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SAFETY BRIEF

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MEDICAL SERIES

Reliability and Safety of Medical Devices: Introduction

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Abstract

The development, manufacture and sale of medical devices is regulated by the Food and Drug Administration (FDA). Companies involved in this specialized area must conduct their business in an atmosphere of formality which is not present in other areas of commercial product development. The cost of non-compliance is significant in terms of both money and image. Past FDA emphasis has been on manufacturing compliance, however, recent indications are that the design phase of product development will receive greater attention.

FEDERAL REGULATION OF MEDICAL DEVICES

The manufacture and sale of medical products for use on humans follows essentially the same development sequence as any commercial product. Medical device development is unique, however, because of two important factors: (1) medical devices play an important, frequently critical role in the practice of medicine, and (2) the medical device industry is regulated by an agency of the Federal Government; The Food and Drug Administration (FDA). The regulatory influence which is present in the development of medical devices presents additional requirements which product designers and manufacturers must contend with.

Historically the FDA's attention has centered only on drug products. However, this changed with the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act which gave the FDA the responsibility and authority to assure that medical devices are safe and effective.

As defined by the amendments, a medical device is an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, ... which does not achieve any of its principal intended purposes through chemical action within or on the body."

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TABLE I

MEDICAL DEVICE SUMMARY

by Functional Category

FUNCTIONAL CATEGORY AND TYPE OF DEVICE	APPLICATION	POSSIBLE FAILURE MODE
DIAGNOSTIC INSTRUMENTS		
Blood Analyzers	Red, white Cell counts General Blood Chemistry	Incorrect or False readings
Oxygen Analyzers	Oxygen level	
Blood Pressure Cuff	Measures blood pressure	
THERAPEUTIC DEVICES		
Intravenous Infusion Pumps	Fluid replacement, medication	Air infusion, unexpected rate changes Over/under Infusion
Insulin Micro	Diabetes control	
Inhalation and Humidifier Systems	Assists breathing, delivers warmed, humidified air	Excessive temperatures Blocked airway, Flooded airway
PHYSIOLOGICAL MONITORING		
Respiration Monitor	Senses breathing cessation	Failure to detect
Glucose Sensor	Blood sugar level measurement	Incorrect treatment response
PROSTHETIC IMPLANTS		
Pacemakers	Regulates heart rate	Arrithmia due to failure of pacer leads, electronics, etc.
Hip/Knee Joints	Replacement for accident or chronic bone disease damage	Multiple surgery, medical complications
Interocular Lens	Restores vision from lens damage or cataracts	Sight impairment, medical complications
Mammary Implants	Cosmetic and reconstructive	Multiple surgery, medical complications
SURGICAL		
Electrical Surgical Units	Cuts and coagulates for clear operating field	Radiated electrical interference affects sensitive instruments, Electrical requires caution around flammable materials
Cateters	Diagnostics, Therapy, Biopsy	Perforation, Breakage
Blood Warmer	Warms blood from blood bank	Too cold: possible arrithmias Too hot: Hemolysis possible kidney damage
HOSPITAL SUPPORT EQUIPMENT		
Sterilizers	Sterilize medical equipment	Insufficient sterilization ETO leaks
Beds (electrically operated)	Examination, Patient Recovery	Pinch points, Electric shock
Miscellaneous Equipment		
Disposable Products Operating Room Supplies - Surgical gloves - Instruments - Gowns,masks,cap - Cut down trays	Patient convenience Products, bedpans, Hospital support, etc.	Non-sterile, Mislabelled, Procedural delays

Medical devices exist in a variety of forms. They can be active or passive in the sense that their function does or does not automatically alter the course of therapy, and can be designed for single disposable use or as permanent equipment.

MEDICAL DEVICE FUNCTIONAL CATEGORIES

Medical devices can be categorized by general function as follows:

- -Diagnostic instruments
- -Therapeutic devices
- -Physiological monitoring devices
- -Prosthetic implants
- -General surgical apparatus
- -Hospital support equipment

Table I gives examples of medical devices in each of these categories, and briefly indicates their uses and the inherent failure modes. It is, of necessity, brief in scope since an exhaustive list would involve thousands of entries, an undertaking which is not in the direct interest of this discussion.

