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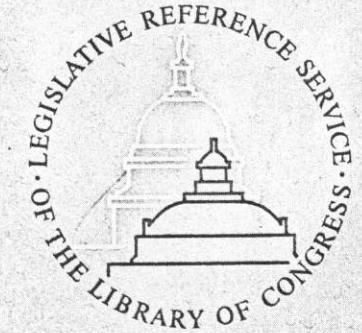

DISCUSSIONS OF MEDICAL DEVICE ISSUES: A Selected Bibliography

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Introduction

The contributions of bio-medical engineering to the field of medical instrumentation have increased tremendously in the past decade. Manufacturers now estimate that over 5,000 types of medical devices are presently on the market, ranging from simple, time-tested thermometers to sophisticated electronic monitoring equipment. There is little question that these medical devices have saved countless lives and eased the doctor's workload. At the same time, however, many of these devices have proved to have serious defects which have reportedly caused death or injury to thousands of patients.

The medical profession, manufacturers, researchers, public health officials, and the Federal Government have become increasingly aware of both the hazards encountered with the use of defective medical devices and the lack of adequate manufacturing and quality control guidelines or regulatory procedures designed to assure the safety and effectiveness of devices. Unlike pharmaceutical products, medical devices have never been subject to rigid pre-marketing clearance procedures administered under the Food and Drug Administration. Under present law, FDA activities in the medical device area have been limited to enforcement of regulations which prohibit misbranding and

adulteration and require devices to bear adequate directions for safe and effective use. Under this authority, FDA may act upon devices in violation of current regulations, but only subsequent to commercial marketing.

In recent years a considerable amount of controversy has been engendered over various legislative proposals which would extend FDA pre-clearance regulatory authority to the field of medical devices. One of the most recent proposals was contained in a special message to Congress delivered in February 1967 by President Johnson where he announced his intention to draft consumer protection legislation which would divide medical devices into several classes subject to differing degrees of regulation. Although legislation incorporating the Johnson Administration's proposal was later introduced into Congress along with a number of other legislative approaches, no further Congressional action on the bill took place.

A Medical Device Safety Act has again been introduced into the current session of Congress. In response to the continuing debate over the safety and regulation of medical devices, this bibliography has been prepared to provide readers with a selected list of articles, statements, and reports which address themselves to various aspects of this issue.

The bibliography is divided into six areas into which citations are categorized: hazards encountered with medical devices in general, hazards associated with device materials, hazards encountered with electrical devices, liability for

defective medical devices, medical device regulation, and medical device safety standards. These are not rigid categories which define the limits of the subject-matter discussed in a particular citation, but are designed only for the convenience of the reader.

Hazards Encountered with Medical Devices in General

Economics of innovation (Lee, M.). Proceedings of the Royal Society of Medicine 61: 1051-1054, 1968.

Excerpts and summary of a national conference on medical devices. JAMA* 210: 1745-51, Dec. 1, 1969.

Hazards of hospitalization (McLamb, J.J., and Huntly, R. R.). Southern Medical Journal 60: 469-472, 1967.

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Hospitals' electronic metamorphosis (Altman, M.). Hospitals 43: 42-5, 1969.

Impact of scientific and technological advances (Schlicke, C.P.). Northwest Medicine 66: 56-65, 1967.

Instrumentation and the delivery of health services (Brown, H.H., and Dickson, J.F.). Science 166: 334-338, 1969.

Medical devices: an unhealthy situation. Consumer Reports 35: 256-259, 1970.

Medical engineering (Davis). International Science and Technology 18: 29-30, Sept. 1964.

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* In this bibliography the following common abbreviations are used:
JAMA - Journal of the American Medical Association
JAAMI - Journal of the Association for the Advancement of Medical Instrumentation.

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Unseen menace (Charlebois, Coring). Canadian Anesthesiology Society Journal 13: 581, 1966.

What is wrong with the biomedical instrument market (Fischmann, G.S.). Instrumentation Technology 16: 41-44, 1969.

What medical instrumentation in 1974? (Reynolds, W.E., and Bazell, S.). Medical Surgical Review 5: 53, 1969.

Which stethoscope? (Hampton,C., and Chaloner, A.). British Medical Journal 4: 388-390, 1967.

Why instrumentation can be a headache (Davis, D.). Modern Hospital 108: 113-114, 1967.

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Materials in medicine. Nature 220: 223-225, 1968.

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Problems in the use of metals as surgical implants (Laing). Journal of Dental Research 45: 1660, 1966.

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Accidental deaths due to electric current. Clinical Pediatrics (Phila.) 8: 4-5, 1969.

Designers of medical instruments face serious questions on safety (Doyle, O.). Electronics 42: 92-95, Feb 17, 1969.

Electric shock hazard in hospitals (Hopps, J.A.). Canadian Medical Association Journal 98: 1002-7, 1968.

Electrical hazard in hospitals (Fisher, T.L.). Canadian Medical Association Journal 98: 1007-8, 1968.

Electrical hazards in hospitals. Rhode Island Med. Journal 51: 405-6, 1968.

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Electrical hazards of medical instrumentation and their prevention (Stanley, P.E.). Transactions of the National Safety Congress 9: 13, 1968.

Electricity is a two edged sword. JAMA 206: 2232, 1968.

Electronics in the lab. (Currie, M.R., Thompson, W.P.). Hospitals 43: 61-64, 1969.

Expert cites hospital electrocutions (Bohne, W.). Electronic News Aug 25, 1969: 2.

Hazards of electrical apparatus (Bruner, J.M.R.). Anesthesiology 28: 396-425, 1967.

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Safe electrical environment in the hospital (Walter, C.W.). Bulletin of the American College of Surgeons 54: 177-186, 1969.

Shock hazards in operating rooms and patient-care areas (Hopps, J.A.). Anesthesiology 31: 142-155, 1969.

Tiny flaws in medical design can kill: errant currents from faulty electronic equipment are reported imperiling patients in certain cases (Gechman, R.). South Dakota Journal of Medicine 21: 27-30, 1968.

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Defective surgical instruments and medical products (Campbell). Defence Law Journal 12: 249, 1963.

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Law and medicine:libel and health care. JAMA 210: 2327-8, 1969.

Legal consequences of physicians orders (Bernstein, A.H.). Hospitals 43: 90-91, 1969.

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Medical devices and paramedical personnel: a preliminary context for emerging problems (Lee, Arthur Allen.). Washington University Law Quarterly Summer 1967: 332-399.

Medical negligence (Nathan, H.). London: Butterworth, 1957.

Medical profession and strict liability for defective products--a limited opportunity. Hastings Law Journal 17: 359-360, 1965.

Products liability: manufacturers responsibility for defective or negligently designed medical and surgical instruments (Edward Swartz). DePaul Law Review 18: 348-407, Summer 1969.

Responsibility of manufacturers and consumers (Orkin, L.R.). JAMA 206: 2888-9, 1968.

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S. 2107--introduction to the medical device safety act of 1969 (Nelson, Gaylord). Congressional Record May 8, 1969: S 4816-4822.

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