, sometimes to make peace with them and at other times to wage war?

House Counsel Should be Ombudsman

As I see the situation, the one who must make the final decision in many important areas—the decision whether a product is a new drug, whether promotional claims are proper, whether the claims in an advertising or labeling piece are within the confines of an approved new drug application, whether there is full disclosure and brief summary, whether an august pronouncement from the gods is valid or invalid and whether or not it should be observed—is the house counsel of the manufacturer. It is he who should, and must, make the final determinations after engaging in comprehensive consultation with, and receiving advice from, the company's physicians, pharmacologists and other scientific personnel. His ability and stature must be such that his decisions will not be reversed because of considerations of such things as sales appeal and internecine competitive pressures. He should, perhaps, report only to the president of the company. It is he to whom the hagridden company medical director must go with his complaint against the occasional over-zealous administrative official

who wishes to make unauthorized or improper claims or inadequate full disclosure.

This is not to say by any means that the expertise of the advertising agency and the skill of the marketing man must not be utilized to their fullest extent. But when we are dealing with drugs and with the parlous situation in which the drug industry now finds itself, we must look inwards, perhaps say *mea culpa,* and search for some meaningful step forward.

It is indeed a grave responsibility which I seek to place upon the unfortunate industry Ombudsman, and my friends who are house counsel for drug manufacturers and distributors may perhaps not welcome this burden, although it may be presently borne by some. My thesis, however, is that no matter by what name we call the official or officials chosen for this purpose, someone must say "no" to a claim, to a warning, or to other aspects of promotional material. I feel that the one best qualified to perform this function is the house counsel, who has been steeped in food and drug law and who undoubtedly has a visceral understanding of the manner in which the government thinks and operates. Of course, he cannot, or at least he should not, make medical or scientific judgments, but he will have to make ultimate decisions upon the basis of the data, material and opinions compiled and submitted by those in his company who are qualified to speak as doctors and scientists.

The Ombudsman will have to possess an interesting array of talents, of course. He must be a sound lawyer, he must have a comprehensive knowledge of food and drug law, he must know the general thinking and philosophy of the government, and he must be confident enough of his own talents and abilities to say "yes" when that is, in his opinion, the proper answer. Perhaps most important, he must have the fortitude to use from time to time the ugliest word in the lexicon of the advertising agency, "no," and withstand the onslaughts of many in his own organization.

It is difficult, as I see the situation, and certainly as Congress, the consumer and the press must view it, to understand a failure to defend regulatory proceedings instituted by the government against a prescription drug or its manufacturer. If, in fact, the claims involved were outside the four corners of the new drug application, if the labeling did not contain adequate full disclosure and did not reveal a fair balance, and if the advertising did not contain adequate brief summary, the proceedings were justified. As I have indicated, we are dealing with potent drugs, not with ships, shoes and sealing wax.

And it is no answer to state the truism that in some instances honest and qualified men may differ on whether there is proper full disclosure, brief summary, fair balance and the like. If the drug company's Ombudsman has determined that there has been compliance with the law and the valid regulations, the company should stick to its guns and contest any regulatory proceedings. Certainly there should never be a situation where it is obvious that the promotional material involved did not comply with the Act.

How can leaders in the drug industry defend, or even rationalize, a situation where from time to time a seizure or prosecution is instituted, there is the concomitant publicity in the press and in Congress, and the company involved meekly acquiesces in the position of the government? Let us take, as an example, a criminal prosecution bottomed on alleged inadequacy of full disclosure in a mailing piece sent to a physician in connection with a prescription drug. If the company does not defend, it is not unreasonable to take the position that the company wilfully or negligently violated the Federal Food, Drug and Cosmetic Act in an important respect, for the law requires a bona fide full disclosure. If the government is correct in its contention that full disclosure was not provided, the company erred grievously and is properly subject to criticism. And remember, no public relations campaign on behalf of the drug industry can outweigh the periodic devastating publicity of a seizure, of a prosecution, of a "Dear Doctor" letter, or of a recall program, predicated, for example, on an alleged failure to furnish adequate full disclosure or brief summary or on the making of unauthorized therapeutic claims. If, however, the Ombudsman reaches the decision, before a mailing piece is employed, that it does contain adequate and appropriate full disclosure, any regulatory proceeding could be vigorously contested.

When the Ombudsman and the FDA Differ

But having an Ombudsman is no guarantee against those few instances where some officials in the Food and Drug Administration may differ with the conclusion reached by the Ombudsman. In such a situation, however, it is unlikely that the Food and Drug Administration would recommend regulatory proceedings, and it is more improbable that the Department of Justice, if it were fairly apprised of the facts, would go along with such a recommendation. It is still more unlikely that the courts, on the basis of such a state of facts, would hold for the government, assuming regulatory action was commenced. In other words, as I see the picture, a drug company

should not be unduly worried by the unusual situation where the Food and Drug Administration might disagree with the company Ombudsman. In any event, where the Ombudsman has made the binding decision upon the basis of which the therapeutic claim was made or the full disclosure or brief summary formulated, any regulatory proceeding should be resisted with vigor and zeal.

Conclusion

In conclusion, I believe that as a generality we should engage in some wholesome self-criticism and soul-searching. Specifically, all promotional material should be examined scrupulously and should have the final imprimatur of the Ombudsman. If this is accomplished, I would hazard the prediction that there will be little trouble of this nature in the future. Those few difficulties which might ensue should be met in a forthright fashion, since industry would be leading from strength and not weakness. **[The End]**

THE ELEVENTH ANNUAL JOINT EDUCATIONAL CONFERENCE TO BE HELD

The Food and Drug Administration and the Food and Drug Law Institute will sponsor the Eleventh Annual Joint Educational Conference to be held at Washington, D. C. on November 27, 1967. The theme of the one-day conference will be "Communicating in the Public Interest." A series of workshops on prescription drug advertising regulations, the establishment of guidelines for good manufacturing practices, the voluntary compliance program, current methods for testing and sampling new drugs, and the drug efficacy study by the National Academy of Sciences-National Research Council will be featured. James L. Goddard, M.D., Commissioner of the Food and Drug Administration, will deliver the major address. Other FDA officials scheduled to speak include Winton B. Rankin, Deputy Commissioner; Kenneth R. Lennington, Salmonella Project Officer, and William W. Goodrich, Assistant General Council of the Department of Health, Education and Welfare.

New Developments in Food and Drug Legislation in Hawaii

By GEORGE H. AKAU

The Following Address Was Given Before the Division of Food, Drug and Cosmetic Law of the American Bar Association. Mr. Akau Is the Food Commissioner and Analyst of the Hawaii State Department of Health.

FOOD AND DRUG LEGISLATION in Hawaii has had a long and honorable history. On May 16, 1898 the President of the Republic of Hawaii signed a bill for an act to provide against the adulteration of food and drugs. This was the basic food and drug law of the land until May 21, 1941 when the Governor of the Territory of Hawaii approved an act relating to food, drugs, devices and cosmetics. This law was patterned after the Federal Food, Drug and Cosmetic Act of 1938. On May 29, 1967 Governor John A. Burns signed Act 152 relating to the Hawaii Food, Drug and Cosmetic Act into law. Act 152 brings state law into conformity with its federal counterpart, but with one significant omission! Whereas the Federal Drug Abuse Amendments of 1965 were amendments to the Federal Food, Drug and Cosmetic Act, the State Drug Abuse Control Act did not amend the state food and drug law. The State Drug Abuse Control Act stands alone. More will be said about Act 286 later on in my talk.

Before proceeding with a discussion of the recently enacted Act 152, a better perspective of this Act might be gained by a brief review of the legislative developments on the federal level. Between 1941 and 1966, several amendments had been adopted in order to strengthen the Federal Food, Drug and Cosmetic Act. Those of major significance were the following: Insulin Amendments of 1941, Antibiotic Amendments of 1945, 1947, 1949 and 1962, Prescription Drug or Durham-Humphrey Amendment of 1951, Pesticide or Miller Amendments of 1954, Procedural or Hale Amendments of 1954 and 1956, Food Additives Amendment of 1958, Color Additives Amendment of 1960, the

Drug or Kefauver-Harris Amendments of 1962, the Drug Abuse Control Amendments of 1965 and the Confectionery Amendment of 1966. While these developments were taking place, only two major amendments were added to the Hawaii food and drug law. These amendments pertained to the use of raw agricultural commodities bearing pesticides deemed to be safe in 1957, and the use of food additives in 1959.

Instead of taking up your time going into the details of Act 152, I would like to touch upon its significant provisions.

In addition to the authority which the Director of Health has had to promulgate regulations relating to food definitions and standards of identity, reasonable standard of quality or fill of container and labeling exemptions for small packages, the new law authorizes him to adopt, amend or repeal regulations concerning: (1) the use of nonnutritive objects or substances in confectionery; (2) any deleterious or poisonous substance, any food additive, any pesticide chemical, or any color additive with respect to any food, drug, device or cosmetic as the case may be; (3) the exemption of labeling or packaging requirements relative to drugs and devices under certain conditions; (4) the removal of drugs from prescription and caution labeling requirements, and (5) the labeling of investigational drugs.

Various definitions including 'pesticide chemical,' 'food additive,' 'color additive' and 'new drug' have been updated. Drug counterfeiting, trafficking in counterfeit drugs or counterfeit drug-making paraphernalia and dispensing a different drug in place of the drug that was ordered or prescribed without permission of the prescriber have been added to the list of prohibited acts.

With regard to food adulteration, it will be permissible to treat a raw agricultural commodity which has been processed to reduce the excess pesticidal residue that may be present to conform with the tolerance prescribed for the processed commodity.

Relative to misbranding, a food ingredient which, when used according to purveyor directions, results in the final food product becoming adulterated or misbranded shall be deemed to be misbranded.

To the provision on drugs deemed to be adulterated was added the requirement that the methods, facilities and controls used in drug manufacture, processing, packing or holding conform with current good manufacturing practice.

With regard to the section on the misbranding of drugs, provision was made for utilization of the 'established name' of the drug, which is the applicable official name under the Federal Act.

A new provision was added to the section pertaining to misbranded cosmetics. Unless the packaging and labeling of a color additive other than one for use only in or on hair dyes are in conformity with the packaging and labeling requirements of the Federal Act, such a color additive shall be deemed to be misbranded.

Undoubtedly many of you who deal with the Federal Food, Drug and Cosmetic Act have perceived that all of the new state provisions which I have outlined are identical with provisions under the Federal Act. In this regard, due credit must be given the Association of Food and Drug Officials of the United States (AFDOUS) for the promotion of uniform legislation through the dissemination of its revised model State Food, Drug and Cosmetic Bill. We found the AFDOUS model bill to be of invaluable assistance in the preparation of Act 152.

I would like now to direct your attention to the second major development in state food and drug legislation. I refer to Act 286 or the State Drug Abuse Control Act.

Before discussing Act 286 permit me to touch briefly upon my personal knowledge of the development of the "Model Act" by the Federal Food and Drug Administration (FDA). As the then President of AFDOUS, I met in Washington, D. C. with members of my Executive Board and representatives of the FDA on December 7 and 8, 1965 to consider the implementation of the drug abuse amendments. As a result of these meetings the AFDOUS board adopted the following statements:

"(1) The Executive Board recommends that the Food and Drug Administration prepare a uniform drug abuse law for state adoption which will stand as a separate law or which may be used to amend the Uniform Food, Drug and Cosmetic Act. It is recommended that the bill incorporate the necessary and desirable features of HR2 and the Uniform Hypnotic and Somnifacient Drug Bill of the Council of State Governments."

"(2) The Executive Board hereby goes on record as approving the proposed pilot program on drugs as presented by the Federal Food and Drug Administration."

The reason AFDOUS had included a recommendation that the Federal Administration prepare a model drug abuse control act which would stand as a separate law was recognition of the fact that in several states, food laws are administered by one state agency while the drug laws are enforced by another agency.

During these Washington discussions we had urged that the "Model Bill" exceed the requirements of the Federal Act in several respects. Some of our recommendations were that a section be added to provide for the seizure of conveyances used to transport drugs in violation of the act; that another section be added prohibiting the

obtaining of stimulant and depressant drugs by fraud, deceit or misrepresentation and the inclusion of more stringent requirements regarding illegal possession. It is my understanding that representatives of other interested national organizations, notably the National Association of Boards of Pharmacy, agreed on the need for a uniform State Drug Abuse Control Act and their recommendations paralleled those of AFDOUS in many respects. On October 21, 1966 the draft of the "Model Bill" was prepared by the FDA and forwarded to the Council of State Governments and to the state regulatory agencies.

For many years in Hawaii the sale and possession of depressant and stimulant drugs had been controlled under the Public Health Regulations of the Department of Health. On the other hand, provisions relating to the sale and possession of the hallucinogenic drugs such as LSD and mescaline were not included under these regulations. There had been some doubt that the state could act to control these drugs under its food and drug law because they fell into the category of 'investigational drugs.'

Since infractions of the Hawaii Public Health Regulations are misdemeanors there was a feeling among some enforcement officials that new legislation was required to make the illegal sale and the possession of dangerous drugs a felony. As the traffic in dangerous drugs and arrests for the illegal sale and possession of these dangerous drugs began to mount, both state and municipal authorities were agreed that new legislation was indeed needed. This in brief was the situation in Hawaii toward the end of 1966 and prior to the convening of the Fourth State Legislature.

The President of the United States in delivering his Message on Crime to the Congress on February 6, 1967 gave new impetus to legislative action when he urged state enactment of the type of model drug abuse control act which the federal authorities had prepared.

State Drug Abuse Control Act

I will now touch upon the significant provisions of Act 286 as I see them. The State Drug Abuse Control Act was patterned after the "Model Drug Abuse Control Act" with some notable exceptions. In general it conforms with the 1965 Amendments to the Federal Food, Drug and Cosmetic Act. It provides for strong state control over the manufacture, distribution, delivery and possession of depressant and stimulant drugs. This law gives the state the authority to take strong enforcement action against distributors and producers of counterfeit drugs. This Act does not apply to narcotic drugs (marihuana, mor-

phine, heroin, opium, etc.) which are regulated by other federal and state narcotic laws.

The Model Law places depressant or stimulant drugs in three categories. In the first category are the depressant drugs; stimulant drugs are listed in the second category while drugs having a potential for abuse are placed in the third category. The drugs in these categories are those designated by regulations promulgated under the Federal Act. Under Act 286 however, depressant or stimulant drugs are placed in six categories. The first and second categories of drugs are similar to the first two categories under the Model Law. Category three pertains to LSD and other hallucinogens; category four includes peyote, mescaline and their preparations; category five includes psilocybin or any like derivative from the Mexican mushroom and category six is reserved for those drugs with a potential for abuse. While drug designations which are employed in the Model Bill are uniform with those promulgated under the Drug Abuse Control Amendments to the Federal Food, Drug and Cosmetic Act, under Act 286 drug designations will be those which have been declared to be habit-forming or have a potential for abuse by regulations of the Director of Health. Under Act 286 the following acts or the causing thereof are prohibited:

1. Manufacturing, compounding, processing, or importation of depressant or stimulant drugs except by authorized persons or institutions.

2. Selling or delivering depressant or stimulant drugs to any unauthorized person.

3. Possession of these controlled drugs except as authorized. Under this part 3, unless a controlled drug was obtained on a valid prescription and is held in the original container in which the drug was delivered, the possessor of such drug can find himself in serious difficulty with the law.

4. Obtaining such drugs by fraud, deceit, misrepresentation or subterfuge; by false assumption of title or identity of a person authorized to possess controlled drugs; or by use of a false name or false address on a prescription. This part 4 does not apply to state or municipal officers or employees while acting in the course of their official duties. In the Model Bill, this part also applies to a drug manufacturer, his agents or employees when they are engaging in investigative activities directed at safeguarding the firm's trademark. Under Act 286, however, reference to the manufacturer and his agents reads as follows: "The Director (Health) is authorized and directed to cooperate with manufacturers, their agents or employees in activities directed toward the safeguarding of said manufacturer's trademark."

5. Making, selling, or concealing counterfeit drug equipment.

6. The commission of any act which causes a drug to be a counterfeit drug, or which causes the sale of a counterfeit drug.