FDA MEDICAL DEVICE CLASSIFICATION

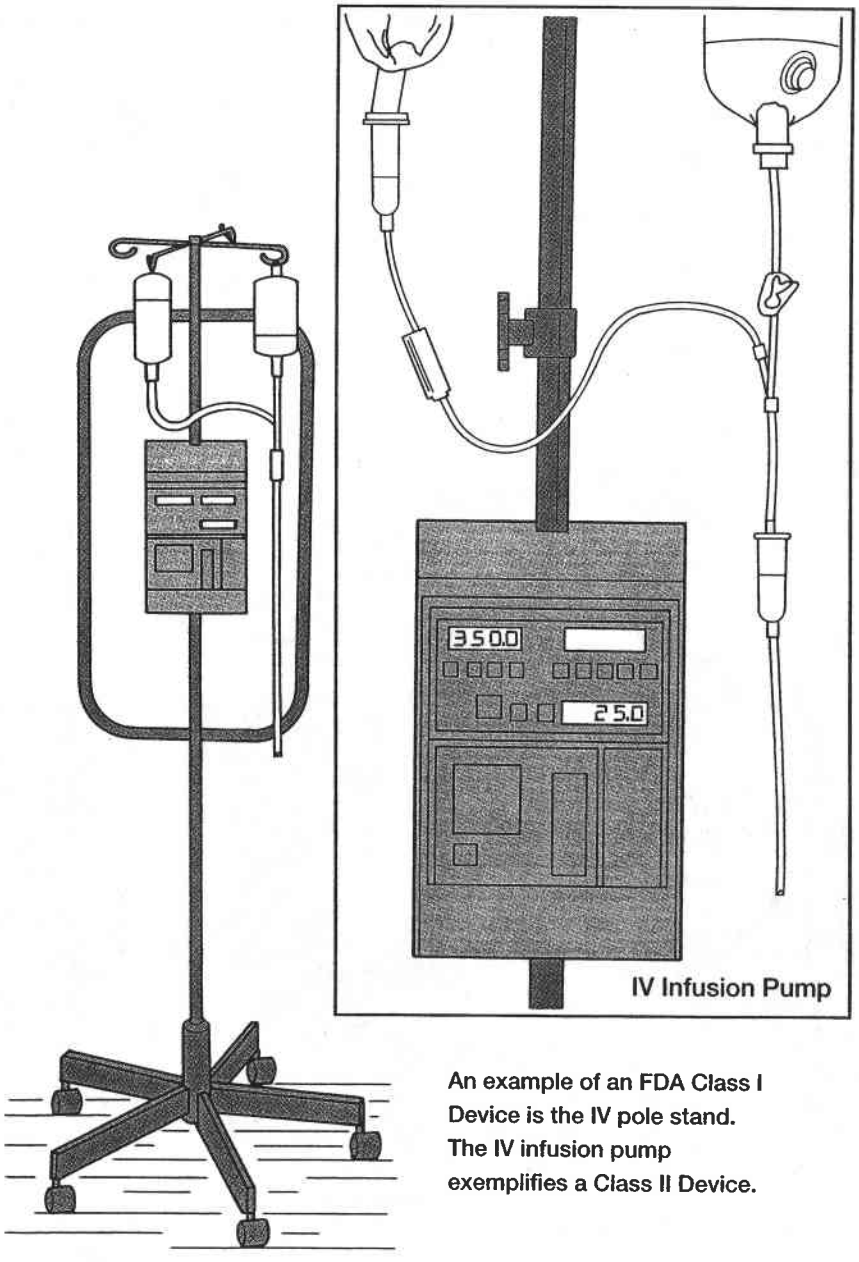
The 1976 device amendments specify three levels of controls intended to assure the safety and effectiveness of medical devices before they can be offered for sale. These levels are formally called device classes and all medical devices must fall into one of the three depending on the criticality of its medical function. The basic intent is for the FDA and the manufacturer to have a common understanding of what the FDA expects from the manufacturer to assure that the device is developed and produced in a manufacturing system which is controlled and error free. An explaination of device classes follows:

Class I Devices

Class I devices require general controls which are intended to prevent the adulteration and misbranding of the medical device. Under the amendments, adulteration may include a failure to follow Good Manufacturing Practice (GMP) Regulations or comply with an applicable FDA requirement. Misbranding may include failure to register production facilities with the FDA, list a device with the FDA, or properly label the medical device. Labeling is not confined to the label on the device itself but includes any literature accompanying the device such as operating or service manuals, and advertisements for the device including marketing and sales materials. Errors or inconsistencies in text or label copy may be considered as both adulterations and misbranding leading to a recall of the product. GMP regulations are unique to the health devices industry and manufacturers are subject to inspection and fines for failure to comply with any of a voluminous number of manufacturing controls including quality assurance, sterility, and personnel training. (Also see section on GMP).

