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TO OUR READERS

The Board of Editors of the HARVARD JOURNAL ON LEGISLATION has voted to change the publication schedule of the JOURNAL from four to three times annually effective with Volume 16, Number 1. From that time, the JOURNAL will publish a Winter, Spring, and Summer issue in each volume. This change in schedule will bring the JOURNAL'S publication program into line with that of the HARVARD CIVIL RIGHTS-CIVIL LIBERTIES LAW REVIEW and the HARVARD INTERNATIONAL LAW JOURNAL and will alleviate production problems that may have been created by the change in Harvard Law School's academic calendar to a 4-1-4 semester format that took place in September 1978.

The JOURNAL anticipates that the number of pages in its volumes will not decrease from that of prior years, despite the reduction in annual issues from four to three. The subscription price for each volume will remain at $7.50 per volume for subscribers in the United States and $9.00 per volume for foreign subscribers. Subscribers are reminded that their subscriptions will be renewed automatically for Volume 16 if they do not send the JOURNAL notices of cancellation.

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REGULATING THE PRESCRIBING OF HUMAN DRUGS FOR NONAPPROVED USES UNDER THE FOOD, DRUG, AND COSMETIC ACT

DAVID A. KESSLER*

Serious hazards from improper drug prescription endanger the public health. Particularly acute is the problem created by the prescribing of drugs for uses not approved by the Food and Drug Administration. The FDA has sought to limit improper prescription by restricting the distribution of drugs subject to use for nonapproved purposes, by instituting misbranding charges against physicians who prescribe for nonapproved uses, and by withdrawing certain drugs from the market. In addition, the FDA has proposed that all nonapproved uses be prohibited.

Mr. Kessler examines these techniques for limiting the dangers of improper prescription and finds that each fails to accommodate adequately the interest of the patients threatened by prescription for nonapproved uses with the interest of patients who are not threatened and who may, in fact, be helped by the nonapproved use. Instead of completely prohibiting nonapproved uses, Mr. Kessler suggests, the FDA should be given authority to disapprove particular uses when the agency encounters widespread dangerous prescribing for nonapproved uses.

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Introduction

Improper human drug prescription by physicians poses a serious threat to the public health.[1] Prescriptions may be improper for a number of reasons: some because they call for a highly toxic agent when an equally effective yet safer drug exists; others, because they are issued without proper precautions against addiction; and still others, because the drug has not been demonstrated to be safe and effective for the purpose the physician intends.[2] Although such improper prescription has always endangered public health, the increasing awareness of the impact of iatrogenic diseases, combined with the added difficulty of establishing a relationship be-

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1 Adverse drug reactions are responsible for 1.0 to 3.5 percent of admissions to medical wards. F. KARCH & L. LASAGNA, ADVERSE DRUG REACTIONS IN THE UNITED STATES: AN ANALYSIS OF THE SCOPE OF THE PROBLEM AND RECOMMENDATIONS FOR FUTURE APPROACHES (Medicine in the Public Interest, 1974). *See* Seidl, Thornton, Smith & Cluff, *Studies on the Epidemiology of Adverse Drug Reactions, Reactions in Patients on a General Medical Service,* 119 BULL. JOHNS HOPKINS HOSPITAL 299 (1966); Caranasos, Stewart & Cluff, *Drug-Induced Illness Leading to Hospitalization,* 228 J.A.M.A. 713 (1974). Adverse drug reactions in hospitalized patients have been reported to occur in 5 to 35 percent of inpatients. Borda, Slone & Jick, *Assessment of Adverse Reactions within a Drug Surveillance Program,* 205 J.A.M.A. 99, 101 (1968). *See* ADVERSE DRUG REACTIONS: THEIR PREDICTION, DETECTION AND ASSESSMENT (D. Richards & R. Rowdel ed. 1972); ASSESSING DRUG REACTIONS — ADVERSE AND BENEFICIAL (7 PHILOSOPHY AND TECHNOLOGY OF DRUG ASSESSMENT) (F. Allan ed. 1976); Brodie, Drug Utilization and Drug Utilization Review and Control (HEW Publication No. 72-3002, 1971).

Of course, not all adverse drug reactions result from improper drug use. Even the proper use of a prescription drug involves some risk. Unforeseen and undesirable reactions may result from idiosyncracies of the patient. Or in other instances, adverse drug reactions may occur as the inescapable result of cancer chemotherapy and the treatment of other diseases. M. DIXON, DRUG PRODUCT LIABILITY § 6.10[5] (1977). "In such instances, the chance of drug induced disease is one of the risk-to-benefit decisions which a physician must make in planning any therapeutic strategy." M. SILVERMAN & P. LEE, PILLS, PROFIT, AND POLITICS 265 (1974).

2 *See* Nightingale, Dormer & DuPont, *Inappropriate Prescribing of Psychoactive Drugs,* 83 ANNALS INTERNAL MED. 896 (1975); Wade & Hood, *Prescribing of Drugs Reported to Cause Adverse Reactions,* 26 BRIT. J. PREVENTIVE & SOC. MED. 205 (1972); Maugh, *Irrational Drug Prescribing and Birth Defects,* 194 SCIENCE 926 (1976); Muller, *The Over-Medicated Society: Forces in the Marketplace for Medical Care,* 176 SCIENCE 488 (1972); Muller, *Medical Review of Prescribing,* 18 J. CHRONIC DISEASES 689 (1965); Miles, *Multiple Prescriptions and Drug Appropriateness,* 12 HEALTH SERVICES RESEARCH 3 (Spring 1977); M. SILVERMAN & P. LEE, *supra* note 1, at 282-304; H. DOWLING, MEDICINES FOR MAN 276-78 (1970).

tween a specific therapy and its long-term consequences,[3] makes the improper prescription all the more problematic.

It may appear that the prescription of a drug which has not been shown to be safe and effective for its intended use is prohibited by the Federal Food, Drug, and Cosmetic Act (FDCA),[4] which requires a showing of safety and effectiveness for the drug to be marketed. According to the FDCA, the Food and Drug Administration (FDA) must determine whether the drug is safe and effective for use under "the conditions prescribed, recommended, or suggested in the proposed labeling thereof."[5] However, a drug may have many potential uses, and approval of the drug for use under any one condition makes the drug physically accessible for any use. Thus, drugs are often prescribed for uses other than those proposed or recommended in the drug's labeling.[6]

The Comprehensive Drug Abuse Prevention Act of 1970 (Controlled Substances Act), like the FDCA, regulates dangerous human drugs. But the traditional view is that it does not deal with this problem.[7] The Controlled Substances

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3 Acute adverse effects of a drug are more easily detected by common toxicologic methods than are adverse effects that occur after a long delay. *See* D. SCHMAHL, C. THOMAS & R. AUER, IATROGENIC CARCINOGENESIS (1977); D. Clayson, *Carcinogenic Hazards due to Drugs* in EXCERPTA MEDICA, 4 DRUG INDUCED DISEASES 91-109 (1972); POTENTIAL CARCINOGENIC HAZARDS FROM DRUGS, 7 UICC MONOGRAPH SERIES (R. Truhaut ed. 1967).

4 21 U.S.C. §§ 301-392 (1970). The FDCA is administered by the Food and Drug Administration of the Department of Health, Education, and Welfare.

5 21 U.S.C. § 355(d) (1970).

6 *See generally* Committee on Drugs of the American Academy of Pediatrics, *Unapproved Uses of Approved Drugs: The Physician, the Package Insert and the FDA*, 62 PEDIATRICS 262 (1978); Peck, *FDA Approval: When Should Your Judgment Outweigh It?* CURRENT PRESCRIBING 26 (Dec. 1975).

The labeling of a prescription drug must, according to FDA regulations, contain: "adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented . . . ." 21 C.F.R. § 201.100(c)(1) (1977).

7 *See Competitive Problems in the Drug Industry: Hearings Before the Subcomm. On Monopoly of the Senate Select Comm. on Small Business*, 94th Cong., 2d Sess. 14,576 (1976) [hereinafter cited as *Hearings on Competitive Problems*].