7. Inducing a minor (under age 20) to buy, traffic in, receive, take or use any depressant or stimulant drug.

8. Failure to prepare, obtain, or keep the required records of manufacture, receipt, distribution or dispensing of the controlled drugs.

9. Refusal to permit access to or copying of any record relating to the depressant or stimulant drugs.

10. Refusal to permit entry or inspection of any place, including a conveyance, where the controlled drugs are processed or sold or where the required records are stored.

11. Refilling prescriptions for these drugs more than five times or more than six months after they were initially prescribed.

The penalties which have been prescribed under Act 286 are more severe than those prescribed for similar offenses under the Federal Act. Under this Act any person violating the prohibited acts one to six inclusive may be subject to not more than a $1,000 fine and not more than 10 years for the first offense. For the second offense the maximum fine is $2,000 and not more than twenty years of imprisonment. Any person who sells or delivers a depressant or stimulant drug to a minor or who induces a minor to buy, traffic in, receive, take, ingest or use any controlled drug shall be subject to a fine of not more than $1,000 and imprisonment for not more than twenty years for the first offense and a fine of not more than $2,000 and imprisonment for life for any subsequent offense.

Prohibited acts 8, 9, 10 and 11 relate to record-keeping, right of entry to make inspections and refilling prescriptions. Any person violating any of these provisions is subject to a fine of not more than $1,000 and imprisonment for not more than one year for the first offense. For a subsequent offense the fine is $2,000 and imprisonment not to exceed three years.

Act 286 will give all law enforcement officials in the state the authorization to deal with the illegal traffic in drugs. Under this law, seizure without warrant is authorized for (1) counterfeit drugs and the equipment used in making them; (2) depressant and stimulant drugs and their containers when held in violation of the law, and (3) any conveyance being used to transport or hold depressant, stimulant, or counterfeit drugs in violation of the law. The confiscated articles must be placed in the custody of the courts following these seizures.

This law allows the Director of Health to authorize enforcement agents to carry firearms, execute and serve search and arrest warrants

and make arrests without warrants for offenses committed in the presence of the agent if there is probable cause to believe that the person has committed such offenses. Enforcement by injunction is also provided under Act 286. The Director is further authorized to promulgate regulations for the efficient enforcement of this law and these regulations shall conform as much as practicable with those issued under the Federal Act.

In addition to Act 152 and Act 286 concerning food and drug amendments and drug abuse control respectively, the Fourth State Legislature enacted: Act 10 which authorized the use of the term "margarine" in addition to the term "oleomargarine"; Act 237 making it illegal to knowingly plant, cultivate and produce a narcotic drug; Act 206 requiring food products, other than food products which are canned, pickled or processed, which have been previously frozen then thawed out and offered for sale to be labeled with the words "product previously frozen"; Act 122 which requires certain kinds of poultry products to bear labeling indicating geographic origin and the words "previously frozen" when these products have been frozen and defrosted, and finally Act 260 which provides for control over the production and marketing of milk.

The Milk Control Act

The Milk Control Act 260 was a major piece of legislation. In the preamble of this Act the Legislature declared that:

". . . . the dairy industry is a prominent agricultural industry . . . the production and marketing of milk . . . . is of significant importance to the economy of the State and to the health of the consuming public . . . . the insularity . . . . of Hawaii . . . . the perishability of milk, the inflexibility of response to changes in demand, and the fluctuations in demand tend to make the industry highly unstable. This tends to lead to . . . . demoralizing trade practices . . . . which jeopardize . . . . the dairy industry . . . . and the supply of wholesome milk for the people . . . . a substantial number of milk producers . . . . find themselves in financial distress . . . . Accordingly, the State of Hawaii deems it to be in the interest of public health and welfare . . . . to stabilize the dairy industry and insure an adequate supply of milk for the inhabitants of this State."

The Milk Control Act will be administered by the Board of Agriculture. At the same time, the regulatory control over the sanitation and quality of milk production will continue to be exercised by the Department of Health. Only milk sheds having a population of 100,000 or more will be affected by the Act. The provision will in effect pertain only to the City and County of Honolulu.

This law is divided into five parts: I. General Provisions; II. Administration, powers, duties; III. Licensing; IV. Setting minimum prices and quotas; and V. Remedies, violations, compacts, construction.

Act 260 gives the Board of Agriculture three general powers. In summary these powers are: (1) to regulate and supervise in a milk shed the production, transportation, processing, storage, distribution, and delivery of milk, the establishment of quotas and the setting of minimum prices to be paid to producers by producer-distributors and distributors; (2) to investigate all matters in a milk shed pertaining to the production, transportation, processing, storage, distribution, and delivery of milk, and the establishment of quotas and the setting of minimum prices to be paid to producers; (3) to subpoena certain persons and records; and (4) to make and enforce all rules and regulations and all orders necessary to carry out the Act.

The Board of Agriculture is authorized to make an audit of milk producing costs when 55 per cent of the producers or 55 per cent of the producers and producer-distributors in a milk shed request it. It is also authorized to audit the milk records of the distributors to insure that dairymen are paid for the proper category of milk under set quotas. On its own motion the Board can request a price-setting study.

Relative to penalties under this Act, any person convicted of violating its provisions shall be fined not less than $25 nor more than $500 or imprisoned not more than six months or both. While these penalties are relatively light, the concomitant possibilities of loss or suspension of a license to continue to operate as a milk producer or milk distributor and damage to one's reputation in the community should have a considerable deterrent effect on potential violators.

An interesting feature of this Act is that whenever any milk distributor sells recombined milk for fluid human consumption such a dairy is required to pay the Board of Agriculture a compensatory payment to be distributed to all producers who supply milk to this dairy. I should explain that recombined milk or reconstituted milk is a product which results from processing a mixture of nonfat milk solids, unsalted butter or cream and water.

I have attempted today to give you as brief an account as I could of the new developments in food and drug legislation in Hawaii. The food and drug problems which assail the federal government and our sister states are not much different from those which face us here in Hawaii. My fondest hope is that we may continue to give our citizens and those of you who visit us, the finest kind of public health and consumer protection services which our laws are designed to achieve. **[The End]**

Products Liability Today: Whither Thou Goest, I Will Go

(A Modern Tale of Biblical Ruth and Naomi)

By WARREN FREEDMAN

The Following Article Was Presented Before the American Bar Association Section of Corporation Banking and Business Law. Mr. Freedman, Counsel to the Bristol-Myers Company, Acknowledges the Assistance of His Associate, Lawrence M. Schopp, in the Preparation of this Paper.

TWO AUTOMOBILES COLLIDE AT AN INTERSECTION, Hollywood and Vine, or Broadway and 42nd Street, or Kalakaua and Kapahulu. The resulting injuries to the drivers and occupants are serious. Just a few years ago this fact situation would result in an automobile liability suit between the parties. Today, however, the accident is frequently not appropriate for automobile liability, because it is a products liability situation. The injured occupants, as well as the owners of the vehicles, have unfortunately been "brainwashed"[1] by plaintiffs' advocates, by crusading critics of the automobile industry, and by the popular press, into believing that there must be something wrong or defective with one or both of the automobiles! Why sue the real tort feasor when one can so much more profitably sue the dealer and the manufacturer of the automobiles! Perhaps the braking system of one vehicle was defective; perhaps the windshield wiper did not function properly; or perhaps the vehicle itself was not designed to be accident-proof![2] This unwarranted extension of prod-

[1] Justice Jefferson of the California Superior Court, City and County of Los Angeles, in *Drummond & Lyford v. General Motors Corp.* (decided July 29, 1966), wrote: "It was not until after the accident of May 16, 1960, that Mr. Drummond, upon reading and studying certain materials, such as Ralph Nader's book, *Unsafe at Any Speed,* and getting the opinions of others, formed an opinion and came to the conclusion that the automobile was dangerous and defective for the average driver. No such opinion resulted from his own experience of driving the Corvair for four months."

[2] Proof of "defect" by the plaintiff is no simple task, according to the Sixth Circuit United States Court of Appeals

(Continued on next page.)

ucts liability to such situations is highlighted when a pedestrian, cut by flying glass (and perhaps *the* witness to the automobile collision), sues upon an alleged warranty the automobile manufacturer and/or glass manufacturer, and *not* the negligent driver of the vehicle, contending that there must have been a "defect" in the shatterproof-glass window of the vehicle! In addition, strangers and/or mere bystanders[3] frequently allege a cause of action in warranty against the automobile manufacturer and/or the glass manufacturer, because, between the negligent driver and the product manufacturer, the latter is financially able and can better afford to pay the judgment or settle

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(Footnote 2 continued.)
in *Gossett v. Chrysler Corp.*, 359 F. 2d 84 (6th Cir. 1966). The "dove tail type" latch on the hood of the truck had been used successfully for over 25 years, and had functioned perfectly for the purpose it was intended, except when misused. Plaintiff's expert had testified that the hood latch was improperly designed. Under Ohio law, the Court pointed out, the manufacturer must "use reasonable care under the circumstances to so design his product as to make it *not* accident or foolproof, . . . The manufacturer is not an insurer that his product is, from a design viewpoint, incapable of producing injury." Senior Circuit Judge Cecil found that "there is no defect in the latch as produced and there was no negligence in its manufacture. It was manufactured strictly in accordance with the design. It functioned perfectly for the purpose for which it was intended. It was only when it was misused that it did not function properly."

[3] See Warren Freedman, "Help for the Third Party Casual Bystander: Extension of Warranty Beyond Foreseeability?" 157 *New York Law Journal* No. 64, p. 1, 1967. Note that under § 2-318 of the Uniform Commercial Code, a seller's warranty is extended *only* to any natural person who is in the family or in the household of the buyer, or who is a guest in his home, if it is reasonable to expect that such a person may use, consume, or be affected by the product, and who is injured by breach of the warranty.

The *Restatement (Second), Torts*, the veritable Bible of Strict Liability enthusiasts, expresses no opinion as to the application of § 402 A to injuries or harm to persons other than the ultimate *user or consumer*, or to their property. Official Comments under § 402 A spell out the necessity that the product may be "expected to reach the *user or consumer* in the condition in which it is sold." The fact that the product "can be damaged in the course of use and thereby become unreasonably dangerous" [see *Jakubowski v. Minnesota M & M Co.*, 42 N. J. 177, 199 A. 2d 826 (1964)] is perhaps a major reason for refusing to extend the benefits of warranties to mere bystanders, strangers, or members of the public. If the warranty is to be a "vehicle of social policy," as expressed by Harper and James [2 *Torts* 1571], then the interest to be protected is that of the *consumer or user* of the product and *not* the stranger or bystander. Accordingly, such warranty protection necessarily excludes bystanders, complete outsiders, and other third parties who happen to be in the path of harm when the alleged danger culminates in an accident. The injury is *not* a foreseeable risk of the manufacturer's enterprise, and considerations for imposing such risks on the manufacturer without regard to his fault do stop with those who undertake to use or consume the product. To extend the warranty benefits beyond the user or consumer presents a distortion of law and equity wholly incomprehensible in terms of "social policy."

out of court for a substantial amount.[4] However, the U. S. Seventh Circuit Court of Appeals last year in *Evans v. General Motors Corp.*,[5] issued this important caveat:

The intended purpose of an automobile does not include its participation in collisions with other objects, despite the manufacturer's ability to foresee the possibility that such collisions may occur.[6]

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[4] Note *Schemel v. General Motors Corp.*, 261 F. Supp. 134 (D. S. D. Ind. 1966). On defendant's motion to dismiss the Court entertained the incredible contention that General Motors had "a duty to refrain from manufacturing and selling cars capable of speeds in excess of 100 miles per hour, unless equipped with a *governor* in the case of sales to the 'ordinary consumer'." Also, plaintiff argued that General Motors had "a duty to refrain from advertising its motor cars in such terms as to incite irresponsible and reckless drivers to drive at speeds in excess of an arbitrarily selected limit." The Court ruled that the injured occupant of an automobile involved in a rear end collision had no cause of action! In Louisiana a housewife sued a pharmaceutical firm for a quarter of a million dollars in Federal Court charging that the oral contraceptive made her sterile. A scheduled pre-trial conference was postponed by her attorney because it seems the plaintiff was pregnant! *Drug Trade News*, April 10, 1967, p. 2.

[5] 359 F. 2d 822, 825 (7th Cir. 1966), Cert. *denied*, 358 U. S. 836 (1966). Herein the widow of a driver of a 1961 4-door Chevrolet station-wagon sued GM for alleged negligence in design. She contended that in an automobile collision with another vehicle her husband lost his life after the left door collapsed upon impact of the collision. The Court affirmed dismissal of the complaint.

Note the following *New York Times* story dated November 30, 1966:

"FORD SUED BY SPEEDER WHO LOST HIS LICENSE

"Elizabeth, N. J., Nov. 30—A defective speedometer in his new car resulted in a speeding ticket and suspension of his driver's license for 30 days, a Union Township man charged today in Superior Court here. [The motorist] filed a damage suit against the Ford Motor Company, manufacturer of the automobile, and Wymand Motors Inc., Maplewood, from which he purchased it June 6, 1964. The plaintiff charged that he was given a summons October 24, 1964, for going 62 miles an hour in a 50-mile zone in Cranbury Township while relying on the speedometer."

In *Mull v. Ford Motor Co.*, 368 F. 2d 713 (2d Cir. 1966), the plaintiff, standing at the rear of his parked car was struck by a taxicab. Evidence showed that the taxicab was disabled (allegedly due to defects in manufacturing and design), and the cab driver was endeavoring to move the vehicle to the curb by "bucking" the accelerator and starter. Suddenly the hood of the cab flew up in front of the windshield, blocking the driver's vision and the taxicab pinned the plaintiff between the rear of his car and the taxicab. The Court ruled that the taxicab driver's conduct amounted to an intervening act of negligence insulating the manufacturer from liability for negligence. On the issue of breach of implied warranty, one member of the Court declared that warranty or strict liability protection does not extend to a mere bystander. The other two members of the court simply held that no non-negligent act by the manufacturer was a legal cause of plaintiff's injury.

Mere bystanders injured by an explosion of a propane tank could not prevail on the theory of warranty because there was no privity of contract, *Fort Pierce Gas Co. v. Toombs*, Fla. 193 So. 2d 669 (Dist. Ct. App. 4th D. 1966). The Florida court cited *Rodriguez v. Shell's City Inc.*, 141 So. 2d 590 (Fla. App. 1962), and *Carter v. Hector Supply Co.*, 128 So. 2d 390 (Fla. 1961).

[6] *See page 489 for footnote 6.*

Another novel warranty pleading in products liability which should be brought in tort or negligence,[7] is the so-called implied warranty by a builder that the uncompleted house will, when completed, be suitable for the purpose intended. In *Mitchem v. Johnson*[8] the substance of the purchaser's complaint against the builder was that the lot and residence were located in an area which had surface water problems,

[6] The United States Court of Appeals for the Second Circuit, in *Mull v. Ford Motor Co.*, cited at footnote 5, specifically ruled that an automobile manufacturer could not be held liable for injury to a pedestrian: "In my view New York law would not permit recovery for breach of implied warranty by a mere bystander."

Note the vigorous dissent of Justice O'Hara of the Michigan Supreme Court in *Piercefield v. Remington Arms, Inc.*, 375 Mich. 85, 133 N. W. 2d 129 (1965): "Nor do we care to become, without clearly demonstrated need, judicial pioneers ordaining new theories for recovery merely because regrettable injury has occurred . . . .

. . . . we are not convinced that we should extend our doctrine . . . to bystanders outside the 'distributive chain'."

A casual guest in the home of purchaser was injured by an allegedly defective chair. Recovery was denied in a suit against the chair manufacturer in *Serrano v. Riverside Dinette Products Co.*, 222 N. Y. S. 2d 537 (1961).

[7] It should obviously be noted that the novelty of the remedy is being questioned—not the issue of liability, if any.