Class II Devices

Class II products require a specific performance standard, as well as the general controls. Devices that measure and process physiological data for diagnostic purposes fall into this category. The amendments gave the FDA authority to require that mandatory performance standards be established for these products. These performance standards primarily describe the expected capabilities of the device in terms of its ability to perform correctly and accurately under specified conditions of operation and use. Class II also contains some devices whose use might involve slight risk to the patient.



An example of an FDA Class I Device is the IV pole stand. The IV infusion pump exemplifies a Class II Device.

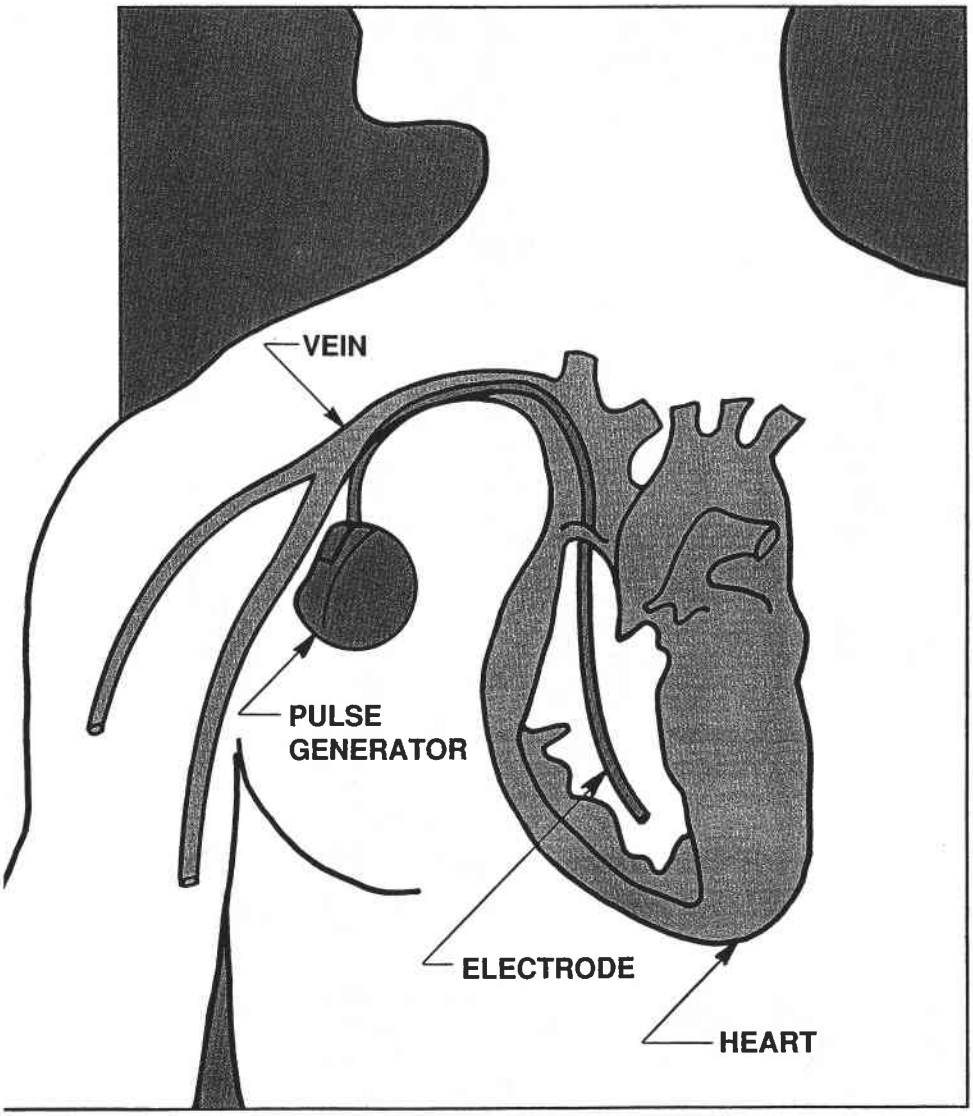
Class III Devices

Class III devices pose a significant risk to health by their use. These include invasive diagnostic devices, life sustaining medical devices and unique forms of device related medical therapies. Many implantable devices are in this class. In order to bring a Class III medical device to market, a manufacturer must demonstrate to the FDA that such devices are safe and effective by submitting laboratory studies, clinical trial data, and other supporting data for review.

Table II displays the basic regulatory requirements associated with each device class along with some related medical device examples.

Even though implementation may require interpretation, the intent of the regulation with respect to drugs and devices is clear; the development, formulation, manufacture and distribution of medical devices must be sufficiently well managed so that all known and controllable risks to the patients are eliminated and all uncontrollable risks are understood, communicated, and accepted by the community of knowledgeable users.

When this system of controls fails in any manner, the drugs and medical devices so affected are termed adulterated products and the manufacturer then has the responsibility to assess the risks involved, produce a plan for corrective action, and notify the FDA of its actions.



A pacemaker is an example of a Class II Device.

PRODUCT RECALLS

The plan for dealing with adulterated products always involves a product recall. The mechanics of a recall may take the form of removing all identified products from use or, in the case of some medical devices, a field modification. The FDA has the power to force a manufacturer to recall products with attendant fines and penalties should they decide that the manufacturer has not taken the appropriate steps in a timely manner.

The FDA has established "Recall Classes." An FDA "Recall" may involve removal of a product from the market or return to the manufacturer for repair. However, FDA also uses the word "Recall" to describe customer notification, field repairs, labeling changes, hazard warnings, and other situations. The FDA classifies product recalls in the manner described in Table III. Notice that the ordering is opposite that of device classifications in terms of severity.