In 1973, Congressional hearings probed for a solution to the problem of improper prescription:

Act[8] and its regulations make it unlawful for a physician to dispense a controlled substance[9] if his prescription is not for a legitimate medical purpose in the usual course of his practice.[10] A practitioner who dispenses controlled drugs without the intent of treating a medically diagnosed disorder

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> Senator Nelson: You are aware of the studies showing the widespread overuse and misuse of anti-infectives for nonindicated situations. It was found in one study that in only 12.9 [percent] of the cases were [sic] this category of drugs used rationally. In one hospital anti-infectives were administered prophylactically in 80 percent of the uncomplicated hernia operations. When you get to a drug of this kind that has a proven history of carcinogenicity why should you not at least require the reporting on it as you do with a narcotic, for example?
> Dr. Simmons [Director, Bureau of Drugs, FDA]: It would probably be almost as much a legal question as a medical question, Senator. We know the problems with this drug. They are increasingly well documented.
> Senator Nelson: You had to cut down the use of amphetamines, did you not?
> Dr. Simmons: Yes; but that is under the drug abuse amendment, and this kind of drug is not covered by that. That is a legal question, I suspect, more than medical. Those are drugs abused in another way.
> Senator Nelson: Well, they are used for nonindicated cases, right?
> Dr. Simmons: Right.
> Senator Nelson: Well, that is what this drug is being used for—
> Dr. Simmons: Yes. The drug abuse provisions are more addressed to narcotic and mind altering drugs, and I do not believe address this particular kind of compound.
> Dr. Edwards: [Commissioner, FDA]: I agree with you. I think drug abuse is drug abuse, by whatever name you want to call it. Although we have not thought about it along the lines you have just suggested, let me say that we are certainly open to any suggestions . . . .

Quality of Heath Care — Human Experimentation, Part I: Hearings before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare, 93d Cong., 1st Sess. 26-27 (1973) [hereinafter cited as *Quality of Health Care Hearings*].

8 21 U.S.C. §§ 801-966 (1970). The Controlled Substances Act is administered by the Drug Enforcement Administration of the Department of Justice.

9 The Controlled Substances Act classifies all narcotic and dangerous drugs into five schedules. Each schedule subjects the substances therein to different controls: Schedule I substances are subject to the most rigid controls, whereas schedule V substances are subject to only minimal controls. Substances are classified according to their potential for abuse and their present value in medical treatment. 21 U.S.C. § 812 (1970).

The Controlled Subtances Act gives the Attorney General authority to add or delete substances from any schedule on the basis of medical information supplied by the Secretary of Health, Education, and Welfare. 21 U.S.C. § 811 (1970). *See* Davis, *Drug Abuse Control: Prescribing Controlled Substance Drugs,* 6 CUM. L. REV. 331, 344 (1975); *see generally* Lewis & Lenck, *Medical Practice under the Law,* DRUG ENFORCEMENT 18 (Dec. 1977).

10 United States v. Bartee, 479 F.2d 484, 487 (10th Cir. 1973). 21 U.S.C. § 841(a)(1970) makes it unlawful for any person to knowingly or intentionally manufacture, distribute, or dispense a controlled substance except as authorized by

would clearly be violating the statute.[11] Short of such extreme conduct, it is unlikely that the well-intentioned physician who prescribes improperly would ever be prosecuted under the Controlled Substances Act.[12]

In the past few years, as congressional awareness of the

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its subchapter. 21 U.S.C. § 802(10) (1970) defines "dispense" as the delivery of "a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance...." 21 U.S.C. § 829(a)&(b) (1970) exempt from § 841 (a)(1) the dispensing of a drug by a written prescription of a practitioner. But abuse by a physician would almost certainly involve the use of the prescription pad. The question that must then be addressed is, When is a written prescription not a "prescription" as contemplated by the Controlled Substance Act? The regulations provide the answer by defining "prescription." 21 C.F.R. § 1306.04(a)(1977) provides: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice...." Thus, a prescription written by a physician for an illegitimate medical purpose would not be exempt from § 841(a)(1).

11 A prescription written by a physician for a non-medical reason is prohibited, and may subject the physician to prosecution under 21 U.S.C. § 841 (1970). United States v. Moore, 423 U.S. 122 (1975), illustrates the activities of an unscrupulous physician whose motives for prescribing are solely profit-oriented. Between September 1, 1971, and February 11, 1972, Dr. Moore prescribed 11,169 prescriptions for a total of 800,000 methadone tablets. The physician employed a "sliding fee schedule," charging patients in accordance with the quantity of pills prescribed — from $15.00 for 50 tablets to $50.00 for 150 tablets. He made no effort to make certain that the patients were in fact heroin addicts. Some patients in turn delivered their methadone to non-patients. Brief for the United States at 6-7, United States v. Moore. *See also* United States v. Larson, 507 F.2d 385 (9th Cir. 1974); United States v. Leigh, 487 F.2d 206 (5th Cir. 1973); United States v. Bartee, 479 F.2d 484 (10th Cir. 1973); United States v. Badia, 490 F.2d 296 (1st Cir. 1973); United States v. Jobe, 487 F.2d 268 (10th Cir. 1973), *cert. denied*, 416 U.S. 955 (1974); United States v. Collier, 478 F.2d 268 (5th Cir. 1973).

The Controlled Substances Act contains two different penalty provisions: 21 U.S.C. § 841 provides for sentences of up to 15 years and fines of up to $25,000, while 21 U.S.C. §§ 842-843, which deals primarily with those who have registered with the Drug Enforcement Administration, provides for more modest penalties. The courts have held that 21 U.S.C. § 841 is applicable to registered physicians who have prescribed for illegitimate medical purposes. *See* United States v. Moore, 423 U.S. 122 (1975). *See generally* Davis, *supra* note 9, at 348.

12 It is unclear what constitutes knowledge or intent that a prescription does not have a legitimate medical purpose. In the majority of cases where a drug is prescribed improperly, the physician believes the prescription to be in the best interests of the patient. *See* R. STEWART, L. CLUFF & J. PHILP, DRUG MONITORING: A REQUIREMENT FOR RESPONSIBLE DRUG USE 18 (1977). Indeed, in United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975), the Ninth Circuit took the position that violation of the Act required that the physician be unable to have a "good faith" belief that he or she was acting for legitimate medical purposes. *Id.* at 197. *See* Annot., 33 A.L.R. Fed. 220 (1977).

The problem is compounded because no guidelines define "legitimate medical purpose." If such guidelines did exist, the physician would at least have clear notice

problem of prescription for improper use has increased, there has been a call for the FDA to respond to the problem. The FDA has traditionally viewed the FDCA as establishing a preclearance procedure for human drugs which limited the agency's role to insuring that sufficient data existed to conclude that a drug was safe and effective under the conditions proposed by the manufacturer. The agency's position was that the physician was free "to prescribe the drug as he saw fit."[13] In 1971 a congressional subcommittee chided the FDA

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that such conduct was improper. However, many believe that the Drug Enforcement Administration (formerly the Bureau of Narcotics and Dangerous Drugs) should not set standards of medical practice. It is argued that such determinations should be made by qualified medical personnel rather than by law enforcement officials. Comment, *Control of Amphetamine Prescription and Production: Critical Analysis of Federal, State and Local Efforts to Control Amphetamine Abuse*, 8 COLUM. J. LAW & SOC. PROB. 426 (1972). Determining when prescribing is improper would certainly require setting standards. Without such standards it is inconceivable that such improper conduct could be prohibited.

Finally, a major obstacle is resource constraints. The Drug Enforcement Administration has given highest priority to prosecuting high-level traffickers of all illicit drugs. STRATEGY COUNCIL ON DRUG ABUSE, FEDERAL STRATEGY FOR DRUG ABUSE AND DRUG TRAFFIC PREVENTION 22 (1976). The case of a physician who sells drugs to non-bona fide patients should certainly be given such priority, but it is doubtful that subtler misconduct will be given such attention. *See generally* Davis, *supra* note 9, at 348.

However, rescheduling a drug to a more restrictive category would be an aid in curbing abuse under the Act. *See, e.g.,* WASH. DRUG & DEVICE LETTER 7 (July 3, 1978).

13 H.L. Ley (former FDA Commissioner), "The Citizen, Chemicals, and Controls," a talk given at Harvard Medical School Alumni Day, June 4, 1971, at Boston, Mass., *reproduced in New Drugs for Nonapproved Purposes (Methotrexate for Psoriasis): Hearings Before a Subcomm. of the House Comm. on Government Operations*, 92d Cong., 1st Sess. 131, 133 (1971) [hereinafter cited as *New Drugs for Nonapproved Purposes*]. The FDA was not oblivious to the occurrence of improper prescribing. It was concerned about such improper use but was under great pressure from the American Medical Association not to tell the doctor what he or she could prescribe.