Another novel fact situation brought under the guise of products liability is found in *Shaw v. Fairyland at Harvey's*, 45 Misc. 2d 493, 257 N. Y. S. 2d 552 (1965), *aff'd*, 26 App. Div. 2d 576, 271 N. Y. S. 2d 70 (1966). Plaintiffs and their daughter were passengers in a gondola of a ferris wheel owned and operated by defendants. During the ride the gondola overturned, the passengers upon being thrown out were injured, and the daughter died as a result of the injuries. Plaintiffs alleged that in selling a ticket for the ride defendants had impliedly warranted that the ferris wheel was fit for the particular purpose. Mr. Justice Munder of the New York Supreme Court, Suffolk County, ruled that the warranty cause of action was "untenable and insufficient in law." The Court found "no sale" and "neither hiring nor bailment." Plaintiffs were relegated to their causes of action in negligence.

In *Berzon v. Don Allen Motors, Inc.*, 23 App. Div. 2d 530, 256 N. Y. S. 2d 643 (1965), the injured passengers in an automobile, which collided with a truck having defective brakes, had no cause of action in warranty against the vendor of the truck. The passengers were *not* contemplated users of the product: — "To extend *Goldberg* further to include bystanders and strangers, such as the plaintiffs, would be such a *radical departure* from established law that, if it is to be accomplished it should be done by legislative action and not judicial pronouncement."

In *Shumard v. General Motors Corp.*, — F. Supp. — (D. S. D. Ohio, decided February 28, 1967), the decedent, an occupant of an automobile, died after a collision with another car when the car in which he was riding erupted into flames. Attorney for the decedent argued that GM had a duty to design the automobile so that it was impervious to fire or fireproof! The obvious "impracticality" and "unreasonableness" of plaintiff's argument was met by the Court in dismissing the Complaint: "An automobile manufacturer cannot construct a fireproof vehicle unless it forsakes the use of any and all combustible materials." And — "No duty exists to make an automobile fireproof; nor does a manufacturer have to make a product which is 'accident-proof' or 'foolproof.'"

[8] 7 Ohio St. 2d 66, 218 N. E. 2d 594 (1966).

and that high water had caused structural damage to the house. The trial court instructed the jury that, as a matter of law, there is an implied warranty of fitness for particular purpose in the sale of the unfinished residence. Justice Schneider of the Ohio Supreme Court *reversed* and observed that "a contract to furnish labor and materials is not a sale if the finished product is not personal property." The Court refused to find that any implied warranty existed "in a contract to construct a dwelling on a lot owned by the contractee," and opined: "One does not purchase land under conditions in any way similar to the purchase of home permanents . . . ."[9]

But unfortunately there is respectable authority to the contrary, imposing a warranty upon house and/or lot as a products liability situtation.[10]

Still another illustration of this irrational approach toward what constitutes a products liability situation today is *Russell v. Community Blood Bank Inc.*[11] Here it was held that the furnishing of blood by a blood bank constituted a "sale" of a product, thereby giving rise to causes of action for breach of implied warranties. Although the majority view is decidedly to the contrary, that is, no warranty can arise out of a "service,"[12] the Florida Court opined that there should be a distinction between a defendant blood bank and a defendant hospital, although admittedly "we have found no case in which such a warranty has been implied." To assuage its collective conscience, the Court declared that the "proof that the defect in the blood is undetectable and unremovable would be a defense to breach of implied warranty."

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[9] See footnote 8 at 218 N. E. 2d 598 (1966). The highest Ohio court also held that, in the absence of an *express* warranty, caveat emptor controls the purchase and sale of a completed structure. However, while it is an *implied* term of sale that the builder will complete the house in a workmanlike manner, the burden is on the plaintiff to show that the defendant failed to exercise ordinary care under the circumstances and that this lack of good workmanship proximately caused the damage. Compare *Staff v. Lido Dunes Inc.*, 47 Misc. 2d 322, 262 N. Y. S. 2d 544 (1965).

[10] Compare *Bethlahmy v. Bechtel*, — Idaho —, 415 P. 2d 698 (1966), wherein the Idaho Supreme Court criticized the majority view illustrated by *Levy v. C. Young Construction Co.*, 46 N. J. Super. 293, 134 A. 2d 717 (1957). The majority view holds that chaotic uncertainty would pervade the entire real estate field if sellers were not subject to liability for implied warranty of fitness. See Comment, 15 *DePaul Law Review* 440 (1966).

[11] 185 So. 2d 749 (Dist. Ct. App. 1966), *aff'd* — Fla. —, — So. 2d — (1967).

[12] The New York Appellate Division, 1st Dept., on March 15, 1966 in *Aegis Productions, Inc. v. Arriflex Corp.*, 25 App. Div. 2d 639, 268 N. Y. S. 2d 185 (1966), an action for damages for an allegedly defective timer in a camera, set forth in a memorandum opinion the following: "Warranties are lim-

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Much of this confusion and overreaching, delineated by the Biblical, "whither thou goest, I will go," can be traced to the adoption of Section 402A of the *Restatement (Second), Torts* by the American Law Institute (ALI). In an unprecedented departure from its traditional role of restating carefully and impartially the law, the ALI in 1965 exceeded its authority by approving a forecast or prophecy of what the law should be![13] Although the Strict Liability in Tort doctrine did not even represent a respectable *minority* view[14] at the time it was adopted by the ALI, the doctrine became a shibboleth to the ALI in the mistaken belief that it was "following the development of the law," that is, "Whither thou goest, I will go." Indeed, any such concept of liability *without* fault, as contemplated by the ALI, is predicated upon an ancient notion that the sole risk of injury, damage, or loss must rest upon the "father," or the product manufacturer, regardless of the fault of the other "non-paternal" parties to the matter. But the dynamics of products liability law has not run the course of the normal growth of the law,[15] that is, adjusting sensibly and predictably to changing circumstances; but rather products liability

(Footnote 12 continued.)
ited to sales of goods. No warranty attaches to the performance of a service (*Perlmutter v. Beth David Hosp.*, 308 N. Y. 100). If the service is performed negligently, the cause of action accruing is for that negligence. Likewise, if it constitutes a breach of contract, the action is for that breach. The distinction in the case of a *sale* of goods is that a warranty gives rise to a cause of action . . . . (Uniform Commercial Code, §§ 2-313, 2-314). No such right has ever been extended to include the consequence of a performance of a service."

[13] It might be observed that when § 402 A was first drafted it applied only to foodstuffs. When § 402 A came before the ALI, it was amended on the floor and applied also to things of intimate bodily contact such as face powders, hair lotions, or even surgical pins inserted into a bone. Two years later in 1965 the Section was again amended so as to apply to any product whatsoever.

[14] California in 1963 [*Greenman v. Yuba Power Products, Inc.*, 59 Cal. 2d 57, 27 Cal. Rptr. 697, 377 P. 2d 897]; New Jersey in 1960 [*Henningsen v. Bloomfield Motors Inc.*, 32 N. J. 358, 161 A. 2d 69]; and New York in 1963 [*Goldberg v. Kollsman Instrument Corp.*, 12 N. Y. 2d 432, 240 N. Y. S. 2d 592, 191 N. E. 2d 81]. As of early 1967 perhaps eleven states can be classified as "strict liability" states, based upon a leading case decision: Illinois [*Suvada v. White Motor Co.*, 32 Ill. 2d 612, 210 N. E. 2d 182 (1965)]; Texas [*Putnam v. Erie City Mfg. Co.*, 338 F. 2d 911 (5th Cir. 1964)]; Connecticut [*Garthwait v. Burgio*, 153 Conn. 290, 216 A. 2d 189 (1965)]; Kentucky [*Dealers Transport Co. Inc. v. Battery Distr. Co.*, — Ky. —, 402 S. W. 2d 441 (1966)]; Oklahoma [*Marathon Battery Co. v. Kilpatrick*, — Okla. —, 418 P. 2d 900 (1965)]; Tennessee [*Ford Motor Co. v. Lonon*, — Tenn. —, 398 S. W. 2d 240 (1966)]; Vermont [*Deveny v. Rheem Mfg. Co.*, 319 F. 2d 124 (2d Cir. 1963)]; and Mississippi [*State Stove Mfg. Co. v. Hodges*, — Miss. —, 189 So. 2d 113 (1966)].

[15] See "Product Liability—How to Minimize the Hazards" (Research Institute of America Report to Management, File 32, March 28, 1960, prepared by staff in cooperation with this author.)

has become a by-product of selfish interests actuated by plaintiffs' bar associations and by uninformed consumer-protection organizations. Even the most common, everyday occurrence is suspected as having products liability "potentialities;" the unusual and unexpected circumstances or episodes, involving even carelessness on the part of the user of a consumer product, have now attracted the interest of high-priced plaintiffs' advocates. During the past three years alone there has occurred such an increase in products liability litigation, based upon the most incredible allegations, that it is no wonder that our courts are crowded and our trial calendars are so far behind. Indeed, these zealous aggrandizers ranting for "more adequate awards" have coerced many courts into accepting the Strict Liability doctrine,[16]

[16] Let us briefly view a few of these recent lawsuits which exhibit the courage of some courts in resisting the "no choice" propaganda:

(1) A cigarette lighter is alleged to have set fire to an automobile in *Halsey v. Ford Motor Co.*, 24 App. Div. 2d 826, 264 N. Y. S. 2d 16 (1965). Here the plaintiff purchased an automobile and two months later returned the car to the dealer complaining that the cigarette lighter did not work properly. Necessary repairs were made and apparently the cigarette lighter functioned perfectly. Approximately five months later, after the car had been driven almost 4,000 miles, the plaintiff alleges that, while the car was parked on a country road for half an hour, the plaintiff, upon opening the door of the car heard a noise, saw flames shoot out of the dashboard, and soon the entire interior of the car became engulfed in flames. Suit was brought against the automobile manufacturer alleging a *defective* cigarette lighter! A jury returned a verdict in favor of the plaintiff for the loss of the car, but the New York appellate court *reversed*, pointing out that speculative, expert evidence should have been given no weight, since the plaintiff did not prove that the cigarette lighter was defective, or that even a defective lighter could have ignited the car. The Court remarked that plaintiff's expert admitted on cross-examination that he could not find anything defective about the particular lighter, that he did not feel qualified to judge that a particular cigarette lighter was defective and that he had never seen a car ignited by such means. Admittedly, a cigarette butt carelessly put in the ash tray or dropped on the seat might have started the fire. (The Court quoted *White v. Lehigh Valley R.R. Co.*, 220 N. Y. 131, 135, 136, 115 N. E. 439, 441 (1917), to the effect that "when the precise cause of an accident is left to conjecture and may be as reasonably attributed to a condition for which no liability attaches as to one for which it does, then the plaintiff is not entitled to recover, . . ." Plaintiff's expert was amazed to learn that the cigarette lighter was equipped with a thermo-safety fuse!

(2) A powder-actuated tool is alleged to have caused a stud to ricochet into the user's eye, although the user was an experienced electrician who had used the tool for several years, but he was apparently careless on this one occasion resulting in his own injury. The tool had a printed statement on its shield, "never operate without setting safety control to minimize possible ricochet." The North Carolina Supreme Court in *Hollenbeck v. Fasteners Co.*, 267 N. C. 401, 148 S. E. 2d 287 (1966), ruled that plaintiff demonstrated no defect in the product, and had not placed any reliance upon the oral statement of the vendor that the tool was safe, if properly used. De-

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a veritable Hobson's Choice.[17]

When Ruth immortalized her mother-in-law, Naomi, twenty centuries ago in the words, "Whither thou goest, I will go," she was expressing a deep, personal conviction that Naomi's righteous way of life was worth following, that the friendship between these two women must continue. *But* this wonderfully charming Biblical story has unfortunately been exploited, and has become the monotonous theme of plaintiffs' trial lawyers and certain consumer groups crying out for that day when the world will be rescued from predatory product manufacturers.[18] Our courts are asked by these exploiters to accept, "Whither thou goest, I will go," and follow unquestioningly the plaintiff-oriented decisions of certain judges, many of whom have been honored by plaintiffs' bar associations. Harried judges have been individually courted, government officials suspiciously honored, and consumer groups feted, in the belief that they will also respond, "I will go," to the constant poundings of plaintiffs' advocates, who readily "goeth." Plaintiffs' leadership is indeed dedicated, resourceful, and

(Footnote 16 continued.)
fendant's motion for a non-suit was granted, and affirmed on appeal.

(3) A used wooden stepladder to which the plaintiff-purchaser had nailed strips of wood on the bottom of both front and back legs, is alleged to have collapsed as its left rear leg broke and plaintiff was injured. Defendant's expert testified that it was wrong for plaintiff to have driven nails into the wood since it weakened the wood; and also it was wrong for plaintiff to have put cleats on the bottom of the ladder, thereby causing the ladder to teeter-totter on an irregular surface, *Erickson v. Sears Roebuck & Co.*, 50 Cal. Rptr. 143, 240 Cal. App. 2d 793 (1966). The California court affirmed the trial judge's instructions to the jury to return a verdict for the defendants, and declared that Strict Liability in Tort requires not only proof of "defect," but also proof that the product was used in a manner intended by the product manufacturer.

(4) An automobile, which subsequent to the accident was junked, was alleged to have had a defective tire which blew out and injured plaintiff-driver in *Shramek v. General Motors Corp.*, 69 Ill. App. 2d 72, 216 N. E. 2d 244 (1966). The Illinois Appellate Court affirmed entry of summary judgment in favor of defendant tire manufacturer and defendant automobile manufacturer because, *in the absence of the tire*, the "plaintiff will not be able to prove, directly or inferentially the essential elements of his case; that is, (1) that the accident which resulted in his injuries was caused by a tire, and (2) that said tire was defective." The Court emphasized that "the cornerstone of plaintiff's cause of action is the existence of a defect in the tire at the time it left the control of the manufacturer or seller."

[17] Hobson's Choice is an expression which means no choice at all. It is derived from the practices of an eccentric English innkeeper and carrier Thomas Hobson (1544-1631) who possessed a stable of 40 horses, but always compelled the traveler to "choose" the horse nearest the stable door. Thus, he was able to exercise all his horses. *Spectator No. 509* (Oct. 14, 1712).

[18] See Warren Freedman, "Products Liability," *New York Law Journal* April 4, 1960, p. 1. See also Warren Freedman, "DRI Monograph on Products Liability" (1963).

geared to the old-fashioned "profit motive," that is, "follow us and get rich," they cry. The Biblical Ruth would not have followed!

Let us now examine several recent "innovations" engrafted by plaintiffs' advocates upon the law of products liability, in exploitation of a Ruth-Naomi friendship:

I. Privity of Contract Is Dead: The Citadel Has Been Assaulted!

II. Strict Liability in Tort Is the Law of the Land; There Is No Such Thing As a Safe Product!

III. Liability Without Fault Is Desirable; Why Worry About Who Is Legally to Blame?

IV. "Defect" in a Product Is Inferred from the Nature of the Injury or Loss; Every Product Is Really Defective!

V. The Uniform Commercial Code Cannot Restrict Developing Products Liability Law: "Whither Thou Goest, I Will Go!"

I. Privity of Contract

"Privity" is the connection or relationship which exists between two or more parties to a transaction. Since *McPherson v. Buick Motor Co.*[19] it has not been an essential ingredient in a cause of action in negligence, but its importance in the warranty cause of action was stressed by the New York Court of Appeals forty-four years ago.[20] In the past several years the courts have been inclined to view "privity of contract" as anachronistic in an age of high-powered product advertising because, it is argued, the public is no longer content to purchase the brand product by reference to the relationship between vendor and purchaser.[21] Judge Cardozo's "assault upon the citadel of privity" culminated in an extension of the benefits of privity to persons other than the purchaser. The Uniform Commercial Code[22] extended the seller's warranty[23] to any natural person who is in the family or in the household of the buyer, or who is a guest in his home,[24] if it is

[19] 217 N. Y. 382, 111 N. E. 2d 1050 (1916).

[20] *Chysky v. Drake Bros. Co.*, 235 N. Y. 468, 139 N. E. 576 (1923).

[21] Compare the view of the Rhode Island Supreme Court in *Henry v. John W. Eshelman & Sons*, — R. I. —, 209 A. 2d 46 (1965), which expressly refused to discard privity of contract in a breach of warranty case. See also *Harnischfeger Corp. v. Harris*, — Ala. —, 190 So. 2d 286 (1966), upholding privity of contract until such time as the legislature effectuates a change.