The very nature of this regulated process can introduce an undesirable degree of inertia on the part of manufacturers when it comes to making beneficial product changes. Attempts by the manufacturer to affect these changes by field modification may be interpreted as a recall and not a product upgrade under the FDA's regulation.

Although a recall may not involve a defect with any direct medical implications it is still a black mark which fails to praise the manufacturer for the prompt implementation of product improvements and corrective actions.

When the spectre of outside government involvement is removed, however, the regulation simply becomes an appeal to use the scientific process to develop, and control the quality, reliability and safety of medical products.

GMP
(Good Manufacturing Practices)

In its present form, medical device regulation treats the manufacturing side of development much more thoroughly than it does the design side of device development. Regulatory emphasis takes the form of Good Manufacturing Practices (GMP), and device complaint

TABLE II

FDA DEVICE CLASSIFICATIONS

CLASS	REGULATORY REQUIREMENT	CRITICALLITY	EXAMPLE
I	General Controls	None	- IV pole stands - Hospital beds - Examination tables
II	General Controls Performance Standard	None to Slight	- Blood Pressure Monitors - Electro Cardiograph - Respiration Monitor - IV Infusion Pump
III	General Controls Performance Standard Premarket FDA Review and Approval	Significant	- Heart Pacemakers - Invasive Electro Cautery Devices - Hemodialysis System - Electro Convulsive Devices

reporting procedures such as Mandatory Device Reporting (MDR).

In essence, Good Manufacturing Practices deals with factors in the manufacturing process which could lead to an adulterated product. The manufacturer must have a quality plan for receiving and inspecting all materials which will be used in the manufacture of the product. Defective or rejected in process products must be clearly marked and held in separate rework or scrap areas and all manufacturing processes must be validated and documented.

A Device Master Record must contain all design details necessary to completely specify the device and its formulation, configuration, critical components and critical process steps. A Device History Record must be used to track and document fabrication, test and inspection details by serial number, batch record and similar means of identification.

PRODUCT COMPLAINT REPORTING

The device manufacturer is also required to have a formal system for receiving and reviewing product complaints. This procedure is often the responsibility of a designated quality/regulatory group within the company. They are expected to analyze complaints and returned products, and conduct technical investigations which provide rational explanations and corrective actions. All complaint files must be available to the FDA for their inspection.