The FDA chose to deal with the problem as an educational matter. *Id.* Enforcement was to be left to state medical societies, and redress could ultimately be sought in civil malpractice suits. *Quality of Health Care Hearings, supra* note 7, at 20. However, as the Chloramphenicol case indicates, *see* notes 24 to 27 and accompanying text *infra*, warnings issued by the FDA have proven ineffective. It is argued that one reason why such warnings are ineffective is that manufacturers can overcome the effects of cautionary warnings by promotional advertising:

> In short, the physician is bombarded with seductive advertising. . . .The doctor is daily overwhelmed with more material than he can possibly read, to say nothing of remembering the vaguely worded warnings, if indeed there is any warning in small print at the back of an advertising brochure. Even where warning is given in an initial brochure, it is frequently followed

for being "grossly remiss in not formulating and enunciating a firm but reasonable policy" regarding the use of new drugs for nonapproved purposes.[14] One year later the FDA shifted its position and proposed such a policy in a proposed regulation (1972 Proposed Regulation), citing several courses of action available to the agency.[15]

This article analyzes the degree to which the FDCA prohibits or should prohibit nonapproved uses of human drugs. The article will illustrate the dilemma faced by the FDA: congressional pressure and a concern for public health require

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by a string of literature which establishes the claimed virtues of the drug so glowingly as to draw all attention away from any hazards in use of the drug.

108 CONG. REC. 19,925 (1962) (statement of Dr. Leona Baumgartner, Commissioner of the New York City Department of Health). *See* Merrill, *Compensating Drug Injuries*, 95 Va. L. Rev. 1, 23-28 (1973); Teeling-Smith, *Advertising and the Pattern of Prescribing*, 61 Proc. Royal Soc. Med. 748 (1968); Garai, *Advertising and Promotion of Drugs*, in DRUGS IN OUR SOCIETY (P. Talalay ed. 1964); Ingelfinger, *Advertising: Informative but Not Educational*, 286 NEW ENG. J. MED. 1318 (1972).

Other factors which have been reported to be influential in the improper prescription habits of physicians include the lack of proper emphasis on clinical pharmacology in the medical curriculum, U.S. DEP'T OF HEALTH, EDUCATION, AND WELFARE, TASK FORCE ON PRESCRIPTION DRUGS, FINAL REPORT 3 (1969) [hereinafter cited as PRESCRIPTION TASK FORCE]; the patient's demand for drugs, Nightingale, Dormer & DuPont, *Inappropriate Prescribing of Psychoactive Drugs*, 83 ANNALS INTERNAL MED. 896 (1975); the physician's public image, Marinker, *The Doctor's Role in Prescribing*, 23 J. ROYAL C. GENERAL PRAC. 26 (1973) ("the doctor may attempt to remain on the pedestal on which his patients have placed him with a lavish supply of prescriptions"); the lack of time that can be allocated to each patient, Muller, *The Overmedicated Society: Forces in the Market Place for Medical Care*, 176 SCIENCE 490 (1972) ("prescribing is, theoretically at least, a means of terminating the interview in a fashion that satisfies both doctor and patient"); and the physician's personal characteristics, Stolley, Becker, Lasagna, McEvilla & Sloane, *The Relationship Between Physician Characteristics and Prescribing Appropriateness*, 10 MED. CARE 17 (1972). *See* Hermmink, *Review of Literature on the Factors Affecting Drug Prescribing*, 9 SOC. SCI. & MED. 111 (1975).

Habit, however, is probably the most important factor in the physician's disregard of warnings. The executive director of the Academy of Internal Medicine told a Senate subcommittee, "I do not pay much heed to all this scientific testing, this measurement of blood levels, this testing in animals. I am accustomed to certain brands and I have good luck with them. The final test is the patient himself. If I want to know if a drug is any good or not, I ask my patients." *Hearings Before the Senate Subcomm. on Competitive Problems in the Drug Industry*, 91st Cong., 1st Sess. 5017 (1969), *cited in* J. GIBSON, MEDICATION LAW AND BEHAVIOR 141-42 (1976).

14 *New Drugs for Nonapproved Purposes, supra* note 13, at 104-05.

15 37 Fed. Reg. 16,503 (1972). The proposed rule has yet to result in final regulations. The Commissioner, in a different Federal Register document issued on April 7, 1975, stated that the 1972 proposed regulation will become a final order in the near future. 40 Fed. Reg. 15,392, 15,394 (1975).

the FDA to respond to the problem of nonapproved uses, but the agency's only statutory basis for action does not give it the authority necessary to resolve the problem.

After exploring the nature of improper uses, this article will analyze three approaches, based on various sections of the FDCA, which have been or could be invoked to prohibit the physician from prescribing improperly: limiting prescription to approved indications[16] through the new drug provisions (section 505);[17] controlling access to the drug through the withdrawal and safety subsections of the new drug provisions (sections 505(d) and (e));[18] and threatening allegations of false or misleading labeling through the misbranding provisions (section 502).[19] Because these provisions provide at best awkward bases for assuring the public's safety, this article concludes by offering a proposal for an additional remedy to the problem.

I. IMPROPER AND NONAPPROVED USES

Since 1950, the number of drugs prescribed per person has more than doubled.[20] This increase in drug use has not, however, produced a substantially healthier populace.[21] This discrepancy between benefit and use, coupled with the fact that all drugs present some risk in their use, suggests the possibility that many drugs are being improperly prescribed.[22]

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16 "Indication" here means the specific use of a drug in the treatment, prevention, or diagnosis of a disease.

17 21 U.S.C. § 355 (1970).

18 *Id.* § 355(d) & (e).

19 *Id.* § 352.

20 Waldron, *Increased Prescribing of Valium, Librium, and Other Drugs: An Example of the Influence of Economics and Social Factors on the Practice of Medicine,* 7 INT. J. HEALTH SERVICES 37 (1977). On the average, the American physician writes 8000 prescriptions each year, four times as many drugs as comparative Scottish physicians. Lawson & Jick, *Drug Prescribing in Hospitals: An International Comparison,* 66 AM. J. PUB. HEALTH 644-48 (1976), *cited in* BOCHNER, HANDBOOK OF CLINICAL PHARMACOLOGY 2 (1978).

21 Lawson & Jick, *supra* note 20.

22 For an analysis of the difficulty of determining, because of scientific uncertainty, what constitutes improper drug use, *see* Avery & Chernick, *On Decision Making Surrounding Drug Therapy: A Continuing Dilemma,* 296 NEW ENG. J. MED. 102 (1977).

In its report in 1968, the Department of Health, Education, and Welfare (HEW) Task Force on Prescription Drugs categorized improper prescription as follows:

> (1) Use of drugs without demonstrated efficacy.
> (2) Use of drugs with an inherent hazard not justified by the seriousness of the illness.
> (3) Use of drugs in excessive amounts, or for extended periods of time, or inadequate amounts for inadequate periods.
> (4) Use of a costly duplicative or "me-too" product when an equally effective or less expensive drug is available.
> (5) Use of a costly combination product when equally effective but less expensive drugs are available individually.
> (6) Simultaneous use of two or more drugs without appropriate consideration of their possible interaction.
> (7) Multiple prescribing, by one or several physicians for the same patient, of drugs which may be unnecessary, cumulative, interacting, or needlessly expensive.[23]

Examples of improperly prescribed drugs are numerous. Chloramphenicol, a broad-spectrum antibiotic, is certainly the most infamous of the improperly prescribed drugs. The drug was first marketed in 1949. In 1952, medical researchers associated the use of the drug with the development of aplastic anemia.[24] Following this discovery the American Medical Association (AMA) issued a warning of the hazard of aplastic anemia with chloramphenicol use.[25] The FDA made countless efforts to direct attention to the fact that, in light of this newly discovered risk, use of chloramphenicol should be almost entirely confined to severe infections in the hospitalized patient.[26] Despite such efforts, studies during the

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23 PRESCRIPTION TASK FORCE, *supra* note 13. For an additional classification of improper drug prescription, *see* A Report by a Working Party 1975, Council of Europe, European Public Health Community, *Abuses of Medicines, Part II, Prescription Medicines,* 10 DRUG INTELLIGENCE & CLINICAL PHARMACY 94 (1976).