[22] Section 2-318 thereof.

[23] Note that California adopted the Uniform Commercial Code without § 2-318. See Lascher, "Strict Liability in Tort for Defective Products: The Road to and Past Vandermark," 38 *Southern California Law Review* 30 (1965).

[24] See *Hochgertel v. Canada Dry Corp.*, 409 Pa. 610, 187 A. 2d 575 (1963), decided by the Supreme Court of Pennsylvania, the first state to enact the Uniform Commercial Code. Justice

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reasonable to expect that such person may use, consume, or be affected by the product, and who is injured in person by the breach of the warranty.[25] In 1963 it was predicted [26] that the courts would apply this limitation sensibly, and not unequivocally renounce the virtues of "privity"[27] which, for example, would justifiably bar a warranty cause of action to an injured stranger, passerby, or mere bystander, whose suit should not be based upon warranty, but upon negligence, if any.[28]

In Connecticut recently a golfer on the 17th green was fatally injured by a parked automobile which ran down an incline, where it had been parked by the vehicle owner who alleged that he had properly parked the car but that, due to an alleged defect in the locking mechanism of the gear, the gear did not lock.[29] The pleadings did not clearly reveal whether such a defect in the vehicle existed; but defendant's demurrer was not sustained.[30] The Connecticut Court

(Footnote 24 continued.)
Eagen pointed out that Pennsylvania courts "did not outrightly reject the 'privity of contract' rule, . . ."

[25] Note that the landmark New York case of *Greenberg v. Lorenz*, 9 N. Y. 2d 195, 213 N. Y. S. 2d 39, 173 N. E. 2d 773 (1961) merely extended the benefits of warranty to the daughter of the purchaser. A year later in *Randy Knitwear Inc. v. American*, 11 N. Y. 2d 5, 226 N. Y. S. 2d 303, 181 N. E. 2d 399 (1962), the concurring opinion of Judge Froessel emphasized that the requirement privity had not been dispensed.

[26] Warren Freedman, "Extension of Benefits of Warranty: A Rebirth of Privity of Contract in New York," *Insurance Law Journal*, May 1963, p. 276.

[27] See cases set forth in footnote 16.

[28] See *Berzon v. Don Allen Motors*, 23 App. Div. 2d 530, 256 N. Y. S. 2d 643 (1965).

[29] *Mitchell v. Miller*, 26 Conn. Sup. 142, 214 A. 2d 694 (1965). Compare the incident referred to in footnote 5 concerning the speedometer on the Ford automobile!

[30] The *Mitchell* case, cited at footnote 29, while representing a decided *minority* of authority, is a fitting example of the efforts of a small number of courts (under the guise of a self-professed, "sound public policy") which permit the third party bystander to sue the product manufacturer directly. In this case the defendant had perhaps imprudently parked a 1962 Buick vehicle on an incline in the parking area of the Wallingford Country Club, which overlooked the 17th fairway of the golf course. Defendant alleged that he had placed the hydramatic transmission gear shift lever in "park" and had locked all the doors of the car. Some time thereafter the car rolled down the incline, striking the decedent who was playing golf on the 17th fairway. It was alleged that the Buick automobile had a "defect", to wit: the failure of the transmission to lock in "Park." The Connecticut court admitted that, according to the Complaint, the decedent "could (not) reasonably have been anticipated by this defendant to have been one who would use, occupy or service the operation of the automobile." At 214 A. 2d 696. And, despite the Strict Liability in Tort doctrine of a "user" or "consumer," the Court determined to give a cause of action against the automobile manufacturer to this casual, innocent bystander! The Connecticut court, it is respectfully submitted, (a) totally ignored the leading 1964 Connecticut case denying recovery to a non-user, to wit: *Kuschy v. Norris*, 25

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was over-anxious to bridge the gap of privity and compensate the innocent bystander, who might have a valid negligence action against the automobile owner; however, this bystander is hardly a "foreseeable plaintiff" from the view of the product manufacturer. In another case, however, Connecticut denied recovery to an injured member of the public upon breach of warranty because the injured person was *not* "in the contemplation of the parties to the contract" and would *not* be "expected to use, occupy, or service the used automobile."[31] The majority of courts[32] do *not* extend the benefits of warranty to casual third party bystanders who have no relationship to the purchaser or to the product manufacturer.[33] It is of interest to note that Section 402A of the *Restatement (Second), Torts,* though delineating strict liability in tort, expresses no opinion as to the application of the Section to persons other than the ultimate user or consumer of the product.[34]

The buyer's *reliance* upon the seller's skill or judgment[35] is an essential element of the warranty cause of action and presupposes the

(Footnote 30 continued.)
Conn. Sup. 383, 206 A. 2d 275 (1964), and (b) rested its determination upon a *single*, opposing case in the State of Michigan, to wit: *Piercefield v. Remington Arms Co.*, 375 Mich. 85, 133 N. W. 2d 129 (1965).

It should be noted that in the *Kuschy* case, the Connecticut court expressly distinguished leading Connecticut cases of *Hamon v. Digliani*, 148 Conn. 710, 174 A. 2d 294 (1961), and *Connolly v. Hagi*, 24 Conn. Sup. 198, 188 A. 2d 884 (1963), as well as the New Jersey landmark decision of *Henningsen v. Bloomfield Motors Inc.*, cited at footnote 14, by flatly stating that "no reported cases can be found which extend the benefits to the members of the public," *Hamon v. Digliani*, at 206 A. 2d 276. Indeed the famed *Henningsen* case left open the question whether a warranty ought to run to members of the public and bystanders who are in the path of harm from a defective automobile.

[31] *Kuschy v. Norris*, cited at footnote 30, which found "no reported cases . . . which extend the benefits to members of the public." The Connecticut court expressly distinguished *Hamon v. Digliani*, cited at footnote 30, and *Connolly v. Hagi*, cited at footnote 30, as well as the famed New Jersey *Henningsen* case, cited at footnote 14.

[32] See *Berzon v. Don Allen Motors Inc.*, cited at footnote 28; *Rodriguez v. Shell's City Inc.*, 141 So. 2d 590 (Fla. App. 1962), and *Mull v. Colt Co.*, 31 F. R. D. 154 (D. S. D. N. Y. 1962).

[33] Note Justice O'Hara's vigorous dissent in *Piercefield v. Remington Arms Co.*, at footnote 6.

[34] *Rodriguez v. Shell's City Inc.*, cited at footnote 32. The injury or loss must be a foreseeable risk of the manufacturer's enterprise. The Florida District Court of Appeals in 1965 opined at 141 So. 2d 591: "Whatever inroads have been made in recent years toward liberalizing the availability of the implied warranty action against one not in privity with the injured, the courts of this state have never relaxed the requirement that the injured be a user of the product involved."

[35] See, for example, Uniform Commercial Code § 2-314. Note *Janko v. Roux Distrib. Co.*, 124 Ohio St. 48, 162 N. E. 2d 124 (1959) dismissing plaintiff's appeal for failure to show reliance upon any express warranty. See also *Wilken v. Holland*, 343 F. 2d 147 (4th Cir. 1965), on the issue of reliance upon a warranty.

existence of some relationship between buyer and seller. That "relationship," however, may be "extended" through many persons or parties who are deemed mere conduits, in the sense that they do not "break the connection" between buyer and seller. It is well to note that Dean Prosser in his 1960 article, "The Assault Upon the Citadel"[36] opined: "No one doubts that unless there is privity, liability to the consumer must be in tort and not in contract." Accordingly, although the citadel of privity may have been successfully assaulted, privity is not dead![37] Let us not bury "privity" prematurely and certainly not without proper regard for the interests of all parties to the transaction.

II. Strict Liability in Tort

Strict Liability in Tort represents a distinctly *minority* position[38] which began to take shape in 1960 when the *Henningsen*[39] case was decided in New Jersey. However, the New Jersey Supreme Court subsequently expressed second thoughts on the subject as evidenced by its 1965 pronouncements that contributory negligence is a valid defense.[40] California, whose liberal Supreme Court has engineered many profound changes in the law of products liability,[41] has nevertheless weighed in with a sensible evaluation of Strict Liability, as delineated in *Drummond v. General Motors Corp.*[42] Here California

[36] 69 *Yale Law Journal* 1099, 1134 (1960). See also Warren Freedman "Prescription or Ethical Drugs: Fallacies as to Warranties, Failure to Warn and Strict Liability in Tort," 21 Food Drug Cosmetic Law Journal 599 (November, 1966) and *Practising Law Institute Monograph* (New York 1966).

[37] See *Serrano v. Riverside Dinette Products Co.*, 222 N. Y. S. 2d 537 (1961). "The plaintiff in his memorandum in opposition to the motion evinces a penchant for literary phrases and Horacean purple patches and Biblical quotations, and constitutes himself in the role of a joyous participant at the funeral rites of the 'doctrine of privity.' However, one need not, in the words of the plaintiff's brief, be guilty of 'judicial myopia' to ascertain that the doctrine of privity is not yet moribund and that one would be guilty of impropriety if he attempted to conduct a funeral without a corpse."

[38] See footnote 14. See also Defense Research Institute "Brief Opposing Strict Liability in Tort" (*Restatement (Second), Torts*, § 402 A) (1966).

Texas has repeatedly refused to extend the doctrine of Strict Liability beyond food cases (*Decker & Sons v. Capps*, 139 Tex. 609, 164 S. W. 2d 828, 1942). See *McKisson v. Sales Affiliates Inc.*, — Tex. Civ. App. —, — S W 2d — (1966); and *Capetillo v. The Crosby County Fuel Assn.*, — Tex. Civ. App. —, — S. W. 2d — (1966).

[39] *Henningsen v. Bloomfield Motors, Inc.*, 32 N. J. 358, 161 A. 2d 69 (1960).

[40] See *Maiorino v. Weco Products*, 45 N. J. 570, 214 A. 2d 18 (1965), and *Cintrone v. Hertz Truck L & R Service*, 45 N. J. 434, 212 A. 2d 769 (1965).

[41] See, for example, *Vandermark v. Ford Motor Co.*, 61 Cal. 2d 256, 37 Cal. Rptr. 896, 391 P. 2d 168 (1964), and *Greenman v. Yuba Products Inc.*, 27 Cal. 2d 57, 27 Cal. Rptr. 697, 377 P. 2d 897 (1963).

[42] See footnote 1.

Superior Court Judge Jefferson concluded from 10,000 pages of testimony by 41 witnesses and about 240 exhibits during 16 weeks of trial, that the product "is not defectively designed nor a defective product," and that the product "matches a standard of safety which does not create any unreasonable risk of harm to an average driver." The California Court emphasized:

> It is an integral part of the law of strict liability in tort for defective products that liability of the manufacturer and seller attaches *only* if the product is being used by the user or consumer in a way it was intended to be used, or is being handled in a normal way by the user or consumer.

California holds that Strict Liability is NOT *absolute* liability![43]

Strict Liability, in essence, requires plaintiff to prove that the product was "UNREASONABLY DANGEROUS";[44] the product contained a specific "DEFECT"[45] or was "IN A DEFECTIVE CON-

[43] Chief Justice Traynor of the California Supreme Court in 32 *Tennessee Law Review* 363, 366, 367 (1965) declared: "It should be clear that the manufacturer is not an insurer for all injuries caused by his products."

See also *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); "No rule of strict liability (whether expressed in terms of breach of an implied warranty, or in terms of a breach of a duty of care in tort) has been applied to a failure adequately to warn of the dangers inherent in the use of the drug." Oregon [*Cochran v. Brooke*, — Ore. —, 409 P. 2d 904 (1966); *Lewis v. Baker*, — Ore. —, 413 P. 2d 400 (1966)]; and Texas [*Cudmore v. Richardson-Merrell, Inc.*, — Tex. Civ. App. —, 398 S. W. 2d 640 (1965)] take the identical position.

[44] *Restatement (Second), Torts* § 402A Official Comment i: "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases . . . (the product) with the ordinary knowledge common to the community as to its characteristics."

In *State Stove Mfg. Co. v. Hodges*, — Miss. —, 189 So. 2d 133 (1966), the Supreme Court of Mississippi, in a 26-page opinion written by Chief Justice Ethridge, who wrote both the majority and minority opinions (4 of the 9 justices, including Chief Justice Ethridge, dissented in part) has recently construed the Strict Liability in Tort Doctrine. The Court ruled, based upon § 402A of the *Restatement (Second) Torts*, that the doctrine imposed no liability upon the product manufacturer because (1) the product as manufactured was not in a defective condition, unreasonably dangerous to the user or consumer or to his property; (2) the product was not expected to and did not reach the purchaser without substantial change in the condition in which it was sold; and (3) the intervening, sole proximate cause of the injury was the negligent failure of a third party to follow the manufacturer's instructions for the installation of the product.

[45] Testimony of "specific defect" may take the form of (1) direct evidence by an expert [*Swift & Co. v. Wells*, 201 Va. 213, 110 S. E. 2d 203 (1959)]; (2) circumstantial evidence by an expert [*LeBlanc v. Ford Motor Co.*, 346 Mass. 225, 191 N. E. 2d 301 (1963)]; (3) direct evidence by the user or other eyewitnesses of the product's failure or malfunction, substantiated by expert opinion evidence [*Comstock v. General Motors Corp.*, 358 Mich. 163, 99 N. W. 2d 627 (1959)]; or (4) inferential evidence of a specific defect by negating all other possible causes [*Delta Oxygen Co. v. Scott*, 383 S. W. 2d 885 (Ark. 1964)].

(Continued on next page.)

DITION";[46] the injury or loss was PROXIMATELY CAUSED by the specific "defect" in the product;[47] the product "reached the user or consumer in the condition in which it was sold"; [48] the product was used in a manner which was reasonably foreseeable;[49] and that the very *use* of the defective product caused the injury or the loss.[50] Indeed,

(Footnote 45 continued.)

In the *Jakubowski* case, 42 N. J. 177, 199 A. 2d 826 (1964), the Court directed that proof of defect must be shown by "direct evidence."

[46] Warren Freedman, "'Defect' in the Product—The Necessary Basis for Product Liability in Tort and in Warranty," 33 *Tennessee Law Review* 323 (1966).

[47] Warren Freedman, "Products Compensation: Who's Pushing Whom?" (Address on August 12, 1964, before ABA Section of Corporation, Banking and Business Law, New York City.)

The issue of Proximate Cause was particularly delineated by the New Jersey Supreme Court in *Caputzal v. Lindsay Co.*, 48 N. J. 69, 222 A. 2d 513, 514 (1966): "'The claim is a bizarre one . . . . Early in November 1961, he [plaintiff] purchased a water softener for his home which was manufactured, sold and installed by defendants. The installation was completed on November 9 and it functioned without difficulty until November 23 . . . . Very early that morning he drew water from a faucet in the kitchen sink and made coffee. He did not look at the water and could not say whether it was discolored. He drank the coffee without any ill effect. A half to three quarters of an hour later, he turned on a faucet in the bathroom to brush his teeth and saw that the water coming from it was brownish or rusty in color. He did not put any of it in his mouth, but, assuming that the water with which he had made the coffee was similarly discolored, thought he had been poisoned . . . . A heart attack immediately ensued . . . .' Plaintiff charged defendants with breach of warranty and negligence. The New Jersey Supreme Court, reversing the judgment of the Appellate Division and reinstating the Law Division's summary judgment for defendants held: 'We have no hesitancy in determining here that plaintiff's heart attack, caused by psychic stimuli, was, under the facts before us, so highly extraordinary a result of any conduct of defendants that any acts or omissions of theirs should not be held to be the legal cause thereof.'" 222 A. 2d 518.

[48] *Restatement (Second), Torts* § 402A. See *Jakubowski v. Minnesota M & M Co.*, cited at footnote 45 at 199 A. 2d 831: "When a product can be damaged in the course of use and thereby become unreasonably dangerous, we cannot hold the manufacturer liable in warranty for the mere failure of the product . . . ." The *Jakubowski* decision makes it clear that the plaintiff has the burden of proving the product to be "defective:" "(I)t is necessary for the plaintiff to show that the dangerous condition which he contends constitutes a breach of warranty had its genesis when the instrumentality was within the control of the manufacturer. Accordingly, in the absence of direct evidence that the product is defective because of a manufacturing flaw or inadequate design, or other evidence which would permit an inference that a dangerous condition existed prior to sale, it is necessary to negate other causes of the failure of the product for which the defendant would not be responsible, in order to make it reasonable to infer that a dangerous condition existed at the time the defendant had control."