For incidents of a severe nature, the FDA's Mandatory Device Reporting requirement (MDR) sets forth special criteria for reporting device related incidents. Incidents involving a death or injury requiring medical intervention must be reported within five days after the manufacturer becomes aware of the incident. Reports which simply imply that the potential for death or serious injury may be present, must be investigated and reported within fifteen days. A proper distinction must always be made by the manufacturer under these circumstances between the inherent limitations of the technology being used and what could be termed a flaw in the design, manufacture or application of the technology. If the manufacturer finds that there is no flaw, they still must convince the FDA.

A recently reported study by the FDA of medical device recalls during the 10 year period from 1976 through 1986 revealed that about half of the recalls were for design problems not directly addressed by GMP regulations. While this now appears to be a serious oversight, it may in fact have been premature for the FDA to try and address design issues because of recent rapid increases in sophistication and the transfer of microprocessor based technology into the medical device area.

MICROPROCESSOR CONTROLLED MEDICAL DEVICES

Medical devices which now incorporate electronic control processes, software decision logic, and their attendant sophistication must be considered somewhat apart from traditional medical devices.

The widespread use of microprocessor based electronics in commercial products has similarly occurred with medical devices, increasing not only the power of the design, but also, concerns about the design execution. The design process must control the application of this complicated technology so that medical devices are not unsafe due to a subtle design oversight or spurious environmental incursions. This technol-

TABLE III

FDA RECALL CLASSIFICATION

Class I Recall

"A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences of death."

Class II Recall

"A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."

Class III Recall

"A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences."

ogy is now commonplace in medical products such as intravenous solution infusion pumps, miniature glucose sensors and, as illustrated by the previously cited recall example, simple blood pressure apparatus. Microprocessor controlled systems are extremely powerful in their capacity to receive information and make programmed decisions to guide the course of therapy in which they are involved. These techniques have, in fact, helped many medical devices evolve to their present level, and portend even greater sophistication as time goes on.

Hardware medical devices can also be part of a system. This system may consist of a disposable or single use component, a drug portion, and the hardware itself. All three elements of this sytem have very different characteristics and each has its own unique requirements in terms of how the manufacturer designs, tests, produces, and markets the product as a system.

The design qualification, and validation of this emerging class of critical hardware electronic systems calls for a certain standardization of the development process which concentrates on design as well as manufacture.

Some manufacturers are already aware of this and are utilizing analysis concepts such as systems safety analysis and a design approach which anticipates that random electronic component failures will occur. This kind of design approach has been utilized by the aerospace and nuclear industries to assure the continued safety of systems and processes even when random failures do occur in the electronic controls.

One organization, The Emergency Care Research Institute, is prominent in performing independent evaluations of the quality and performance of medical devices. As an independent evaluator of devices for the hospital and medical community they are a strong proponent of medical device safety. Their publication HEALTH DEVICES reports on performance as well as problems encountered by users for a wide variety of hardware medical systems.

In this climate of growing awareness, the FDA has recently published a guideline to the development of medical devices. It is a tentative step towards the regulation of medical devices and places emphasis on microprocessor software.

It seems certain that medical device manufacturers will stand more accountable for the diligence with which inherent risks have been accounted for during the process of designing their products.

EXAMPLE OF MEDICAL DEVICE RECALL

Medical Device:	Non-Invasive Blood Pressure Monitor Model #90731
Manufacturer:	Space Labs, Inc.
FDA Recall Listing:	Class II

Problem

Device utilizes a microprocessor. Device specifications and accompanying literature state that device is capable of reading and displaying diastolic pressure at a lower limit of 40-mm/mercury. However software in microprocessor displays "no reading" message at that level.

Corrective Action Plan

Manufacturer to contact all affected users by certified mail. Field service technicians will make necessary corrections in field to enable software to display the correct lower diastolic limit.

Triodyne Comment

This is one example of a Class II device requiring both general controls and performance standards. The problem is design related and should have been caught by a procedure of software validation and final quality assurance testing prior to release. The recall is also a Class II recall of adulterated product since it is either misbranded or it does not meet its own performance specification. The consequences is not viewed as significant.