24 *See* Similey, Cartwright & Wintrobe, *Fatal Aplastic Anemia Following Chloramphenicol (Chloromycetin) Administration,* 149 J.A.M.A. 914 (1952).

25 Editorials and Comments, *Blood Dyscrasia Following the Use of Chloramphenicol,* 149 J.A.M.A. 840 (1952).

26 *See* Merrill, *supra* note 13, at 26.

27 Ray, Federspiel & Schaffner, *Prescribing of Chloramphenicol in Ambulatory Practice,* 84 ANNALS INTERNAL MED. 266 (1976); Stolley, Becker, McEvilla, Lasagna,

last decade demonstrate that the drug continues to be used in a wide range of cases.[27]

Other broad-spectrum antibiotics are also misused as "shotgun weapons" against infections of undetermined cause. Ampicillin, for example, is often used in hospitals to treat surgical wound infections, despite the fact that most of the organisms likely to cause such infections are usually resistant to the drug.[28] The excessive use of broad-spectrum antibiotics can result in the emergence and overgrowth of resistant strains.[29] In addition, the use of antibacterial drugs may result in the development of other bacterial infections when administered to patients with viral infections. Finally, improper use may prevent or interfere with proper diagnosis and consequently prolong the patient's illness.[30]

Propoxyphene (Darvon), an analgesic, is one of the most frequently prescribed drugs in the United States.[31] One risk with the use of propoxyphene is its potential for addiction.[32] Accepting this risk would be justified if propoxyphene were decidedly superior in effectiveness when compared with alternative, less risky drugs. Yet several controlled studies have found the contrary proposition to be true: the drug is no more effective than aspirin or codeine and may in fact be inferior to such products.[33] Propoxyphene's use, rather than the use of other equally effective but nonaddicting drugs, can only be considered highly questionable.

Amphetamines were introduced into clinical medicine as inhalants to reduce nasal congestion and as a treatment for nar-

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Gainor & Sloane, *Drug Prescribing and Use in an American Community*, 76 ANNALS INTERNAL MED. 537 (1972); Meade, *Prescribing of Chloramphenicol in General Practice*, 1 BRITISH MED. J. 671 (1967).

28 16 THE MEDICAL LETTER 93 (1974).

29 6 THE MEDICAL LETTER 85 (1964).

30 *See* G. YOUMANS, P. PATERSON & H. SOMMERS, THE BIOLOGIC AND CLINICAL BASIS OF INFECTIOUS DISEASES 773 (1975).

31 *See* Maronde, *A Study of Prescribing Patterns*, 9 MED. CARE 383 (1971).

32 14 THE MEDICAL LETTER 37, 38 (1972); 12 THE MEDICAL LETTER 5 (1970).

33 Beaver, *Therapeutics—Mild Analgesics, A Review of Their Clinical Pharmacology, Part II*, 251 AM. J. MED. SCI. 576 (1966); Miller, Feingold & Paximos, *Propoxyphene Hydrochloride: A Critical Review*, 213 J.A.M.A. 996 (1970); Moertel, Ahmann, Taylor & Schwartau, *A Comparative Evaluation of Marketed Analgesic Drugs*, 286 NEW ENG. J. MED. 813 (1972); 12 THE MEDICAL LETTER 5 (1970).

colepsy.[34] They were subsequently used as an antidote to fatigue, and in the treatment of depression and obesity.[35] The major disadvantage in the use of amphetamines lies in their addictive property, which was first reported in 1938. Though such a risk would suggest limited usage, these drugs are still widely prescribed by physicians, often without adequate diagnoses, proper testing, or appropriate precautionary measures.[36]

Combinations of estrogens and progestagens, hormones that are used in birth control pills, are also widely prescribed for pregnancy testing, for the prevention of miscarriages, and for other complications of pregnancy. These hormones continue to be used despite evidence of a relation between these agents and birth defects.[37] Despite FDA warnings in 1973 and 1974, during the latter year, physicians wrote 553,000 prescriptions for use of the hormones during pregnancy, only 10 percent less than the number written in 1972.[38]

Elderly patients are particularly susceptible to iatrogenic diseases from improperly prescribed drugs. In fact, four specific syndromes resulting from the inappropriate prescription of drugs in a geriatric unit have been identified: pseudomentia, the iatrogenic confusional state, the medical

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34 *See* Prinzmetal & Bloomberg, *The Use of Benzedrine for the Treatment of Narcolepsy,* 105 J.A.M.A. 2051 (1935).

35 *See* Wade & Wood, *supra* note 2, at 206.

36 *See* Wand, *The Effects of Toxic Doses of Benzylmethyl Carginamine (Benzedrine) in Man,* 110 J.A.M.A. 206 (1938); L. GRINSPOON & P. HEDBLOOM, THE SPEED CULTURE: AMPHETAMINE USE AND ABUSE IN AMERICA 271 (1975). *See also Hearings on Competitive Problems, supra* note 7; Parry, Balter & Mellinger, *National Patterns of Psychotherapeutic Drug Use,* 28 ARCHIVES GENERAL PSYCH. 759 (1971); Parish, *The Family Doctor's Role in Psychotropic Drug Use,* and *Wolfe, The Social Responsibility of the Physician in Prescribing Mind-Affecting Drugs,* in SOCIAL ASPECTS OF MEDICAL USE OF PSYCHOACTIVE DRUGS (R. Cooperstock ed. 1974); *Bensiodiazepines: Use, Overuse, Misuse, Abuse?* 1 LANCET 1101 (1973). An interesting attempt at regulating misuse of amphetamines was taken by the State of Wisconsin, which instituted a ban on the prescription of amphetamines except in certain situations. WASH. DRUG AND DEVICE LETTER 7 (Nov. 7, 1977).

37 *See* J. Nora & A. Nora, *Birth Defects and Oral Contraceptives,* 1 LANCET 941 (1973); J. Nora & A. Nora, *Can the Pill Cause Birth Defects?* 291 NEW ENG. J. MED. 731 (1974). *But see* Rothman & Louik, *Oral Contraceptives and Birth Defects,* 299 NEW ENG. J. MED. 522 (1978).

38 *See* Maugh, *supra* note 2.

madness syndrome, and the institutionalized person syndrome.[39]

The above examples are a fair illustration of the drug prescription problem with which the FDA must deal. One method suggested by the FDA to control improper prescription is to limit physicians to prescribing only for approved uses, or conversely, to forbid the prescription of drugs for nonapproved uses. The value of this proposal turns on the assumption that every nonapproved use is an improper use. While further sections of this article will develop the significance of the above proposition and demonstrate its invalidity, it is appropriate here to lay the groundwork by defining nonapproved uses and presenting some examples. Obviously the illustrations will foreshadow the ultimate conclusion: every nonapproved use is *not* an improper use.

Essentially, a nonapproved use is a use of a drug which fails to conform to the drug's labeling.[40] The failure may arise

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39 *See* Rudd, *Prescribing Methods and Iatrogenic Situations in Old Age,* 14 GERONTOLOGICA CLINICA 123, 125 (1972).

40 For the present required labeling of a prescription drug, *see* note 6 *supra.* The FDA has proposed regulations that would revise the current labeling requirements by "providing standards with regard to the kind of information that must be included under each of the specific section headings, by eliminating extraneous information which can best be obtained from the published literature, by providing explicit information on indications of use, and by replacing generalities with specifics." 40 Fed. Reg. 15,392 (1975). Under the proposed regulations, the label would contain information under the following section headings: Description, Clinical Pharmacology, Indications and Usage, Contraindications, Warnings, Precautions, Adverse Reactions, Overdosage, Dosage and Administration, and How Supplied. 40 Fed. Reg. 15,396 (1975). The section on Indications and Usage would require in part that the label state explicitly:

> (a) That the drug is indicated in the treatment, prevention, or diagnosis of a recognized disease or condition, *e.g.*, penicillin is indicated for the treatment of pneumococcal pneumonia; or
>
> (b) That the drug is indicated for the treatment, prevention, or diagnosis of an important manifestation of a disease or condition, *e.g.*, chlorothiazide is indicated for the treatment of edema in patients with congestive heart failure; or
>
> (c) That the drug is indicated for relief of symptoms associated with a disease or syndrome, *e.g.*, chlorpheniramine is indicated for the symptomatic relief of nasal congestion in patients with vasomotor rhinitis. If the drug is used for a particular indication only in conjunction with a primary mode of therapy, *e.g.*, diet, surgery, or some other drug, the drug shall be labeled as an adjunct to such mode of therapy. All such indications shall be supported by substantial evidence based on adequate and well-controlled studies as defined in § 314.111(a)(5)(ii) of this chapter.