[49] See *Spruill v. Boyle-Midway Inc.*, 308 F. 2d 79 (4th Cir. 1962). In the *Greenman* case, cited at footnote 14, at 64, the California court emphasized that the plaintiff must prove that "he was injured while using the (power tool) in a way it was intended to be used. . . ."

[50] See Uniform Commercial Code § 2-314 and a fine article, Rapson, "Products Liability Under Parallel Doctrines: Contracts Between the Uniform Commercial Code and Strict Liability in Tort," 19 *Rutgers Law Review* 692 (1965).

Strict Liability in Tort is, in reality, a thinly disguised "implied warranty imposed by law," against which a federal court many years ago declaimed: "To imply a warranty which imposes a greater liability than the law fixes, may operate most unjustly, and is really a fiction probably far from the actual intentions of the parties."[51]

Recognized defenses to Strict Liability in Tort[52] include not only plaintiff's burden of proving a prima facie case[53] but also (a) contributory negligence,[54] (b) assumption of the risk,[55] (c) abnormal or unintended use,[56] and (d) intervening cause.[57] Implicit in the language of the California Court in the *Greenman*[58] case are the requisites that "plaintiff prove a defect in design and manufacture of which plaintiff was not aware," and "plaintiff prove that he was injured while using the Shopsmith (product) in a way it was intended to be used."[59] Indeed, plaintiff's failure to exercise reasonable care (or contributory negligence) is a bar to strict liability in tort.[60] The *Restatement (Second), Torts*[61] equates this defense with "assumption of the risk," predicating non-liability upon plaintiff's voluntary and unreasonable conduct in encountering a known danger in the product.

[51] *Woolworth v. Wilson*, 74 F. 2d 439, 442 (5th Cir. 1934).

[52] See Warren Freedman, "Are There Any Defenses to Strict Liability in Tort?," *New York Law Journal* (May 2 and 3, 1966), p. 1.

[53] See *Oppenheimer v. Sterling Drugs Inc.*, 7 Ohio App. 2d 103, 219 N. E. 2d 54 (1964), to the effect that there was nothing in the record indicating anything the product manufacturer did or did not do that was contrary to the *standard of ordinary care*. Plaintiff accordingly denied recovery for negligence and for breach of warranty.

[54] See cases collected in 4 *A.L.R. 3rd* 501. See also *Kopera v. Fisher Scientific Co.*, 23 App. Div. 2d 851, 259 N. Y. S. 2d 165 (1965).

[55] See *Restatement (Second), Torts* § 402 A, and also 19 *S. W. L. J.* 61 (1965). Justice Peters of the California Supreme Court, in his concurring opinion in *Seely v. White Motor Co.*, 63 Cal. 2d 9, 45 Cal. Rptr. 17, 403 P. 2d 145 (1965), declared that Strict Liability "permits the defense of assumption of the risk." See also *McDaniel v. Williams*, 23 App. Div. 2d 729, 257 N. Y. S. 2d 702 (1965), and *Hogge v. U. S. Rubber Co.*, — Fla. App. —,— So. 2d — (1966).

[56] See generally Bushnell, "Illusory Defense of Contributory Negligence in Product Liability," 12 *Cleve.-Mar. L. Rev.* 412 (1963).

[57] See *Magee v. Wyeth Laboratories Inc.*, 214 Cal. App. 2d 340, 351, 352, 29 Cal. Rptr. 322, 328 (1963): "Failure to follow an unchallenged method of use prescribed by the manufacturer constitutes a break in causation which exonerates the manufacturer from any liability."

[58] 59 Cal. 2d 57, 27 Cal. Rptr. 697, 377 P. 2d 897 (1963).

[59] See also *Colvin v. Superior Equipment Co.*, 96 Ariz. 113, 392 P. 2d 778 (1964).

[60] See footnote 53. Note *Ferraro v. Ford Motor Co.*, 423 Pa. 324, 223 A. 2d 746, 748 (1966): "(I)f the buyer knows of the defect and *voluntarily* and *unreasonably* proceeds to use the product or encounter a known danger, this should preclude recovery and constitute a complete defense to the action even in cases of strict liability."

[61] *Restatement (Second), Torts* § 402 A, Official Comment n.

In *Cintrone*[62] the highest New Jersey Court (though not referring to Section 402A) held that a jury would find that the plaintiff "with knowledge of the danger presented by defective brakes failed to take the care of his own safety, which a reasonably prudent person would have taken under the circumstances." In the *Maiorino*[63] case the highest New Jersey Court spoke of contributory negligence in its "broad sense" as a defense to a warranty action. The Michigan Court of Appeals in *Baker v. Rosemurgy*[64] rendered summary judgment for the manufacturer, distributor, and retail vendor of a rifle with an alleged defective safety mechanism because the plaintiff (injured when he dropped the rifle) was aware of the defect "through three hunting seasons." The Court ruled, *as a matter of law,* that contributory negligence barred the action in strict liability.

The defense of "abnormal use" of the product by the plaintiff goes to the question of foreseeability, and in *Preston v. Up-Right Inc.*[65] the California District Court of Appeal affirmed the jury finding that not only was the product not defective but plaintiff's injury resulted from improper abnormal use of the product. Citing the famed *Greenman*[66] case the Court ruled: "It is incumbent upon a plaintiff to prove that he was injured *while using the article in a way it was intended to be used,* as a result of a defect in design and manufacture of which plaintiff was not aware that made the article unsafe for its intended use."[67]

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[62] *Cintrone v. Hertz Truck Leasing & Renting Serv.*, see footnote 40 at 459.

[63] *Maiorino v. Weco Products*, cited at footnote 40 at 574: ". . . (W)here a plaintiff acts or fails to act as a reasonably prudent man in connection with the use of a warranted product or one which comes into his hands under circumstances imposing strict liability on the maker or vendor or lessor, and such conduct proximately contributes to this injury, he cannot recover."

[64] — Mich. App. —, (decided September 13, 1966).

[65] 243 Cal. App. 2d 636, 52 Cal. Rptr. 679 (1966).

[66] See footnote 41. Similarly, the United States Court of Appeals for the Seventh Circuit in *Neusus v. Sponholtz,* — F. 2d — (Aug. 11, 1966), and applying Illinois law, held that misuse of the product established, *as a matter of law,* that the injured plaintiff was contributorily negligent.

[67] *Preston v. Up-Right Inc.*, cited at footnote 65 at 639. See also *Brandenberg v. Weaver Mfg. Co.*, 222 N. E. 2d 348, 77 Ill. App. 2d 374 (1967), which affirmed a directed verdict for the defendant in an action for damages for injuries sustained when an automobile bumper jack slipped causing injuries. Commenting on the concept of strict liability as enunciated in *Suvada*, cited at footnote 14, the Court stated at 222 N. E. 2d 350: "*Suvada* is a landmark decision which effectively destroys lack of privity as a defense. It decides the sufficiency of a complaint. We do not read it as providing the open sesame to the strongbox of producers nor that it ipso facto embalms and lays to rest defenses based on the fault, misuse or misconduct of the plaintiff which contributed in whole or in part to his injuries. We do not believe that it hatched a philosophy of liability with-

(Continued on next page.)

It should be noted that an allergic response by the user of the product does not make the product "defective."[68] (The "defect" is in the person, *not* in the product!) Comment "h" to *Restatement (Second), Torts,* Section 402A, expressly states that "a product is not in a defective condition when it is safe for *normal* . . . consumption." Comment "j" points out that "the seller may reasonably assume that those with common allergies . . . will be aware of them, and he is not required to warn against them." Comment "k" adds that the seller of a product "is not to be held to strict liability for the unfortunate consequences." In *Magee v. Wyeth Labs, Inc.*[69] the California Supreme Court in 1963 agreed that the manufacturer may "assume a normal use, and is not liable where the injury is due to some allergy or other personal idiosyncrasy of the consumer."

In the persistent pursuit of the *absolute* (engendered by plaintiffs' advocates of Strict Liability in Tort),[70] many courts and particularly governmental agencies have sought to impose upon product manufacturers, liability for the *absolute* safety of their products. The 1962

(Footnote 67 continued.)
out fault in products liability cases nor permits one to recover for injuries which are properly traceable to and occasioned by his own fault. Plaintiff must still prove that it was the unreasonably dangerous condition of the product which proximately caused the injuries."

See also *Ragain v. Rex Chainbelt, Inc.*, — Ill. 2d —, — N. E. 2d — (Jan. 19, 1967).

[68] See *Kaspirowitz v. Schering Corp.*, 70 N. J. Super. 397, 175 A. 2d 658 (1961).

[69] See footnote 57. See also *Howard v. Avon Products Inc.*, 155 Colo. 445, 395 P. 2d 1007 (1964).

[70] In discussing Strict Liability, § 402 B of the *Restatement (Second) Torts* should not be overlooked: "One engaged in the business of selling chattels who, by advertising, labels, or otherwise, makes to the public a misrepresentation of a material fact concerning the character of quality of a chattel sold by him is subject to liability *for physical harm* to a consumer of the chattel caused by justifiable reliance upon the misrepresentation, even though (a) it is not made fraudulently or negligently, and (b) the consumer has not bought the chattel from or entered into any contractual relation with the seller." This section imposes liability for false representations about the product without requiring *scienter* or knowledge of the falsity on the part of the manufacturer or seller. The ALI here again "stepped off the precipice," as it did by proposing a legally unsupportable Section 552 D, the text of which was set forth in the *Lonon* case, — Tenn. —, 398 S. W. 2d 240, 246 (1966), decided by the Tennessee Supreme Court: "One engaged in the business of selling chattels who, by advertising, labels or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability *for pecuniary loss* caused to another by his purchase of the chattel in justifiable reliance upon the misrepresentation, even though it is not made fraudulently or negligently."

See also footnote 33, *Tennessee Law Review* 341 (1966). Indeed strict liability cannot rest upon absence of fraud and absence of care. The "fault" principle is righteously ingrained in the sinews of our law, and liability should not be predicated upon innocence, inadvertence, or biased interpretations and meanings.

amendments to the Federal Food, Drug and Cosmetic Act,[71] enacted under public hysteria due to irresponsible newspaper, radio, and television coverage, curbed the physician's right to prescribe[72] and imposed unjustifiable liability as well upon the drug manufacturer. The most common substances, such as water, salt, and sugar[73] can become unsafe and even deadly to various segments of the population, but neither the FDA nor any court has sought to remove these "products" from the market. The point is that there is no product which is safe under all conditions of use, and it is grossly unfair to the public to deny to patients a particular drug, for example, simply because the drug is not safe for everyone nor without side effects. Safety is relative—a calculated risk must be taken when *any* product is administered, consumed, or used. When the FDA seeks to regulate prescription drugs to total safety, for example, this respected federal agency ignores the logical necessity for regulating everything else which a given patient may have simultaneously ingested, contacted, or even breathed. Disrespect for the judgement of the physician prescribing the drug is evident in such legislation, and the product manufacturer is made to foot the bill. Strict Liability in Tort must not become a bonanza for users of a product without some recognition of those legal prerequisites for invoking the doctrine of Strict Liability.

III. Liability Without Fault

A well-known plaintiffs' trial lawyer just last year stated in a letter to the U. S. State Department: "The principle of liability without fault contravenes legal tradition that goes back centuries."[74]

This advocate also pointed out that absolute liability is "a flagrant deviation from American judicial principles of liability based on fault." There is indeed historical support for this position, a crowning triumph of reason and morality: liability for "fault" is predicated upon the axiom that each of us is responsible for his own conduct.[75] Our society encourages maximum productive activity, bounded by the

[71] 76 Stat. 780, 21 U. S. C. §§ 301-92, (1962).

[72] See Turkel, "The Physician's Right to Prescribe," *Med. Trial Tech.* (Sept. and Dec. 1966).

[73] Daily intake of water could make many persons ill or decidedly uncomfortable, yet it is essential to maintain the health of a patient with diabetes insipidus. Salt can cause death in a patient with dropsy caused by a congestive heart failure. Sugar may precipitate a metabolic crisis in a patient with diabetes mellitus.

[74] Lee S. Kreindler, Chairman of Aviation Committee of American Trial Lawyers Association, as reported in *The New York Times*, April 23, 1966, p. 62.

[75] See Warren Freedman, "Consumers Are Getting the Breaks in Cosmetic Cases," 92 *Drug and Cosmetic Industry* 559 (May 1963).

limits of honesty and reasonable care,[76] and so liability can only be based upon "fault."[77] (Legal and moral fault is equated in the sense that it is just to make the actor compensate his victim where the actor has done some wrong to the victim.)[78] A "dangerous product," once marketed, implies "fault" on the part of the manufacturer, and liability ensues.[79] "Fault" is the basis for breach of warranty, as the New York Court of Appeals in 1963 held in labeling the breach of warranty as "a tortious wrong."[80] Another New York Court in the same year emphasized by reference that "breach of implied warranty is a wrongful act, a default. . ."[81]

Foreseeability is a basic element of liability predicated upon "fault." The U. S. Fifth Circuit Court of Appeals in the *Lartigue*[82] case pointed out that in no instance had the so-called Strict Liability in Tort doctrine been applied, even in food cases, except when the harm from the defective condition or "defect" was a foreseeable consequence thereof. Indeed, where harm or loss is foreseeable, the "fault" of the product manufacturer ensues, if he had not taken the necessary measures to warn or guard against the occurrence of the specified harm or loss.[83]

Some limitation on "liability without fault" must be recognized, that is, a seller, for reasons of sound business experience, may want to restrict his liability for the product. A disclaimer[84] which is not unconscionable is enforceable; the Uniform Commercial Code provides for disclaimer of all warranties.[85] Disclaimers may be express[86]

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[76] See Warren Freedman, "Fault—The Basis of Warranty in Products Liability," *Insurance Law Journal*, January 1964, p. 25.

[77] Also, note Warren Freedman, "The Three-Pronged Sword of Damocles: Cutter, Henningsen and Greenberg," *DRI Monograph on Products Liability* (1964).

[78] Compare 2 Harper and James, *Torts*, 752-758 (1956).

[79] But, the United States Seventh Circuit Court of Appeals in the *Neusus* case, cited at footnote 66, observed: "We have not yet reached the state where a manufacturer is under a duty of making a machine accident proof and foolproof."

[80] *Goldberg v. Kollsman Instrument Corp.*, 12 N. Y. 2d 432, 240 N. Y. S. 2d 592, 191 N. E. 2d 81 (1963).

[81] *Gay v. A & P Food Stores*, 39 Misc. 2d 360, 240 N. Y. S. 2d 809 (1963).

[82] *Lartigue v. R. J. Reynolds Tobacco Co.*, 317 F. 2d 19 (5th Cir. 1963).

[83] See Warren Freedman, "Fault—The Basis of Warranty in Products Liability," cited at footnote 76.

[84] The North Carolina Supreme Court in *Lilley v. Manning Motor Co.*, 262 N. C. 468, 137 S. E. 2d 847 (1964), ruled that "there can be no implied warranty of quality . . . where there is an express warranty (of disclaimer) . . . ." At 137 S. E. 2d 849. See Warren Freedman, "Disclaimers of Implied Warranty Liability," *New York Law Journal*, Dec. 16, 1966, p. 1.

[85] Uniform Commercial Code § 2-316. See also *Williams v. Chrysler Corp.*, 148 W. Va. 655, 137 S. E. 2d 225 (1964), and *Weik v. Ace Rents Inc.*, 249 Iowa 510, 87 N. W. 2d 314 (1958).

[86] *Lumbrazo v. Woodruff*, 256 N. Y. 92, 175 N. E. 2d 525 (1931).

or implied,[87] and must be brought to the attention of the buyer;[88] accordingly, such disclaimers could be binding upon third parties.[89]

In the final analysis, "liability without fault" is a paradox for it belies our system of law based upon legal fault.[90] Such an invidious concept can never be welcomed by a moral society, nor be entertained under the rule of law.