FREEDOM OF INFORMATION

Because of the complaint reporting requirement, all reported medical device related injuries must be investigated and documented by the manufacturer. This data is collected by the FDA for the purpose of regulating the industry.

The FDA is required through the Freedom of Information Act to supply these records on request. Data on specific manufacturers and medical device types is retained by their device experience network which records complaints and a summary by the manufacturer of each action taken. A synopsis of product recalls for specific devices is also available. Information may be obtained by written request from the:

Federal Drug Administration
FOI Office HFI-35
5600 Fishers Lane
Rockville, MD 20857

Since many manufacturers have facilities located outside of the United States we have found that it is best to specify "all producing facilities" and "all complaints relating to device failure, injuries and adverse reactions." Specifying a time frame may also reduce the need for additional correspondence.

The Emergency Care Research Institute may also have performance data for many medical devices which have been developed in the course of their own evaluations. This independent view is often helpful in sorting out the strengths and weaknesses of many product designs. The office of ECRI may be reached by writing to:

Emergency Care Research Institute
5200 Butler Pike
Plymouth Meeting, PA 19462

It is Triodyne's experience, that a phone call prior to writing will be help to establish the most appropriate person within ECRI for specific product information.

What Is a Defect?

The definition of defective product in a state may be found in its case law. Triodyne relies on the trial bar for selection of the cases cited.

Hawaii

Ontai v. Straub Clinic and Hospital, Inc., 66 Haw. 237, 659 P. 2d 734 (1983)

Plaintiff Ontai went to the Straub Clinic for an air contrast barium enema examination of the colon which required that he be x-rayed in several positions on a tilting x-ray table. For one of the x-rays the table was in the near vertical position when the footrest at the bottom end gave way and Ontai fell to the floor.

Ontai filed suit against G.E. on the basis of strict liability in tort, negligence and implied warranty.

The rule of strict liability as formulated in the Second Restatement of Torts., §402A says, "one who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer or his property..."

In this case the court upheld its previous ruling which eliminated the requirement that the defective product must have been unreasonably dangerous:

> "Under the formulation of the rule of strict products liability, the plaintiff need not show that the article was dangerous to an extent beyond that which would be contemplated by the ordinary user who purchases it... It is enough that the plaintiff demonstrates that because of its manufacture or design, the product does not meet the reasonable expectations of the ordinary consumer or user as to its safety."

Armstrong v. Cione, 69 A.H. No. 10805, 738 P.2d 79 (June 1, 1987)

Plaintiff Armstrong was injured while attempting to close the shower door in an apartment he was renting from the defendant. The shower door had three panes of glass, two of which folded into the shower in a V-shape to pull the third pane out of the way to permit entry and exit. The glass was ordinary glass not safety glass. The plaintiff was trying to push the door closed when his hand slipped off the hinged portion and went through the glass cutting his arm.

The plaintiff testified that the glass was cracked and the shower door was difficult to close prior to the accident. The jury ruled that the plaintiff was 67% at fault and the defendant 33% at fault for this accident. The lower court ruled that the plaintiff could not recover anything because his fault was greater than the defendant's.

The high court ruled that a plaintiff's negligence reduces but does not defeat his claim sounding in strict products liability even if his negligence is found to be greater than the plaintiff's:

> "Our desire to protect consumers and hold manufacturers and distributors accountable for placing unsafe goods in the market is best served by insuring that application of comparative negligence principles does not inadvertently create an "all or nothing" bar to plaintiffs' recovery. See, Kaneko, 62 Haw. at 464, 654 P.2d at 354 Mulherin v. Ingersoll-Rand Co., 628 P.2d 1301, 1303-04 (Utah 1981); V. Schwartz, Comparative Negligence s 12.5 (2d ed. 1986). See ed. 1986). (See also 4 F. Harper, F. James & O. Gray, The Law of Torts ss. 22.7, at 317 n. 44 (2d ed. 1986). Employing modified comparative negligence principles in the strict products liability context would create such a bar by "allowing defendant to escape liability which the jury has allocated to him, irrespective of the responsibility allocated to the plaintiff. See Murray v. Fairbanks Morse, 610 F.2d 149, 162 (3d Cir. 1979)." Duncan v. Cessna Aircraft Co., 665 S.W.2d 414, 429 (Tex. 1984).
>
> Moreover, our desire to create economic incentives for safer products is best served by preventing the creation of a complete bar to plaintiffs' recovery where the manufacturer or distributor is partially responsible for the injuries sustained. Such a bar would result in inefficient economic incentives to produce safe products. See Murray, 610 F. 2d at 161; Duncan, 665 S.W.2d at 428. Obviously, this would significantly reduce the incentives for creating safer products that are often or easily misused or altered by consumers and for placing the cost for partially unsafe products on the consumer. See Mulherin, COPR. (C) WEST 1987 NO CLAIM TO ORIG. U.S. GOVT. WORKS."