40 Fed. Reg. 15,396 (1975). The section on Warnings would require, in part, that "A

in a number of ways. One example is the use of a drug for indications not specifically mentioned on the label. One drug often so prescribed is Depo-Provera, whose use as a contraceptive is not mentioned on the label and is contrary to sound medical judgment. Depo-Provera is a progesterone derivative that was approved for marketing in 1960 for use in endometriosis.[41] In 1963, its safety and efficacy as a contraceptive were investigated,[42] and serious questions concerning the drug's safety emerged.[43] Despite the fact that those questions remain unanswered,[44] the drug remains on the market[45] because it has been found safe and effective for other uses. An estimated 10,000 women received the drug in 1976 for use as a contraceptive.[46]

One drug prescribed for indications not specifically mentioned on the label, but whose prescription was consistent

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specific warning relating to a use not provided for under the 'Indications and Usage' section of the labeling may be required if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard." *Id.*

41 Later, in 1972, Depo-Provera was also approved and marketed for metastatic endometrical carcinoma. *Quality of Health Care Hearings, supra* note 7, at 20. *See* S. CARTER, M. BAKOWSKI & K. HELLMANN, CHEMOTHERAPY OF CANCER 158 (1977).

42 *Quality of Health Care Hearings, supra* note 7, at 102-03.

43 The drug was found to cause prolonged and possibly permanent infertililty. When administered to beagles at dosage levels comparable to the human dosage, benign tumors developed. At 25 times this dosage both benign and malignant tumors developed. No tumors were found in experimental rats, rabbits, mice, or monkeys who received the drug. 38 Fed. Reg. 27,940 (1973).

44 The package insert stated, "The use of Depo-Provera (medroxy-progesterone acetate) for contraception is investigational since there are unresolved questions relating to its safety for this indication. Therefore, this is not an approved indication." PHYSICIAN'S DESK REFERENCE 1697 (1978).

45 *Quality of Health Care Hearings, supra* note 7, at 21. In September 1974, the FDA announced approval of Depo-Provera as an injectable contraceptive for those patients for whom other means of contraception are not possible. However, the FDA required both a brief patient leaflet and a more detailed brochure explaining the drug's risks. 39 Fed. Reg. 32,907 (1974). The approval was stayed in October 1974, because of congressional pressure. 39 Fed. Reg. 38,226-27 (1974). On March 7, 1978, the FDA informed the Upjohn Corporation that approval of Depo-Provera for contraception had been denied. 8 FDA DRUG BULL. (No. 2) 10 (1978); *see* S. Wolfe & A. Johnson, Depo-Provera—A Contraceptive for Poor Women (comment filed with HEW, Dec. 16, 1976) (Public Citizen Health Research Group).

46 WASH. DRUG & DEVICE LETTER 2 (Jan. 3, 1977). Depo-Provera has the advantage of needing to be administered only once every 90 days. It has been approved and used in 38 countries. *Quality of Health Care Hearings, supra* note 7, at 102-03.

with sound medical judgment, is propranolol, the first beta-adrenergic receptor-blocking agent to be introduced into clinical practice. Introduced in November 1967, it was indicated for use in cardiac arrhythmias and idiopathic hypertrophic subaortic stenosis.[47] One study, however, revealed that propranolol was widely used for a variety of indications not contained in the drug's labeling. Of the patients receiving the drug, 52.9 percent received it for angina pectoris and 7.8 percent for hypertension, even though neither indication had been approved at the time of the study. The study also cited a review of propranolol by the AMA Department of Drugs which listed the first two therapeutic indications for propranolol as angina pectoris and hypertension but made no mention that these indications were not approved by the FDA.[48] Subsequently, propranolol was approved by the FDA for use in angina pectoris in September 1973, and for hypertension in June 1976.[49]

Diethylstilbestrol (DES) is another drug whose nonapproved use was contraception. *Id.* at 24. DES was established to be effective as a post-coital contraceptive. *Id.*; Morris & Wagenen, *Compounds Interfering with Ovum Implantation and Development*, 96 AM. J. OB. & GYN. 804, 804-05 (1966). But in 1971, Herbst reported seven cases of vaginal adenocarcinoma in daughters of women who had taken DES to prevent miscarriage during pregnancy. Herbst, Ulfelder & Poskanzer, *Adenocarcinoma of the Vagina: Association of Maternal Stilbestrol Therapy with Tumor Appearance in Young Women*, 284 NEW ENG. J. MED. 878 (1971). Over 60 additional cases have been reported. Heinonen, *Diethylstilbestrol in Pregnancy: Frequency of Exposure and Usage Patterns*, 31 CANCER 573 (1973). The indiscriminate use of DES, especially by various university health services, was documented in a report of the Health Research Group. Health Research Group Report on the Morning After Pill, December 8, 1972, *reprinted in Quality of Health Care Hearings, supra* note 7, at 201. Subsequently, the drug was approved for emergency use only as in case of rape, and not as a routine method of birth control. Kuchera, *Postcoital Contraception with Diethylstilbestrol*, 218 J.A.M.A. 562, 562 (1971). The FDA required that adequate information be given each patient. 21 C.F.R. § 210.501 (1977).

47 PHYSICIAN'S DESK REFERENCE 570 (1973); *New Drugs for Nonapproved Uses, supra* note 13, at 19.

48 Mardy, Fleckenstein, Mazzullo, Sundaresan, Weintraub & Lasagna, *Current Medical Practice and the Food and Drug Administration*, 229 J.A.M.A. 1744 (1974) [hereinafter cited as *Current Medical Practice*].

49 Telephone interview with Henry Perdue, Department of Regulatory Affairs, Ayerst Pharmaceuticals, (Nov. 16, 1977).

Methotrexate provides another example of a drug with a nonapproved but proper use. Methotrexate is a folic acid antagonist indicated on the drug label for use in the treatment of uterine choriocarcinoma and for the palliation of acute and subacute leukemias. A 1971 congressional hearing documented the use of methotrexate for psoriasis. *New Drugs for Nonapproved Purposes, supra* note 13. The FDA has

A second illustration of a use which fails to conform to the drug's labeling is the use of a drug without regard to the special precautions listed on the label.[50] The failure to isolate

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subsequently approved methotrexate for use in "severe, recalcitrant, disabling psoriasis which is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation." PHYSICIAN'S DESK REFERENCE 835 (1973).

At the hearings the Deputy Commissioner of the FDA also cited the following examples of drugs that were used for nonapproved indications: Xylocaine (lidocaine hydrochloride) — approved as a local anesthetic but used in the treatment of cardiac arrhythmias for 6 years prior to FDA approval of this indication; Valium (diazepam) — an anti-anxiety agent widely used for status epilepticus, although for 2 years the labeling of this drug did not contain this indication; Methadone hydrochloride — marketed since 1947 as an antitussive and analegsic but used, beginning in the early 1960's, in the long-term maintenance treatment of heroin addicts. At the time of the hearings 250 IND's were active for this indication and the manufacturer had submited an NDA. *New Drugs for Nonapproved Purposes, supra* note 13, at 19.

50 The FDA-proposed format for drug labels, *see* note 40 *supra*, would require the section Indications and Usage to include "[a]ny specific tests [*e.g.*, microbe susceptibility tests] needed for selection or monitoring of the patients who need the drug...." Four other sections of the proposed format contain information that must be taken into account before prescribing:

(1) Contraindications:

[T]hose situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. Such situations include: Administration of the drug to patients known to have a hypersensitivity to it; use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by it....

(2) Warnings:

Under this section heading, the labeling shall state serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps which should be taken if they occur. A warning shall be included in labeling as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved....

(3) Precautions:

Under this section heading, the labeling shall contain the following subsections as appropriate for the drug product:

(i) General: Under this subsection of the labeling shall be listed any special care to be exercised by the practitioner for safe and effective use of the drug, e.g., precautions concerning drug abuse or use of other drugs that may be harmfully additive.

(ii) Information for the patient: Under this subsection of the labeling, information to be given to patients for safe and effective use of the drug shall be included, e.g., precautions concerning driving or use of drugs that may be harmfully additive. Any printed patient information shall be referenced under the "Precautions" section of the labeling and, when appropriate, reprinted at the end of the package insert.