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[87] Note *Gray v. Cox*, 107 Eng. Rep. 999 (K. B., 1825), and *Crofoot Lumber, Inc. v. Ford*, 191 Cal. App. 2d 238, 12 Cal. Rptr. 639 (1961).

[88] *Willard Van Dyke Productions Inc. v. Eastman Kodak Co.*, 12 N. Y. 2d 301, 239 N. Y. S. 2d 337, 189 N. E. 2d 693 (1963).

[89] See *McVey v. Phillips Petroleum Co.*, 288 F. 2d 53 (5th Cir. 1961).

[90] The availability of such tort defenses in warranty actions as (1) contributory negligence of the user; *Dallison v. Sears Roebuck & Co.*, 313 F. 2d 343 (10th Cir. 1962); *Maiorino v. Weco Products*, 45 N. J. 570, 214 A. 2d 18 (1965); *Cintrone v. Hertz*, 45 N. J. 434, 212 A. 2d 769 (1965); see *Gardner v. Coca Cola Bottling Co.*, 267 Minn. 505, 127 N. W. 2d 557 (1964): "An action based on breach of warranty at least has its roots in tort and . . . contributory negligence is a defense." At 511; (2) assumption of the risk; *Friedendall v. Abraham & Straus, Inc.*, 279 N. Y. 146, 18 N. E. 2d 11 (1938); (3) unusual or abnormal use of the product; *Vincent v. Tsiknes Co.*, 337 Mass. 726, 151 N. E. 2d 263 (1958); and (4) independent, intervening act of negligence; *Strahlendorf v. Walgreen Co.*, 16 Wis. 2d 421, 114 N. W. 2d 823 (1962), which also attests to the principle that "fault makes for liability, and no fault makes for no liability." See generally Warren Freedman, "Are There Any Defenses to Strict Liability in Tort?," *New York Law Journal* May 2, 3, 1966, p. 1. Judge Wachtel of the New York Civil Court tersely restated the principle: "Though the action may be brought solely for the breach of implied warranty, the breach is a wrongful act, and, in its essential nature, a tort. . . ." *Gay v. A & P Food Stores*, cited at footnote 81, at 362. Judge Wachtel concluded that contributory negligence may properly be asserted as a defense to a warranty action. The U. S. Second Circuit of Appeals has similarly held that *misuse* of the product barred recovery even under the strict liability doctrine. *Swain v. Boeing Airplane Co.*, 337 F. 2d 940 (2d Cir. 1964). In *Greeno v. Clark Equipment Co.*, 237 F. Supp. 427 (D. N. D. Ind., 1965), Federal Judge Eschback agreed that "'(m)isuse' would include much conduct otherwise labeled contributory negligence and would constitute a defense." The New Jersey Supreme Court, four years after the *Henningsen* case, 32 N. J. 358, 161 A. 2d 69 (1960), ruled: "When a product can be damaged in the course of use and thereby become unreasonably dangerous, we cannot hold the manufacturer liable in warranty . . ." *Jakubowski v. Minnesota M & M Co.*, 42 N. J. 177, 199 A. 2d 826, 831 (1964).

Assumption of the risk has also been recognized as a defense by the California Supreme Court. *Seeley v. White Motor Co.*, 63 Cal. 2d 9, 45 Cal. Rptr. 17, 403 P. 2d 145 (1965). Even § 524 (2) (a) (b) of the *Restatement of Torts* bars recovery where the plaintiff "negligently causes the activity to miscarry." It is stated in 3 Williston, *Sales*, § 614 b (Rev. ed.), that "(i)f the buyer's own fault or negligence contributed to the injury, as by using the goods with knowledge of their defects, he cannot recover consequential damages since such damages were under the circumstances not proximately due to the breach of warranty."

In a warranty action the U. S. District Court for the Western District of Texas in directing a verdict for the defendant in *Lindsey v. Clairol Incorporated* (Civil Action No. 3191, 1965) emphasized: "The plaintiff must show that there is some dereliction of duty on the part of the manufacturer. . . ."

IV. "Defect" in the Product

"Defect" in the product cannot be inferred from the nature of the injury or loss.[91] If a product is defective, it is defective in a specific or particular way which the complainant must identify and prove,[92] to wit: (1) an "unreasonably dangerous" product;[93] or (2) a product which involved "unexpected dangers";[94] or (3) a product without adequate warning;[95] or (4) a product producing an allergic response[96] not adequately warned against; or (5) a product containing a harmful substance not "natural to the product;"[97] or (6) a product which itself created "an ultrahazardous condition."[98] An alleged injury or loss[99] not attributable to a proven "defect" in the product provides no basis for liability, either in tort or in contract.

Existence of the "defect" in the product can be shown by circumstantial evidence, such as the testimony of an expert who has

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[91] See *Vines v. State*, 24 App. Div. 2d 680, 261 N. Y. S. 2d 445 (1965), wherein defendant rented plaintiff a pair of skates with an allegedly defective toe strap which broke and caused him to fall. The New York Court of Claims had simply ruled that "the record is devoid of any proof as to how or why the incident occurred."

See generally Warren Freedman, "'Defect' in the Product: The Necessary Basis for Products Liability in Tort and in Warranty," *Tennessee Law Review* (1966).

[92] Justice Lyons of the Illinois Appellate Court in *Shramek v. General Motors Corp.*, 69 Ill. App. 2d 72, 216 N. E. 2d 244, ruled that "the cornerstone of plaintiff's cause of action is the existence of a *defect* in the tire at the time it left the control of the manufacturer or seller . . . . even in the expanded area of strict tort liability, . . . " At 216 N. E. 2d 247, 248. See also *Williams v. U. S. Royal Tires*, 101 So. 2d 488 (La. App. 1958); *Senter v. Goodrich*, 127 F. Supp. 705 (D. C. D. Colo. 1954); *Wojciuk v. U. S. Rubber Co.*, 120 N. W. 2d 47 (Wis. 1963); and *Ziffrin Truck Lines Inc. v. Armstrong*, — F. 2d — (7th Cir. 1966).

[93] Note *Greenman v. Yuba Products Inc.*, 27 Cal. 2d 57, 27 Cal. Rptr. 697, 377 P. 2d 897 (1964).

[94] See *Ross v. Philip Morris Co.*, 328 F. 2d 3 (8th Cir. 1964).

[95] See *Restatement (Second), Torts*, § 402 A, Official Comment "j". Note *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964).

[96] *Corneliuson v. Arthur Drug Stores Inc.*, 153 Conn. 134, 214 A. 2d 676 (1965). Note *Howard v. Avon Products Inc.*, 155 Colo. 445, 395 P. 2d 1007 (1964), citing the treatise Warren Freedman, *Allergy and Products Liability*, Ch. 7 and 8 (1960): the allergic reaction was not compensable because (a) plaintiff did not prove that product would or did harmfully affect a substantial number of users; (b) plaintiff was not a member of a substantial, identifiable class of persons allergic to the product; and (c) the product manufacturer was entitled to assume a *normal* buyer.

[97] Note Chief Justice Traynor's reference to harm to consumer's teeth from sugar in a bottled beverage in 32 *Tennessee Law Review* 363 (1965). The presence of sugar does not constitute a "defect." See also *Webster v. Blue Ship Tea Room, Inc.*, 347 Mass. 421, 198 N. E. 2d 309 (1964).

[98] See *Wights v. Staff Jennings, Inc.*, 241 Ore. 301, 405 P. 2d 624 (1965).

[99] See *U. S. Rubber Co. v. Bauer*, 319 F. 2d 463 (8th Cir. 1963), and *Zampino v. Colgate Palmolive Co.*, 8 N. Y. 2d 1069, 207 N. Y. S. 2d 284, 170 N. E. 2d 415 (1960).

examined the product after the accident and who identifies the specific defect.[100] Invocation of res ipsa loquitur does not spell out the necessary proof of defect.[101] Proximate cause of injury or loss, when proved by plaintiff, should pinpoint the specific defect.[102] It has been contended that whether or not a given product is "defective" is a question of law for the court, and not a question of fact for the jury.[103]

The nature and scope of a "defect" in a product has seldom been more clearly postulated than in 1964 by the New Jersey Supreme Court in the *Jakubowski*[104] case:

> The plaintiff must show that the goods of which he complains were *unreasonably dangerous* for their intended use, and that the *unreasonably dangerous condition* existed when the goods left the defendant's hands.[105]

Should a product involve *unexpected dangers* in its intended use, the product may still not be "defective" unless the given danger was foreseeable[106] because of the existence of the specific defect. Inadequate warning of harm or damage from the use of the product can spell out "defect."[107] But simply because a given product can produce an allergic reaction in a particular susceptible person does not mean that the product is "defective"—the defect is not in the product, but in the person.[108]

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[100] *Standard Motor Co. v. Blood*, 380 S. W. 2d 651 (Tex. Civ. App. 1964); *Lewis v. U. S. Rubber Co.*, 414 Pa. 626, 202 A. 2d 20 (1964). See also *Erickson v. Sears Roebuck & Co.*, 240 Cal. App. 2d 793, 50 Cal. Rptr. 143 (1966), holding that plaintiff offered no expert testimony as to the "defect," if any; did not offer any evidence to show the ladder was inherently dangerous; and failed to show that he was using the ladder in a way it was intended to be used.

[101] *Love v. New Amsterdam Cas. Co.*, — La. App. 2d —, 175 So. 2d 398 (1965). See also *Santor v. A. & M. Karagheusian Inc.*, 44 N. J. 52, 207 A. 2d 305 (1965), and *Erickson v. Sears Roebuck & Co.*, cited at footnote 100.

In *Campos v. Weeks*, — Cal. App. 2d —, 53 Cal. Rptr. 915 (1966) the doctrine of res ipsa loquitur was expressly held *not* applicable in a suit for damages by a patient who suffered an anaphylactic shock reaction due to penicillin. Such a reaction is so rare that negligence on the part of the physician was not probable.

[102] *Manzoni v. Detroit Coca Cola Bottling Co.*, 363 Mich. 235, 109 N. W. 2d 918 (1961).

[103] See *Magee v. Wyeth Laboratories, Inc.*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963).

[104] *Jakubowski v. Minnesota M & M Co.*, 42 N. J. 177, 199 A. 2d 826 (1964).

[105] See footnote 104 at 199 A. 2d 829. Judgment under Strict Liability in Tort for an injured plaintiff against the manufacturer and vendor of an automobile was *reversed* because the Missouri trial court had failed to instruct the jury that the alleged defect in the automobile must have existed at the time that the vehicle left the manufacturer's possession and control, *Williams v. Ford Motor Co.*, — Mo. —, — S. W. 2d — 1966).

[106] See *Lartigue v. R. J. Reynolds Tobacco Co.*, cited at footnote 82.

[107] See *Crane v. Sears Roebuck & Co.*, 218 Cal. App. 2d 855, 32 Cal. Rptr. 754 (1963).

[108] Warren Freedman, "Allergy and Product Liability Today," 24 *Ohio State Law Journal* 479 (1963).

Indeed, it should be obvious that proof of "defect" in the product is essential to a cause of action in warranty, in negligence, and in Strict Liability in Tort.[109] Otherwise, the product manufacturer becomes the insurer of his product under an untenable and undemocratic system of absolute liability, to wit: CAVEAT VENDOR.

V. Uniform Commercial Code and Products Liability

In a leading article, "Products Liability Under the Uniform Commercial Code,"[110] it was contended that the applicability of the Uniform Commercial Code to products liability[111] was "limited to the *sale* of the product." Sections 2-102, 2-106 (1), and 2-204 affirm the necessary contractual basis of the sale in order to predicate liability against the product seller or manufacturer.[112] Accordingly, the following specifications of products liability within the Uniform Commercial Code can be cited:[113]

(1) a four-year statute of limitations may control;[114]

[109] The Seventh U. S. Circuit Court of Appeals in *Markwell v. General Tire & Rubber Co.*, 367 F. 2d 748 (1966), ruled: "(I)n the absence of proof of the existence of a defect, a defendant may not be held liable for negligence in manufacture, nor responsible on the theory of implied . . . . (or) express warranty."

[110] Warren Freedman "Products Liability Under the Uniform Commercial Code in New York and other states," 19 Food Drug Cosmetic Law Journal 178 (March 1964) and 10 *Prac. Law.* No. 4, p. 49 (April 1964).

[111] Note § 2-715 (2) (b) of the *Uniform Commercial Code*, relating to the buyer's damages, which states that consequential damages of a seller's breach of warranty include "injury to person or property proximately resulting from any breach of warranty." See also §§ 2-719 (3) and 2-607.

[112] See Warren Freedman, "Warranty Liability—In the Absence of a Sale", *New York Law Journal* Feb. 13, 1964, p. 1.

[113] See Warren Freedman, "Six Problem Areas of Products Liability Under the Uniform Commercial Code," 14 *Defense L. J.* 504 (1965) and 2 *Chi.-Kent L. Rev.* 163 (1965).

[114] Section 2-725. In *Gardiner v. Philadelphia Gas Works*, 413 Pa. 415, 193 A. 2d 612 (1964), the Pennsylvania court ruled that this 4-year statute of limitations superseded the old 2-year statute. See also Warren Freedman, "Statutes of Limitations in Products Liability Actions", *Insurance Law Journal*, June 1964, p. 328.

As to the statute of limitations, it should be observed that under most "borrowing statutes," the *shorter* period of time will generally apply where a state has not adopted § 2-725 and where its own statute of limitations is indeed shorter. See *Alyssa Originals, Inc. v. Finkelstein*, 22 App. Div. 2d 701, 254 N. Y. S. 2d 21 (1964) where the New York court ruled at p. 701 that where the essence of the action is defendant's negligence, the shorter statute of limitations is applicable: "The test for determining which statute of limitations is applicable in a given situation is: What is the 'essence of the action', not 'its mere name' . . . ." Plaintiff had contended that the longer statute was applicable since the action was based upon alleged breach of covenants under a lease. See *Thurston Motor Lines Inc. v. General Motors Corp.*, 258 N. C.

(Continued on next page.)

(2) *reliance*[115] upon seller's skill or judgment is essential to the cause of action for breach of implied warranty (Sections 2-314 and 2-315);

(3) an allergic reaction[116] is not a breach of the *implied* warranty of fitness for particular purpose, unless the seller at the time of the sale had reason to know of the buyer's idiosyncrasy[117] or predisposition to the product (Section 2-315);

(4) the benefits of warranties[118] are extended to persons in the family or household of the buyer or to a guest in the home if it is reasonable to expect that such person may use, consume, or be affected by the product, *and* who is injured in person by the breach of warranty (Section 2-318);

(5) disclaimers[119] which are not unconscionable are enforceable (Sections 2-316, 2-312 [1], 2-719 [3], and 1-102 [3]);

(Footnote 114 continued.)
323, 128 S. E. 2d 413 (1962), and *Raskin v. Shulton, Inc.*, 92 N. J. Super. 315 (1965). Compare *Aced v. Hobbs-Sesack Plumbing Co.*, 55 Cal. 2d 573, 12 Cal. Rptr. 257, 360 P. 2d 897 (1961).

The time of accrual of the action for breach of warranty is generally the time of sale of the product, or the time when tender of delivery is made, *Citizens Utilities Co. v. American Locomotive Co.*, 11 N. Y. 2d 409, 230 N. Y. S. 2d 194, 184 N. E. 2d 171 (1962).

[115] The necessity for reliance upon an *express* warranty is delineated in *Yount v. Positive Safety Mfg. Co.*, 319 F. 2d 324 (6th Cir. 1963). See also, 79 *ALR.* 2d 333, and note *Oppenheimer v. Sterling Drugs, Inc.*, 7 Ohio App. 2d 103, 219 N. E. 2d 54, 59: "The record fails to disclose any reliance by the plaintiff upon anything published or said by the defendant." An implied warranty was not breached where the buyer had purchased the product upon the basis of his own judgment and not that of the seller, *McMeekin v. Gimbel Bros.*, 223 F. Supp. 896 (D. W. D. Pa., 1963).

[116] For an interesting commentary, see Warren Freedman, "Sensitizers and a Sensitive Bureaucracy," in *American Perfumer and Cosmetics*, Vol. 78, p. 40 (March 1963). See generally, Warren Freedman, *Allergy and Products Liability* (1961).