Hao v. Owens-Illinois, Inc., 69 A.H. No. 11184, 738 P.2d 416 (June 10, 1987)

In Hao, the Supreme Court reiterated the rule of pure comparative negligence in strict products liability cases.

Mr. Hao was a shipyard worker for 31 years. He was exposed to asbestos dust and fibers in his work. He was also a smoker. He developed several asbestos related diseases. He sued many asbestos manufacturers and distributors and all settled with him except Owens-Illinois.

The jury found Mr. Hao 51% at fault for his illnesses because of his smoking and all the asbestos manufacturers 49% at fault with 2% of that fault being Owens-Illinois'.

The trial court entered judgment for Owens-Illinois because the plaintiff's negligence exceeded the defendant's.

The Supreme Court said that the trial court erred in barring recovery. The court should have reduced Hao's award by the percentage of his negligence.

Johnson v. Raybestos - Manhattan, Inc., 69 A.H. No. 11516, 740 P.2d 548 (July 22, 1987)

In Johnson, the plaintiff sued a number of asbestos products manufacturers because of his illness and death resulting from asbestos exposure in his workplace. State-of-the-art evidence was presented at the trial to prove the manufacturer could not know his product was dangerous or defective at the time of manufacture and sale. The jury returned a verdict for the defendant. The Supreme Court ruled that state-of-the-art evidence is irrelevant in a strict products liability action: "in a strict products liability action, the issue of whether the seller knew or reasonably should have known of the dangers inherent in his or her product is irrelevant to the issue of

liability. See Boudreau v. General Electric Co., 2 Haw. App. 10, 15, 625 P.2d 384, 389 (1981). Although highly relevant to a *negligence* action, it has absolutely no bearing on the elements of a strict products liability claim. See Kisor v. Johns-Manville Corp., 783 F.2d 1337, 1341 (9th Cir. 1986). We, therefore, hold that in a strict products liability action, state-of-the-art evidence is not admissible for the purpose of establishing whether the seller knew or reasonably should have known of the dangerousness of his or her product. See Carrecter v. Colson Equipment Co., 499 A.2d 326, 330-31 (Pa. Super. 1985)."

Cases selected by Calvin E. Young of Libkuman, Ventura, Ayabe, Chong and Nishimoto, 737 Bishop St., Suite 3000, Honolulu, Hawaii 96813-3286.

Kentucky

Nichols v. Union Underwear Co., Inc., Ky., 602 S.W. 29429 (1980)

In Nichols v. Union Underwear Co., Inc., a product liability suit was brought against the Union Underwear Company by the father of a four year old. The child was badly burned when the T-shirt he was wearing caught fire after the child had been playing with matches. The suit was brought under a strict liability theory alleging that the shirt was defective due to its tendency to catch fire. The sole issue to be determined by the Kentucky Supreme Court was whether the trial court erred in instructing the jury on the definition of a defective product.

The court recognized that Kentucky has adopted a strict liability standard in product liability cases. This strict liability standard was adopted in accordance with §402A of the Second Restatement of Torts which holds a manufacturer liable if the product is "in a defective condition unreasonably dangerous to the user or consumer or to his property." The problem, therefore, becomes defining what is and what is not "unreasonably dangerous."