(iii) Essential laboratory tests: Under this subsection of the labeling shall be listed laboratory tests which are needed to follow the patient's response or to identify possible adverse reactions.

the specific strain of an infectious agent and to determine its antibiotic sensitivity may, for example, be contrary to the instructions in the labeling.[51]

A third instance arises when a drug is administered in a different dosage or by a different route from that suggested on the label.[52] It is common for medical texts to recommend a different dosage from the one cited on the label.[53]

II. REGULATING USES THROUGH THE NEW DRUG PROVISIONS

Regulating the uses for which drugs are prescribed is far different from regulating the availability of new drugs. The regulation of uses would broaden the reach of the FDA and

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(iv) Clinically significant drug interactions: . . . .
(v) [Test results regarding carcinogenicity, mutogenicity, and impairment of fertility].
(vi) [Use of the drug in pregnancy].
(vii) [Use of the drug in labor and delivery].
(viii) [Use of the drug in nursing mothers].
(ix) [Use in pediatrics].
(4) Adverse reaction:
An adverse reaction is an undesirable effect reasonably associated with the use of the drug, which may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence.

40 Fed. Reg. 15,392, 15,397-98 (1975). *See* E. MARTIN, HAZARDS OF MEDICATION 4 (1971); J. GIBSON, MEDICATION LAW AND BEHAVIOR 166-74 (1976); M. DIXON, DRUG PRODUCT LIABILITY § 6.10[4] (1977).

51 A survey of 169 hospital patients receiving cephalexin, an antibiotic, revealed that in 65.9 percent of the cases cephalexin was used prophylactically in the absence of any infection and that in 48.6 percent of the cases it was used without prior bacteriologic cultures. The drug was administered after a bacteriologic culture only 21.7 percent of the time. *Current Medical Practice, supra* note 48, at 1745, 1747. The label of the drug stated that "Note—Culture and susceptibility tests should be initiated prior to and during therapy." PHYSICIAN'S DESK REFERENCE 891 (1973).

52 The proposed FDA format for drug labels, *see* notes 40 & 50 *supra*, would require the section Dosage and Administration to

> [s]tate the recommended usual dose, the usual dosage range, and, where appropriate, an upper limit beyond which the drug should not be prescribed; dosages shall be stated for each indication when appropriate. The section shall include the intervals recommended between doses, the optimal method of titrating dosage, the usual duration of treatment, and any modification of dosage needed in special patient populations, e.g., in children, in geriatric age groups, or in patients with renal or hepatic disease.

40 Fed. Reg. 15,392, 15,397-98 (1975).

53 In its guidelines for antimicrobial drug dosage, the MANUAL OF ACUTE BACTERIAL INFECTIONS recommends an upper limit that exceeds the dose cited in the

would have an added effect on the clinical decisions reached by patient and physician. Under such an expanded role, the FDA would regulate not only 127 drug manufacturers,[54] but also 375,000 physicians.[55]

The 1972 Proposed Regulation attempted to delineate the agency's policy regarding the regulation of uses. But the failure of the agency, after six years, to adopt the regulation indicates that it recognizes that a rethinking of the issue is in order.

This section will attempt such a rethinking by examining the elements of authority, practicality, and public policy involved in such regulation. After reviewing the New Drug Provisions of the FDCA, this section will analyze the extent of the FDA's statutory authority, and it will view the 1972 Proposal as a statement of what the FDA believes it can administratively accomplish. This section will conclude by elaborating the problems which follow from an extension of the FDA's authority to regulate uses. Such an analysis reveals the inappropriateness, as a matter of public policy, of regulating uses through the New Drug Provisions.

A. *New Drug Provisions: The Approval Process*

To insure that every drug is proven safe and effective prior to its availability in the marketplace, section 505 of the FDCA establishes a framework for the preclearance of "new drugs."[56] That section begins by prohibiting, in subsection (a), the introduction or delivery for introduction into interstate commerce of "any new drug, unless an approval of

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drug's label for five different drugs. It also states that for meningitis some consultants give gentamicin intrathecally in single daily doses of up to 8 mg. for adults. P. GARDNER & H. PROVINE, MANUAL OF ACUTE BACTERIAL INFECTIONS 240-43 (1975). The drug's label indicates an upper limit of 5 mg. in life threatening infections. PHYSICIAN'S DESK REFERENCE 1257 (1973). *See* G. MCCRACKEN, JR. & J. NELSON, ANTI-MICROBIAL THERAPY FOR NEWBORNS 35 (1977).

54 One hundred twenty-seven pharmaceutical companies are members of the Pharmaceutical Manufacturers Association (PMA) and account for most of the total domestic sales of prescription drugs. PMA, Annual Survey Report, Ethical Pharmaceutical Industry Operations 1976-1977, at ii.

55 L. GOODMAN, PHYSICIAN DISTRIBUTION AND MEDICAL LICENSURE IN THE U.S., 1976, at 11 (1976).

56 "New drug" is defined in 21 U.S.C. § 321(p) (1970):

For the purposes of this chapter—

an application filed pursuant to subsection (b) is effective with respect to such drug." A violation of section 505(a) is a prohibited act within the terms of the enforcement provisions of the FDCA.[57] Accordingly, the government may enjoin an act in violation of section 505(a),[58] seek criminal sanctions,[59] seize the offending drug,[60] or withdraw its approval of the drug if approval had been previously granted.[61]

For a manufacturer to market a new drug interstate and avoid FDCA sanctions, a New Drug Application (NDA) must have been approved by the FDA.[62] To be approved the NDA must include "adequate tests by all methods reasonably applicable" showing that the drug "is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling."[63] The NDA must also include "substantial

> . . . The term "new drug" means—
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> (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or
>
> (2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

See also, 21 C.F.R. § 310.3(h) (1977). "Old drugs," drugs that are generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in the labeling, could become (or be reclassified as) "new drugs" in a number of ways: by changing an active or inactive ingredient of an old drug, by using a new combination of old drugs, by altering the proportions of ingredients of an old combination, by using an old drug to treat a different disease, or by changing the duration or dosage of administration. C. DEMARCO, PHARMACY AND THE LAW 106 (1975).

57 21 U.S.C. § 331(d) (1970).

58 *Id.* § 223(a).

59 *Id.* § 222(a).

60 *Id.* § 334.

61 *Id.* § 355(e).

62 To make an NDA effective, the Drug Amendments of 1962, § 104(b), require a positive act of approval instead of permitting the automatic approval of an NDA not disapproved. Note, *Drug Efficacy and the 1962 Drug Amendments*, 60 GEO. L. J. 185, 192 (1965) [hereinafter cited as *Drug Efficacy*].

63 21 U.S.C. § 355(d)(1)&(2) (1970). A complete listing of the information required as part of an NDA is found in 21 U.S.C. § 355(b) (1970), which states:

evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling."[64] "Substantial evidence," the level of proof for effectiveness, is defined in section 505(d) as

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.[65]

Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use, and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used for the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

64 21 U.S.C. § 355(d)(5) (1970). The Secretary is also required to deny an NDA if: the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; . . . upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe under such conditions; or . . . based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application.

Id. § 355(d)(3),(4)&(6). Because the NDA contains all the raw data from the preclinical and clinical trials necessary to demonstrate the drug's efficacy and safety, it is often quite lengthy. The NDA for ketamine was 72,200 pages, while the one for norlestrin was 12,370 pages. Lasagna, *Research Regulation, and Development of New Pharmaceuticals: Past, Present and Future, Part I*, 263 AM. J. MED. SCI. 16 (1972). Because of the enormous amount of raw data, the FDA's review relies on the sponsor's summary of the raw data included in the NDA, with random selection and review of some of the raw data. Review Panel on New Drug Regulation, Interim Reports, Vol. II, FDA's Review of Initial IND Submissions: A Study of the Process for Resolving Internal Differences and an Evaluation of Scientific Judgments (May 31, 1977) C40 [hereinafter cited as FDA's Review of Initial IND Submissions]. *See* Crout, *In Praise of the Lowly Package Insert*, 29 FOOD DRUG COSM. L.J. 139 (1974).

65 21 U.S.C. § 355(d) (1970.)