On the application of the Rule of Reason to allergic responses, see *Casagrande v. F. W. Woolworth Co.*, 340 Mass. 552, 165 N. E. 2d 109 (1960); *Kennedy v. General Beauty Products, Inc.*, 112 Ohio App. 505, 167 N. E. 2d 116 (1960); *Bonowski v. Revlon Inc.*, 251 Iowa 141, 100 N. W. 2d 5 (1959); and *Grau v. Procter & Gamble Co.*, 324 F. 2d 309 (5th Cir. 1963).

[117] See Warren Freedman, "Allergy and Products Liability Today," 24 *Ohio State Law Journal* 479 (1963). See also, Warren Freedman, "A Hatband and a Tube of Lipstick: The New Jersey Minority Rule on Allergic Responses," 21 Food Drug Cosmetic Law Journal 293 (May 1966) and 43 *University Detroit Law Journal* 355 (1966).

[118] Judge Skeel of the Ohio Court of Appeals in *Lonzrick v. Steel Corp.*, 1 Ohio App. 2d 374, 205 N. E. 2d 92, 93 (1965) declared: "This statute (U. C. C.) does not deal with the rights of third persons not parties to the sale who come into possession of the goods and use them in the manner intended by the manufacturer and are thereby injured. . . ."

Benefits of warranties cannot be extended beyond the named persons under § 2-318. Pennsylvania, the first state to enact the U. C. C., has repeatedly refused to permit a sub-purchaser to recover from a product manufacturer on the basis of breach of implied warranty. See *Atlas Aluminum Corp. v. Borden Chemical Corp.*, 233 F. Supp. 53 (D. E. D. Pa. 1964), citing with approval *Hochgertel v. Canada Dry Corp.*, 409 Pa. 610, 187 A. 2d 575 (1963).

[119] See *Williams v. Chrysler Corp.*, 148 W. Va. 655, 137 S. E. 2d 225 (1964).

All warranties may be disclaimed, not only by exclusion or modification as under § 2-316, but also, as a matter of law, when the warranty is itself unconscionable. See *Maryland Casualty*

(Continued on next page.)

(6) timely notice of injury or loss[120] is still required (Section 2-607 [3]).

It should also be observed that the Uniform Commercial Code applies the "rule of reason" to its determination as to whether warranties have been breached.

Conclusion

"Whither Thou Goest, I Will Go" in its Biblical simplicity should never have been transposed into the field of products liability law. The inherent distortion of this Ruth-Naomi epigram must not be overlooked. While we cannot afford obsession with legal precedent, we must respect the rule of law, because we cannot cast ourselves adrift from certainty and predictability in the law. Ruth was confident that Naomi's friendship and love were hers. Courts today must replace bitterness and partisan advocacy with respect for the rule of law.

[The End]

REGULATIONS REVISION PROPOSED

The status of timed-release medications, which has not been formally defined by the 1962 Drug Amendments, may soon be clarified. The Food and Drug Administration has proposed a regulations revision which would classify newly developed timed-release products as new drugs. As such they would be subject to the 1962 requirement that new drugs be proved not only safe, but also effective. This revision would, the FDA feels, prevent any inadvertent violation of this efficacy requirement.

(Footnote 119 continued.)
Co. v. Owens Illinois Glass Co., 116 F. Supp. 122, 123 (D. S. D. W. Va. 1953), wherein the federal court opined: "Not only is there no express warranty, but there is an express provision excluding any warranty. In the presence of such an agreement between the parties (a disclaimer), no implied warranty arises." Chief Justice Traynor of the California Supreme Court in the *Seeley* case, 63 Cal. 2d 9, 45 Cal. Rptr. 17, 403 P. 2d 145 (1965), though applying Strict Liability, recognized the validity of a disclaimer: "Had defendant not warranted the truck to serve the plaintiff's business needs." Judge Peters' concurring opinion agreed that the product manufacturer should be allowed to disclaim liability "in certain cases." See also *Brown v. Chrysler Corp.*, 112 Ga. App. 22, 143 S. E. 2d 575 (1965).

[120] See *Kopet v. Klein*, — Minn. —, — N. W. 2d — (1967), and *Truesdale v. Friedman*, 270 Minn. 109, 132 N. W. 2d 854 (1965).

Good Manufacturing Practices Regulations in the Food Industry

By ALFRED BARNARD

This Paper Was Presented by Alfred Barnard, the Director of the Bureau of Regulatory Compliance, of the Food and Drug Administration of the U. S. Department of Health, Education, and Welfare. It Was Given at the Annual Meeting of the Association of Food and Drug Officials of the United States, at St. Paul, Minnesota on June 21, 1967.

GOOD MANUFACTURING PRACTICES REGULATIONS for the food industry have been thought about off and on in the Food and Drug Administration (FDA) for many years. I am pleased to tell you that, today, it is the policy of the FDA, under the leadership of Dr. Goddard, that Current Good Manufacturing Practices (CGMP) regulations for the food industry will be promulgated and that the advantages which we believe can be reaped therefrom will become available to everyone.

Everybody nowadays is talking about the advantages of CGMP's for the food industry, and the idea is about to become the greatest thing since sliced bread. It might, however, be profitable to take a little bit of time to see why steps have not previously been taken in this direction.

Section 402(a)(4) of the Food, Drug and Cosmetic Act defines a food as adulterated if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health. This section and the related Section 402(a)(3) dealing with products actually adulterated with filth provided, in 1938, the first basis for effective enforcement by FDA in the field of filth and insanitation in food manufacturing establishments.

Many tasks faced the Administration in beginning to apply the various new and highly significant provisions of the 1938 law. While

some thought was given to interpretive regulations in the very early stages, it appeared that many more important chores needed attention first.

During the 1940's a number of highly successful actions were brought involving Sections 402(a)(3) and (4), and tremendous progress was made in improving sanitary conditions in bakeries, candy plants and many other types of food processing establishments particularly amenable to insanitation problems.

Around 1950, the need for GMP regulations for the food industry again began to be considered. In fact, we actually prepared and issued what amounted to one set of GMP's. I am referring here to the so-called "elevator check list" which we developed for use in inspecting and appraising grain elevators, especially country houses. This sets forth, in a sense, Good Manufacturing Practice guidelines for this particular industry. As you know, copies are furnished to elevator management at the conclusion of an inspection.

Court Decisions

At about this same time, we filed a criminal action against a pickle firm in the St. Louis area based on the introduction into interstate commerce of pickles and pickle relish which were alleged to have been adulterated within the meaning of Section 402(a)(4). The defendant, Mr. Berger, was convicted and appealed on two grounds, one of which is important to this discussion. He challenged the constitutionality of Section 402(a)(4) on the ground of vagueness.

This appeal caused grave concern among the constitutional lawyers on the Department's staff. It also caused concern to some of us engaged in administering the provisions of this section. We ourselves were not always certain what constituted violations of Section 402(a)(4) in borderline situations, and, therefore could not escape the feeling that there was some validity to the defendant's contention that he was unable to define a standard for the legal conduct of his business.

Interestingly, the Eighth Circuit brushed aside this argument, almost with a summary wave of the hand. The court said that anybody should know what insanitary conditions are, especially since Congress spelled out insanitary conditions which may result in contamination of the product with filth. This affirmation by the appellate court that the statute was clear, simple, and free from ambiguity or vagueness discouraged attempts on the part of administrators to write interpretive regulations. I suppose that the motivation here was largely in the "don't rock the boat" category, but, nonetheless, there was the feeling that well enough might as well be left alone.

The idea remained more or less dormant until the current interest developed. In the meantime, however, the Seventh Circuit, in the so-called Smith Canning Company cases dealing with several seizures of tomato paste, made plain its view that the statute is broad enough to provide authority for the promulgation of interpretive regulations under Section 402(a)(4) and expressed the view that, at least in the areas involved in that case, the administrators should possibly have done so by now.

In 1962, as you know, Congress passed the Kefauver-Harris Amendments with a provision which, in effect, states that a drug shall be deemed to be adulterated if it has been manufactured under conditions which do not accord to CGMP. The legislative history clearly anticipates that the Secretary will promulgate interpretive regulations spelling out what constitutes CGMP. The basic philosophy behind this provision is one of locking the door before the horse is stolen, rather than after. In other words, it is now no longer necessary for us to find on the market, in interstate commerce, at least one sample of a drug which might kill somebody before we can do something to stop introduction of the product into interstate commerce if the hazard arises from poor manufacturing practices.

The analogy between this situation and botulism in smoked fish was one of the things that led us in FDA to the current, serious thinking about CGMP regulations for the food industry. Under existing law we can, of course, move to foreclose the channels of interstate commerce to smoked fish which has been prepared under insanitary conditions whereby it may have been rendered injurious to health. This, however, is difficult in the absence of any definitive standards as to the conditions which may result in danger to health. It left us, in the past, in the position of being more or less obligated to locate interstate shipments containing at least viable spores if not toxin itself before we were in a strong position to initiate regulatory action. If we can promulgate regulations spelling out CGMP in the smoked fish industry, we are in a much stronger position to deal with industry, and industry is in a much better position to achieve compliance. Further, when it becomes necessary to go to court, we are in a much stronger position with the court in seeking an injunction or other enforcement of compliance with CGMP's. This, I think, is obviously true even though these regulations are interpretive, just as are the Kefauver-Harris drug CGMP regulations, and may not have the full force and effect of law as do, for example, food standards promulgated under the authority contained in Section 401. I say

"may not" because the recent Supreme Court decision in the drug and color additive cases may have, in effect, given them such force and effect by providing for judicial review in a declaratory judgment type action.

Problems and Potential Pitfalls

The historic reasons are not the only reasons why there was reluctance on the part of FDA to attempt to write regulations under this section. There are some problems and some potential pitfalls, not the least of which lies in the fact that it is impossible to write regulations to cover everything. I well recall a Florida crabmeat plant which was operating under what appeared then to be almost ideal conditions, but which continued to turn out occasional shipments of polluted crabmeat. Several inspections had revealed nothing but the best of conditions, including stainless steel and tile, in contrast to the country outhouse type construction of most of the other plants in the area. The plant was really a model plant.

One day the inspector happened to be in the plant at lunch time, and while he was there the manager's wife came down from home with his lunch pail. She also brought with her the baby, and before she left to go back to the house she spread the baby out on one of the picking tables and changed its diaper.

There is no question how the crabmeat became polluted, but I doubt that any GMP regulations ever written would or should be detailed enough to be sure to cover this situation. The point I am trying to make is that there is a definite risk that GMP regulations can become a plant checklist by which both management and the inspector can be deluded into the conclusion that everything is perfect when, in fact, things as bad as the baby episode are going on.

Concern has also been expressed in some quarters about the extent to which immunity is more or less granted to firms operating in compliance with the regulations and yet doing things which are reprehensible, but which are not specifically covered. In other words, the argument states that a man may come into court and say he has done everything you have told him to, so why are you now concerning yourself to such an extent over his operation. This argument has no legal basis. Action under Section 402(a)(4) will still have to be based on evidence sufficient to prove a violation of the section and evidence sufficient for this purpose will sustain conviction, regardless of the existence or content of CGMP regulations. Nonetheless, there is, perhaps, some validity to the contention that this argument can engender sympathy among judges, juries, or prosecutors.

Also, there are, of course, many difficulties in trying to write regulations of this kind. If they are too broad, they become essentially meaningless because they add nothing to the statutory language. If they are too narrow, they become vastly overdetailed and fail to recognize that in most areas there is more than one way to do a given job properly. There is one further difficulty which I will elaborate on more in a moment.

New Aproaches

I think you will be interested in how the FDA plans to approach this problem. Our present plan calls for the publishing of a proposed sort of umbrella of sanitation regulations dealing with CGMP in the food industry. This will be a sort of home, motherhood, and against sin document. It will outline, in general, what everybody in the food industry ought to be doing, regardless of the particular food business involved.

We then contemplate the subsequent issuance of a series of appendices dealing with specific industries. One of the early appendices under consideration is one for the hot smoked fish industry. This one will be designed to eliminate the problems of both botulism and salmonella from hot smoked fish and will, like all of these appendices, be quite detailed. If, for example, we can obtain agreement among scientists that the heating of fish in the smoking process to X degrees for Y minutes will assure the elimination of botulism, then the regulations will go so far as to spell out in detail the fact that this time-temperature relationship must be achieved as a minimum for compliance with CGMP.

This brings me to the other problem I referred to before. A man who gets the assignment to prepare one of these appendices has to become just about the leading expert in the food technology of the particular product involved, or at least he has to accumulate knowledge from all of the leading food technologists in the field before he can intelligently develop an appendix which will provide an accurate reflection of what really is CGMP in the particular industry involved.

Let us turn for a moment to some of the advantages we see in the promulgation of GMP's for the food industry. In the first place, it will provide an internal standard by which FDA itself can judge conditions in food manufacturing plants. I would be less than candid if I did not admit to you that there have been times when we suspect that there may have been some slight degree of inconsistency between

some FDA districts in reporting and reaching administrative conclusions in this area.

In other words, with CGMP regulations, we can compare the operations of a firm with the regulations at one inspection. Then, subsequently, we can make the same comparison during a second inspection, and thereby have a basis for concluding whether the firm has improved or become worse.

In addition to the benefits that we see for FDA, we also see benefits both to industry and to you as State and local officials. The regulations will provide for industry minimum standards to be met. These will serve much the same purpose as performance standards serve in the employee relations field. They will provide industry with knowledge of the yardstick by which it is being judged as well as a basis for appraising its own performance.

For you, as state and local enforcement officials, it will provide, for the first time, a clear picture of the standards being applied by FDA in the insanitation area. This will enable, among other things, more effective joint planning and working relationships between us. It will provide a basis for understanding what does or does not constitute violative conduct in this field. We think all of these things are major pluses.

As most of you know, there has, for some time, been extensive interest in a rating or scoring system by which some numerical measure of the extent of compliance or noncompliance with CGMP regulations can be established. Such a system, to be meaningful, would, of course, have to be weighed so that minor items would be properly distinguished from serious faults. At the present time, we in FDA do not contemplate the development and issuance of scoring systems related to CGMP regulations. We have, however, been looking into the possibility of some approach of this kind to in-house measures of program effectiveness.

Progress to Date

Last, but perhaps not least, I think you may be interested in what progress has been made in FDA so far. We are currently dispatching to all 17 field districts, in draft form, the umbrella part of the regulations. After we have obtained criticism, comment, and evaluation from our field districts and have made indicated changes, we will publish them as proposed regulations.

We anticipate that there will be extensive subsequent input from industry and that amendments will be necessary. The Supreme Court decision in the drug and color additive cases mentioned above has, of

course, provided an additional mec nism which can lead to delay in the promulgation of regulations of 's type. Frankly, I would not care to try to forecast when regulatic might ultimately be expected to become effective, but at least we ar n the road. When the regulations are published as proposals you will all have full opportunity to comment, and I would like to strongly urge that each and every one of you give these regulations thorough consideration and give FDA the benefit of your comments, whether they be negative or positive.

In addition to the umbrella, we have already issued inspectional guidelines in several food programs to our field district inspectors. These include such areas as smoked fish, salmonella in non-fat dry milk, etc. While we do not feel that these inspectional guidelines are as yet sufficiently polished to be published as proposed appendix regulations, we are currently gaining experience with them through their application by our inspection staff, and we hope through this experience and further study to soon be able to publish several of these modified inspectional guidelines as proposed appendices of the type I mentioned in outlining the general scheme. Our office of Legislative and Governmental Services is working with the Association to make these inspectional guidelines available to all of you through some as yet undecided manual system.

While it is not the primary purpose, the development of GMP's constitutes one more step on the part of FDA in the direction of working more broadly and more closely with all concerned in an effort to bring about improved total consumer protection in the many areas for which it presently has responsibility. As Paul Pumpian[1] has already made plain, we not only welcome but urge your increased partnership in this public service endeavor. **[The End]**

PERSONNEL CHANGES IN THE FDA

Jean Paul Smith, formerly the chief of the Special Studies Branch of the Division of Drug Studies and Statistics in the Bureau of Drug Abuse Control, has been appointed Director of the Division.