After evidence was presented by both parties in the lower court, the jury was instructed to find the T-shirt unreasonably dangerous if the product was more dangerous than an ordinary consumer would expect. On appeal, the child's father strenuously objected to this definition since he felt that a danger beyond a consumer's contemplation was only one of several factors to be taken into consideration. In agreeing with the child's father and holding that the lower court had erred in its definition of a defective product, the Kentucky Supreme Court stated:

> "It is clear that [the lower court definition] limited the jury to finding the product unreasonably [dangerous] if, and only if, it was more dangerous than an ordinary adult would expect it to be. In effect, the product cannot be unreasonably dangerous if the omnipresent and elusive 'reasonable man' - ordinary adult - knows about the danger. Under this instruction, the obviousness of the danger becomes the sole determinant of the reasonableness of a danger, rather than simply being one of many factors.
>
> The effect of this instruction is to insulate a product from liability simply because it is patently dangerous, or because it is no more dangerous than would be anticipated by the ordinary person. . . .
>
> We believe that consumer knowledge, the factor considered below, is only one of the factors that should be before the jury in determining whether a product is unreasonably dangerous. We will not set out an exclusive list of the factors which lead to this determination. In Jones, supra, we discussed deviation from industry standard as a factor; in Kasco Abrasives, supra, we recognize the obviousness of the danger and presence of a warning as relevant. Noted commentators have suggested many factors. But the facts of the individual case will determine what is relevant to each action."

Ulrich v. Kasco Abrasives Company, Ky., 532 S.W. 2d 197 (1976)

In Ulrich v. Kasco Abrasives Co., the plaintiff was employed by the Marley Company as a welder which required the occasional use of portable grinding machines. The abrasive discs which were attached to the grinding machines came with instructions regarding the "do's and don'ts" of their operation. One instruction specified that the disc should never exceed 6000 rpm. However, the governor valve on the grinder which Mr. Ulrich was using was inoperable and a later test revealed that the grinder was running in excess of 9000 rpm. The abrasive disc which was attached to the grinder "exploded" and struck the plaintiff. Mr. Ulrich brought this suit against Kasco Abrasives, manufacturer of the abrasive disc, and Aro Corporation, manufacturer of the grinder, under the theory that neither product contained adequate warnings regarding the danger of using the product.

The Ulrich court recognized Kentucky's adoption of strict liabililty as stated in Section 402A of the Restatement of Torts which holds a manufacturer liable if a product is sold "in a defective condition unreasonalby dangerous to the user or consumer or to his property." In defining whether a product is defective, the court was required to define the term "unreasonably dangerous."

> "Our opinion in Jones was not meant, as suggested in the comment appearing at 62 Ky.L.J. 866, 867 (1974), 'to define a defect as a variation from industry standards for similar products in such a way that it was negligent to produce such a variation'. To the contrary, it was and is our view that such a variation can amount to no more than *evidence bearing on the ultimate factual issue of whether the product was unreasonably dangerous.*
>
> The product either is or is not unreasonably dangerous to a person who should be expected to use or be exposed to it. If it is, it can make no difference whether it is dangerous by design or by accident. As aptly observed in 62 Ky.L.J. 866, 875 'the important factor is how safe or dangerous the product is when used as it was intended to be used' [or should reasonably have been anticipated to be used]. If the danger is unreasonable because it is not obvious and may not be apprehended by such a person, then it may be obviated by an adequate warning, so provided or affixed that in the ordinary course of events it will reach and should be understood by that person. Whether such a warning is so provided is nothing more than one of the factors determining whether the product is unreasonably dangerous."

Although the court stated the foreseeabililty of a danger is an important element in deciding whether a product is defective, it is only one of several factors to be taken into consideration when deciding whether the grinder is "unreasonably dangerous."

Defining whether a product is defective is a factual determination to be made on a case by case basis. The court ultimately held that the abrasive disc and grinder were not unreasonably dangerous. This decision rested upon the fact that neither Kasco or Aro could have anticipated the possibility of an injury as incurred by Mr. Ulrich.

"Applying the foregoing standards to this case, we are of the opinion that a jury could not justifiably find either the grinder or the wheel, marked and labeled as it was, unreasonably dangerous in the sense that a prudent manufacturer of similar products fully apprised of the condition and tendencies of the product when he put it in the stream of commerce would have anticipated a substantial likelihood of injury to a workman using the grinder and exercising ordinary care for his own safety. Hence neither product was 'unreasonalby dangerous'."

Foreseeability of the potential danger was relied upon by the court in holding that the disc and grinder were not unreasonably dangerous. However, the court stressed that each issue presented by the parties as to why a product may be dangerous must be reviewed before a product can be termed defective.

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