In addition to evidence concerning the drug's safety and efficacy, the sponsor must also submit, as part of the NDA, copies of the label and all other labeling to be used for the drug.[66] If the drug is to be used only by prescription, its labeling must "bear information for the use under which practitioners licensed by law . . . can use the drug safely and for the purposes of which it is intended, including all the purposes for which it is advertised or represented."[67] This information is included in a brochure, usually called the "package insert," which is included with the drug package or container when shipped to the pharmacist.[68]

In order to accumulate the pharmacological information required for the NDA and to meet the burden of developing "substantial evidence" of effectiveness, the sponsor of the application must engage in extensive pre-clinical and clinical investigations. Since the clinical investigations necessary to support an NDA may involve several thousand patients,[69] shipment of the drug to a number of clinical investigators in various states is often required. Such an interstate shipment of a nonapproved drug would be prohibited by section 505(a), but in order to facilitate the investigation of new drugs, section 505(i) permits the Secretary to establish regulations under which a drug under investigation may be shipped interstate without an NDA in effect.[70] To meet the re-

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66 *See* note 6 *supra.*

67 21 C.F.R. § 201.100(c)(1) (1977).

68 M. DIXON, DRUG PRODUCT LIABILITY § 6.10[4] (1977). Since the package insert is sent with the drug to the pharmacist, the physician, unless he makes a specific request, does not see it. However, the information provided in the package insert is reproduced in a book, PHYSICIAN'S DESK REFERENCE (PDR), which is distributed free to physicians. The patient also does not see the package insert, since the pharmacist removes it before dispensing the medication. *Id.* at § 3.02. PDR is available in medical book stores.

69 Prior to the submission of the NDA for the drug tolmetin, clinical investigations were conducted which involved over 1500 patients. Review Panel on New Drug Regulation, Interim Reports, Vol. II, IND/NDA Study—Tolmetin (May 31, 1977) D20 [hereinafter cited as IND/NDA Study — Tolmetin].

70 21 U.S.C. § 355(i) (1970). The Secretary may condition the granting of an IND on the submission of reports on pre-clinical tests which are adequate to justify the proposed clinical test; on the submission of agreements signed by each investigator limiting the availability of the drug to patients under the investigator's personal supervision (or to patients under the supervision of investigators responsible to him); on the establishment and maintenance of such records, and the making of such

quirements of the regulations promulgated pursuant to section 505(i), the drug must be labeled as investigational[71] and the person claiming the exemption must file a "Notice of Claimed Investigational Exemption for a New Drug" (IND) with the FDA.[72] If the FDA does not refuse the IND within thirty days, the sponsor is free to begin the clinical trials.[73]

The review of the NDA often proceeds as the information supporting the NDA is developed. Many of the FDA's questions about the pharmacology of the drug may be resolved

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reports to the Secretary, of any data obtained through the use of the IND which the Secretary finds will enable him to evaluate the safety and effectiveness of such drug should an NDA be filed; and on such other requirements as the Secretary finds necessary for the protection of the public health. The granting of an IND *must* be conditioned on the promise of each investgator to inform any persons to whom the drug is administered that the use of the drug is investigational and the promise to gain each person's consent, except where not feasible or contrary to the best interests of such persons. *Id.*

71 21 C.F.R. § 312.1(a)(1) (1977). The label of such drug must bear the statement "Caution: New drug—Limited by Federal (or United States) law to investigational use." *Id.*

72 21 U.S.C. § 355(i) (1970); 21 C.F.R. § 312.1f(a)(2) (1977). The IND is required to include many things: (a) Complete chemical and manufacturing data. (b) Data from all preclinical animal investigations. (These studies should be directed toward defining the safety, toxicity, and action of the drug rather than its efficacy. The data must demonstrate that human test-subjects will not be unreasonably endangered.) (c) A detailed description of the intended investigation. (d) Qualifications of the clinical investigators. (e) Copies of all informational material supplied to each investigation. (f) An agreement from the sponsor to notify the FDA and all investigators if any adverse reactions arise during the animal or human trials. (g) Assurances that informed consent will be obtained from patients participating in the trial. (h) Agreement to file annual progress reports and commitments regarding disposal of the drug when studies are discontinued. *See* Gyartas & Wetch, *The IND Procedure: Assuring Safe and Effective Drugs,* FDA PAPERS 27 (1969), *reprinted in* R. GOODMAN & P. RHEINGOLD, DRUG LIABILITY—A LAWYER'S HANDBOOK 347 (1970).

Three phases of clinical research are conducted under an IND. Phase I is aimed at determining the drug's action, its absorption in the body, its proper means of administration, and its safe dosage range; much of Phase I testing is on healthy human test-subjects. Phase II involves testing on a limited number of patients with a specific disease to evaluate the drug's efficacy. Phase III is permitted only if the information generated in Phases I and II reasonably assures the safety and effectiveness of the drug. Phase III trials use a large group of subjects and are conducted to determine the drug's safety, effectiveness, and most desirable dosage in treating a specific disease. After completion of Phase III, if the sponsor is convinced of the drug's safety and effectiveness he may submit an NDA. *See* Pines, *A Primer on New Drug Development,* FDA CONSUMER (Feb. 1974) (also includes a detailed discussion of the IND and NDA approval procedures within the FDA). *See also* FDA's Review of Initial IND Submissions, *supra* note 64, at C12-42.

73 21 C.F.R. § 312.1(a)(2) (1977). The sponsor is usually a drug manufacturer who has arranged for investigators-physicians to perform the clinical trials. In certain instances the sponsor is a physician. *See* note 141 *infra.*

during the investigational stages.[74] As a result, the principal activity of the FDA following the submission of the NDA may be only the review of the package insert. That review is primarily accomplished by the FDA after consultation with the sponsor.[75]

In summary, the prohibition of section 505(a), that no new drug may be shipped interstate without an effective NDA, sets up a lengthy process for the manufacturer and an early role, in the development of new drugs, for the FDA. The FDA becomes involved when the manufacturer begins the clinical trials, as an IND will typically be required. The manufacturer will usually need to conduct extensive clinical and preclinical investigations in order to demonstrate, by substantial evidence, the drug's effectiveness and safety. Because the FDA has been involved throughout the investigational stages, the submission of the NDA may require only review of the drug's proposed labeling. Once that review is completed final approval or disapproval follows.

B. *The FDA's Authority to Regulate Nonapproved Uses*

1. The 1972 Proposed Regulation

The 1972 Proposed Regulation revealed the FDA's interpretation of section 505 of the FDCA. It concluded that section 505 permits an approved new drug to be shipped in interstate commerce with the approved package insert only if neither the shipper nor the recipient intends that it be used

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74 IND/NDA Case Study—Tolmetin, *supra* note 69, at D24-25, Appendix B35.

75 The review of the package insert for the drug tolmetin has been well-documented. The drug was described in the package insert as equal and sometimes superior to aspirin in pain relief and inflammation reduction; as effective as indomethacin but with fewer central nervous system side effects; as less ulcerogenic than indomethacim, ibuprofen, or phenylbutazone; as tolerable to 75 percent of patients who could not tolerate indomethacin; and as useful in the treatment of juvenile rheumatoid arthritis. The labeling warned only against use in pregnant or nursing females, children under the age of two, and patients with histories of peptic ulcers.

During the process of revision, involving 9 meetings between the FDA and the sponsor over a period of 6 months, almost every claim initially made was deleted. The sponsor could claim only that tolmetin was "at least as effective" as aspirin and indomethacin with a lower incidence of gastrointestinal side effects and ringing in the ears than aspirin and a lower incidence of central nervous system side effects

for a nonapproved purpose.[76] Shipment for a nonapproved purpose is to be permitted only if an IND is in effect. The FDA reached this conclusion by inference from the major provisions and objectives of the 1938 and 1962 drug laws.[77] The FDA cited no explicit statutory authority for its conclusion.

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than indomethacin. There was some addition to the labeling: numerous warnings concerning potential side effects were required.

IND/NDA Case Study — Tolmetin, *supra* note 69, at 62. *See generally* Comment, *Package Inserts for Prescription Drugs as Evidence in Medical Malpractice Suits,* 44 U. CHI. L. REV. 398, 405-15 (1977).

76 37 Fed. Reg. 16,503 (1972).