A. Harris Kenyon, the Food and Drug Administration's field liaison officer for the past year, has been appointed Assistant Commissioner for Field Coordination. In this newly created post, Mr. Kenyon will be coordinator of the activities of the FDA's Regional Assistant Commissioners as well as District Office programs.

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[1] Director, Office of Legislative and Governmental Services, FDA.

Does the Term "Special Dietary Use" Apply to All Baby Foods?

By FRANKLIN M. DEPEW

Mr. Depew Is President of the Food and Drug Law Institute, Inc.

THE ARTICLE BY DOCTORS FREDERICK J. STARE AND CHARLES A. JANEWAY (*New England Journal of Medicine,* Vol. 277, No. 10, September 7, 1967, p. 532) gives the sound practical views of nutritionists as to the reasons why strained and chopped baby foods should not be considered special dietary foods *per se.* It points out that these convenience foods for baby feeding offer no special nutrients or proportions of dietary essentials to fill any need peculiar to infants. Such foods are common to the diet of persons of all ages, but when strained or chopped they are prepared in such a way that they are in a form which the baby will readily eat. The supplier has only saved the mother the time and trouble of buying the fruit or vegetable and then straining or chopping it for her child.

Is the position taken by these eminent physicians legally sound? The language of the law and regulations supports the view that it is and that the mere fact that a food is a baby food does not make it a food for special dietary use.

Regulations Adopted by the FDA

The interpretation accorded the phrase "special dietary uses" by regulations adopted in 1941 by the Food and Drug Administration (FDA), the agency selected by Congress to enforce the Federal Food, Drug and Cosmetic Act, is found at 21 C. F. R. Par. 1.11, and reads as follows:

> The term "special dietary uses," as applied to food for man, means particular (as distinguished from general) uses of food, as follows:
>
> (1) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of disease, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight.

(2) Uses for supplying particular dietary needs which exist by reason of age. including but not limited to the ages of infancy and childhood.

(3) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

This regulation is an interpretative ruling which merely states the meaning accorded the phrase by the FDA, and was not issued pursuant to hearings, evidence and detailed findings of fact. The regulations prescribing the information required to appear on the labels of foods for special dietary uses appears at 21 C. F. R. 125.1, et seq. These regulations were adopted after notice and hearings. The propriety of issuing the general regulation, contained in Par. 1.11, in this way was upheld in *U. S. v. 353 Cases * * * Mountain Valley Mineral Water,* 247 F. 2d 473 (C. A. 8, 1957), Kleinfeld-Dunn (1953-57 at 750).

In 1962, FDA published a proposed new set of regulations for special dietary foods, 27 Fed. Reg. 5815 (June 20, 1962). The proposal eliminated Section 1.11, but the definition of the term "special dietary uses" was set forth in Section 125.1 (b) (1) (2) and (3). The wording was identical with that in Section 1.11 (a) (1) (2) and (3) except that the word "that" was substituted for "which" in subparagraphs (1) and (2) so that they read "needs that exist" instead of "needs which exist." This change did not in any way alter the meaning of the overall language. Thereafter, in 1966, FDA published a further revision based on comments and other pertinent information. 31 Fed. Reg. 8521 (June 18, 1966). The term "special dietary use" (not "uses") is defined in Section 125.1 (a) of this proposal as follows:

(a) The term "special dietary use" as applied to food used by man means a particular use for which an article purports to be or is represented, including but not limited to the following uses:

(1) Supplying a special dietary need that exists by reason of a physical, physiological, or other condition, including but not limited to the conditions of convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, overweight, diabetes mellitus, or the need to control the intake of sodium. Except as otherwise provided by Sec. 5.5 of this chapter, the use of an artificial sweetener in a food shall be considered to be a use for reducing or maintaining body weight or for use in the diets of diabetics.

(2) Supplying a special dietary need for infants or children.

(3) Supplying a vitamin, mineral, or other dietary property to supplement a diet.

(4) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

The dietary regulations obviously are not intended to cover *all* foods. The language of the present regulations, 21 C. F. R. 1.11, recognizes this and states that a special dietary use means a particular use as distinguished from a general use of a food. Such a use, so far as

infant food is concerned, may occur only when the food supplies a *particular* need that exists by reason of infancy. The language of the latest proposed regulations (31 Fed. Reg. 8521) also recognizes this. It says with relation to baby food that it must be food used to supply "a special dietary need for infants or children" to become subject to the regulations.

This point of view is also supported by the fact that since the Special Dietary Regulations were adopted in 1941, industry has considered and treated such strained and chopped foods as general purpose foods in a form suitable for use by infants, without any objection from FDA. This administrative construction of the regulations supports the view that this was the concept underlying the law. Finally, the FDA has specifically ruled on this point in an interpretation which appeared in 31 Fed. Reg. 129 on July 6, 1966, as follows:

(g) With respect to Sec. 125.4(b) of the order of June 18, 1966 (31 F. R. 8521), the term "such food" relates to Sec. 125.4(a). It does not apply to a food which is merely prepared in a form suitable for use by infants, such as pureed spinach, where the product does not otherwise purport to be and is not represented for special dietary use for infants.

The regulations prescribing the information required to appear on the labels of food for special dietary uses also recognize there may be general purpose baby foods, for they provide in Sec. 125.5 that "If a food which purports to be or is represented for special dietary use is a food for infants, the label shall bear * * *." The findings of fact on which Section 125.5 are based were published in 6 Fed. Reg. 5921 (November 22, 1941). The findings in respect to infant food are findings 72 through 86; they read as follows:

72. The value of a food for special dietary use may depend on its suitability as a food for infants.

73. The diet of infants is more restricted than that of normal persons of other age groups and the suitability of a food for infant use depends on its ingredients or character.

74. Information necessary fully to inform the purchaser of the value of a food for such use includes the common or usual name of each ingredient thereof.

75. Infants are more susceptible to allergies resulting from plant or animal substances than persons of other age groups.

76. Information concerning the source of a food of plant or animal origin for use by infants is necessary properly to evaluate its suitability for use by particular infants.

77. The value of an infant food may depend on its simulation of, or suitability as a complete or partial substitute for, human milk.

78. Normal human milk contains adequate quantities of all factors essential to human nutrition, except that its content of vitamin C, vitamin D, and iron is insufficient in many cases to prevent scurvy, rickets and nutritional anemia, respectively.

79. The value of a food as a complete or partial substitute for human milk in infant feeding depends on its content of such factors as moisture, protein, fat,

carbohydrates, crude fiber, calcium, phosphorous, iron, and vitamins A, B^1, C and D, and the calories supplied by such food.

80. Information necessary to evaluate a food as a complete or partial substitute for human milk in infant feeding includes a statement of the per cent by weight of moisture, protein, fat, available carbohydrates, crude fiber, calcium, phosphorous, and iron, a statement of the number of available calories, and a statement of the number of units of vitamin A, vitamin B^1, vitamin C, and vitamin D supplied by the food.

81. The most common dietary deficiency diseases in infants are scurvy, rickets, and nutritional anemia caused respectively by deficiencies of vitamin C, vitamin D, and iron in human milk or in preparations used as substitutes for human milk, including among others, cow's milk and evaporated milk in which the quantities of such substances have not been increased.

82. Many persons are unaware of the deficiencies in these respects of such substitutes.

83. Such substitutes are customarily diluted and mixed with a soluble carbohydrate for infant feeding. In the proportions usually recommended by pediatricians each 100 calories of the substitute must contain 30 U.S.P. units of vitamin C, 50 U.S.P. units of vitamin D, and 0.75 milligram of iron to supply the minimum daily requirements of infants for such substances.

84. Where a food for use as a complete or partial substitute for human milk in infant feeding contains less than such quantities of vitamin C, vitamin D, or iron, information necessary for the purchaser to determine the value of the food includes a statement that such factors must be supplemented from other sources.

85. The value of cow's milk and evaporated milk used as a complete or partial substitute for human milk in infant feeding is sufficiently well known that aside from their deficiency in vitamin C, iron, and vitamin D when the amount of vitamin D has not been adequately increased, a statement relative to their constituents is not necessary to inform the purchaser of their value for such use.

86. 135 U.S.P. units of vitamin D per quart of cow's milk and 7.5 U.S.P. units per avoirdupois ounce of evaporated milk, the equivalent of 135 units per quart of milk when the evaporated milk is reconstituted by the addition of water, being usually sufficient, when fed in customary quantities, for the prevention of clinical rickets in normal infants due to its greater efficiency in milk, a statement that vitamin D must be supplied from other sources is not necessary when the milk or evaporated milk contains such quantity of vitamin D.

These findings of fact recognize that a food for babies *may* be a special dietary food and they make further findings as to special dietary needs of infants and the information needed to properly inform the purchaser with respect to such special foods. These are found to be substantially foods which may be substituted in whole or in part for human milk. The need for additional vitamin C, vitamin D and iron in the infant's diet is emphasized. These regulations and findings clearly recognize that babies may ingest general purpose foods in addition to those that supply these special dietary needs.

Legislative History of Federal Food, Drug and Cosmetic Act of 1938

An examination of the law on this point would not be complete without a detailed review of the legislative history of the Federal Food, Drug and Cosmetic Act of 1938. The entire legislative history is

carefully detailed in the book by Charles Wesley Dunn, *Federal Food, Drug and Cosmetic Act* (New York: G. E. Stechert & Co., 1938).

In 1933, a bill prepared in the U. S. Department of Agriculture with the approval of the President was introduced in the Senate (June 12, 1933) by Dr. Copeland and was given the identification number S. 1944. It was then referred to the Senate Committee on Commerce for study. The bill contained no section dealing specifically with special dietary foods, but covered the labeling requirement of all foods in the following manner: "The Secretary of Agriculture is authorized to prescribe such regulations as he may deem necessary for the efficient enforcement of the functions vested in him * * *." (Dunn, p. 49) This broad grant of power was deleted in the second draft of the bill as introduced in the 73rd Congress on January 4, 1934, as S. 2000. This bill contained the following paragraph:

(g) If it is for special dietary uses, such as by infants or invalids or for other special nutritional requirements, and its label fails to bear, if so required by regulations as provided by section 22, statements concerning its vitamin, mineral, and other dietary properties which fully inform the purchaser as to its nutritional value. (Dunn, p. 56)

The Committee to which this bill was referred made certain revisions and reintroduced it in the Senate on February 19, 1934 as S. 2800. Paragraph (g), as quoted above, was not modified. (Dunn, p. 75)

On January 3, 1935, a further revision of the bill was introduced in the Senate and identified as S. 5. Paragraph (g) was now identified as Section 403(j) and was slightly modified by use of the phrase "If it purports to be or is represented for special dietary uses . . ." instead of "If it is for special dietary use . . . ."

In the House of Representatives the bill was again modified and, under date of May 31, 1935, Section 403(j) was redrafted to read:

(j) If it purports to be or is represented for special dietary uses, such as by infants or invalids or for other special nutritional requirements, and its label fails to bear, if so required by such regulations as may be prescribed by the Secretary as necessary for the protection of the public health, statements concerning its vitamin, mineral, and other dietary properties which fully inform the purchaser as to its nutritional value. (Dunn, p. 535)

Two years later, on January 6, 1937, the same bill, S. 5, was introduced to the 75th Congress with the following revised phraseology:

(j) If it purports to be or is represented for special dietary uses, by infants or invalids, or for other special dietary uses, unless its label bears, if so required by regulations prescribed by the Secretary, statements concerning its vitamin, mineral, and other dietary properties which fully inform the purchaser as to its value for such uses. (Dunn, pp. 665-666)

The phraseology was further modified to read as shown below, and finally enacted into law:

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary prop-

erties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses. (Dunn, pp. 9-10)

In discussing S. 2800, Mr. Stevens, reporting for Dr. Copeland from the Committee on Commerce stated:

Paragraph (g) deals with articles offered for special dietary uses, such as infant foods, invalid foods, slenderizing foods, and other dietary products intended for special nutritional requirements. It authorizes the establishment of regulations, subject to approval of the Committee on Public Health, provided by Section 22, requiring statements concerning vitamin, mineral, or other properties needed for the intelligent use of the food by the consumer. The science of nutrition is rapidly extending the field of its usefulness. In order to keep abreast of these developments it is necessary that regulation-making power be given here. It is particularly essential in the field of baby foods. (Dunn, p. 121)

A subsequent report from Dr. Copeland on S. 5, dated March 13, 1935, was identical in phraseology except that paragraph (g) was now paragraph (j). (Dunn, p. 248) A further report on S. 5, dated May 13, 1935, contained a condensed and revised report with the following paragraph: "Paragraph (j) deals with articles offered for special dietary uses. It is particularly essential in the field of baby foods." (Dunn, p. 480)

In another report from the House of Representatives dated May 22, 1936, Mr. Chapman, representing the Committee on Interstate and Foreign Commerce, commented that the new proposed bill S. 5 would state that "Informative labeling of foods as to quality and composition is required for the information and guidance of consumers. Special emphasis is placed on the informative labeling for infant and invalid food." (Dunn, p. 553)

In itemizing the specific import and meaning of Section 403(j), Dr. Copeland, from the Committee on Commerce, under date of February 15, 1937, reported that this section "7. Requires fully informative labeling of infant and invalid food." (Dunn, p. 680)

Under date of April 14, 1938, the year in which the bill became law, Mr. Lea of the House of Representatives, reporting for the Committee on Interstate and Foreign Commerce, stated that the principal respect in which the proposed new measure differed from the current law of 1906 in regard to Section 403(j) was the requirement that:

Informative labeling of foods as to quality and composition is required for the information and guidance of consumers. Emphasis is placed on the informative labeling of special dietary foods, such as that for infants and invalids. (Dunn, p. 816)

Dr. Copeland, in introducing S. 2800, submitted the following statement in this regard to this particular section: "In the case of dietary foods, it demands properly informative labeling." (Dunn, p. 89)

In further discussion of S. 2800 on the floor of the Senate, and in extended remarks that were made a part of the Congressional Record, Dr. Copeland commented:

> Full and complete information to the consumer concerning the composition of a food is a prime necessity where the food is offered for special dietary purposes. Because of the increasing recognition of the importance of the daily diet in maintaining health there are being offered to the consumer an increasing number of preparations alleged to contain this or that vitamin, or mineral salt, or mysterious combinations of these, with special proteins, carbohydrates, and the like. Every field of nutritional science, in which a vast amount of research work is being done, has been or will be exploited by preparations of this character. It is essential to the well-being of the public that provisions be made to keep abreast of these developments and to require informative labeling to accord with the facts as they are uncovered from time to time. For this reason S. 2800 delegates the power to the enforcing agency to establish regulations requiring fully informative labeling on these special dietary preparations. No provision of this kind occurs in the present law. (Dunn, p. 161)

In the House debate, Mr. Lea commented specifically on the meaning of Section 403(j) in the following language:

> Informative labeling of foods as to quality and composition is required for the information and guidance of consumers. Emphasis is placed on the informative labeling of special dietary foods, such as that for infants and invalids. (Dunn, p. 848)

Conclusion

While the Congressional Record gives a definite impression that those supporting the bill were clearly concerned with securing proper labeling for baby foods which supplied special needs of infants, such as foods simulating human milk or supplying added vitamins or minerals, it further is quite clear that they, too, recognized that not all baby foods were of a special dietary nature. The language "such as by infants", which could possibly be interpreted as intending that all baby foods were foods for special dietary uses, was eliminated in the language of Section 403(j) as finally enacted into law. This Section, as enacted recognizes that most all persons, regardless of age or physical or physiological conditions, can consume general purpose foods as well as special dietary foods.

As Section 403(j) only authorizes regulations requiring label information with respect to special dietary foods, it is clear that the present and proposed regulations are correct in recognizing that there are general purpose foods for infants. The power granted by this Section does not convey authority to adopt regulations making general purpose baby foods into special dietary foods. Regulations must have a basis in the statute and be within the authority granted the administrative agency. *Review Comm. Venue VII, etc. v. Willey*, 275 F. 2d 264, 272 (CA 8, 1960). **[The End]**

FOOD DRUG COSMETIC
LAW JOURNAL
PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS
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