77 *Id.* The FDA advances the following general requirements for approval of new drugs:

> Section 505 of the Federal Food, Drug, and Cosmetic Act prohibits the introduction or delivery for introduction into interstate commerce of any new drug without the filing of an investigational new drug plan or approval of a new drug application . . . .
>
> The major objective of the drug provisions of the Federal Food, Drug, and Cosmetic Act is to assure that drugs will be safe and effective for use under the conditions of use prescribed, recommended, or suggested in the labeling thereof. . . . When a new drug is approved for marketing, the conditions of use that have been approved are required to be set forth in detail in the official labeling. . . . The labeling is derived from the data submitted with the new drug application. It presents a full disclosure summarization of a drug use information, which the supplier of the drug is required to develop from accumulated clinical experience, and systematic drug trials consisting of preclinical investigations and adequate, well-controlled clinical investigations that demonstrate the drug's safety and the effectiveness it purports or is represented to possess.

37 Fed. Reg. 16,503 (1972). It then argues that its contention is supported by the 1938 and 1968 Drug Laws. *Id.* Continuing, it says:

> Thus, although it is clear that Congress did not intend the Food and Drug Administration to regulate or interfere with the practice of medicine, it is equally clear that it did intend that the Food and Drug Administration determine those drugs for which there exists substantial evidence of safety and effectiveness and thus will be available for prescribing by the medical profession, and additionally, what information about the drugs constitutes truthful, accurate, and full disclosure to permit safe and effective prescription by the physician. As the law now stands, therefore, the Food and Drug Administration is charged with the responsibility for judging the safety and effectiveness of drugs and the truthfulness of their labeling. The physician is then responsible for making the final judgment as to which, if any, of the available drugs his patients will receive in the light of the information contained in their labeling and other adequate scientific data available to him.

Id. at 16,504. Without citing any further statutory authority, the proposal concludes that when

> the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public. Several alternative courses of action are available to the

The American Medical Association has repeatedly contended that the FDA has no authority to approve or disapprove uses of a drug; it argues that the FDA's statutory authority is limited to approving what the manufacturer may say on the label.[78] Although the AMA has also not explained the basis of its position on the FDA's power, it must have reasoned as follows. According to sections 505(c), (d), and (e), the relevant provisions, the FDA's authority extends only to a review of an NDA. And a review of an NDA consists only of approval of the statements on the new drug's label. Further, an NDA is required only for each "new drug." A new use of an already marketed drug, it is asserted, does not constitute a "new drug" within the meaning of section 505(a), which forbids "the introduction or delivery for introduction of any new drug, unless an approval of an application . . . is effective." Therefore, section 505 does not authorize the FDA to approve or disapprove uses of a drug. If this argument were carried one step further, however, it would result in permitting the manufacturer of a drug with an effective NDA based on certain indications to promote and market the drug for other indications without violating section 505.[79]

The rival conclusions of the FDA and the AMA are difficult to evaluate, largely because of Congress's failure to consider the problem of nonapproved uses in relation to the prescribing physician. However, the legislative history of the 1962 Drug Amendments indicates that Congress did consider the problem of nonapproved uses in relation to the manufacturer.[80]

Food and Drug Administration under these circumstances, depending upon the specific facts of each case.

Id.

78 Archer, *Instrument or Impediment?: The Regulatory Monograph in Medical Communications*, 220 J.A.M.A. 1474, 1476 (1972) (the author was with the Department of Drugs of the AMA). The article argues that "FDA-approved uses" is a misnomer which must be replaced by the term, "FDA-approved labeling." *Id.* at 1477. *See also* Letter from H. Simmons to the Editor, *Investigational Exemption Procedures for New Drugs*, 213 J.A.M.A. 1902 (1970).

79 This is not to suggest that such a manufacturer would be free from legal difficulties. An action may be brought based on the misbranding provisions of the FDCA. *See* notes 173 to 215 and accompanying text *infra*.

80 S. REP. NO. 1744, 87th Cong., 2d Sess. 59 (1962) (views of Senators Dirksen and Hruska).

At the time of the 1962 Amendments, Senator Kefauver expressed some concern over the situation in which a drug approved initially for certain indications is subsequently promoted and marketed for new indications without the new indications having been approved by the FDA. He was particularly concerned that if such action occurred, only the Act's misbranding section would be violated: the FDA's enforcement remedies would thus be limited.[81] The Senate report indicates that the members of the Judiciary Committee felt that Senator Kefauver's interpretation was incorrect. They insisted that the words "for use under conditions prescribed, recommended, or suggested in the labeling thereof" found in section 505(d)[82] and section 201(p)[83] could only mean that "it is the use claimed for a drug that determines whether or not it is a new drug and that a new drug application under section 505 with respect to any drug is limited to the particular use or uses presented in the application. . . ."[84] In support of their position, the Committee members cited an FDA regulation which asserted that the newness of a drug could arise by reason of "the newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body."[85]

Thus, the legislative history tends to undermine the AMA's logic and thereby casts doubt on the AMA's conclusion that the FDA has no authority to regulate uses. The Senate report indicates that the FDA may control the

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81 Senator Kefauver was concerned about the difference in the FDA's burden of proof as provided in § 502(a) and in § 505. He stated that "the ability of the FDA to act against excessive claims for efficacy would be limited to its existing and relatively ineffective power to seize the drug as misbranded." 108 CONG. REC. 10,278 (1962). Such seizure power was ineffective because, unlike a § 505 charge which required the FDA to prove simply lack of approval, a § 502(a) charge required the FDA to prove the falsity of the efficacy claim.

82 21 U.S.C. § 355(d) (1970).

83 *See* note 56 *supra*.

84 S. REP. NO. 1744, 87th Cong. 2d Sess. 59 (1962).

85 *Id.* at 60. The regulation was originally set forth in 21 C.F.R. § 130.1 (f)(4), which is presently part of 21 C.F.R. § 310.3(h)(4) (1977). *See* note 56 *supra*.

manufacturers' practice of promoting the use of approved drugs for nonapproved uses through section 505. More significantly, although the report discusses the problem only in relation to manufacturers, the reasoning, that a new use of an approved drug constitutes a "new drug," is equally applicable to the problem of nonapproved uses in relation to physicians. That reasoning would allow the FDA to argue that if a violation of section 505(a) is to be avoided, each new indication for a drug requires an NDA.[86]

Although the Senate report to the 1962 Drug Amendments is not conclusive, the FDA must be empowered to regulate uses in order to achieve the congressional intent to protect the public health.

At the heart of the FDA's evaluation of an NDA is an assessment of the risks and benefits associated with the use of a new drug. But such risks and benefits will vary as the drug is put to different uses. A drug effective in treating one disease is not necessarily effective in treating another disease. More importantly, a drug that is safe in patients with one disease is not automatically safe in patients with other diseases. While the drug's ability to produce carcinogenic, mutagenic, or teratogenic manifestations is likely to be similar for all patient populations, the presence of a certain disease may alter the absorption, distribution, and elimination properties of the drug, possibly causing adverse reactions.[87] While further sections of this article will argue that the realities of drug development may justify permitting the physician to evaluate, for his patients, a marketed drug's effectiveness in diseases for which the drug has not been specifically indicated, it must be stressed that the treating physician may not be adequately informed as to the drug's

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86 The legislative history indicates that it made no difference if the drug was originally marketed as an "old" or a "new"drug. Even a new drug with an NDA in effect would require a second NDA for a subsequently discovered indication. S. REP. NO. 1744, 87th Cong., 2d Sess. 60 (1962).

87 S. SMITH & M. RAWLINS, VARIABILITY IN HUMAN DRUG RESPONSE 5-6 (1973). For example, the hyperthyroid patient can tolerate larger doses of morphine than an individual with normal thyroid function can, but responds to dosages of epinephrine that do not affect the normal individual. R. LEVINE, PHARMACOLOGY: DRUG ACTIONS AND REACTIONS 257 (1973).

safety and effectiveness in all patient populations. Thus, the patient and the public in general are left unprotected in the absence of an FDA assessment of risks and benefits with respect to each use. In theory, if not in practice, unless the drug is being administered under an IND, a NDA should be in effect for each particular use of a drug.

2. The Interstate Commerce Limitation

Considered alone, the FDA powers asserted by the 1972 Proposed Regulation appear to be expansive. In fact, however, the FDA considers itself substantially limited. The 1972 Proposal asserted that the FDA's control would only extend to the interstate shipment of drugs which were ordered or shipped with the intention that the drugs be prescribed for nonapproved purposes.

The reason for the limitation is the FDA's interpretation of section 301(d) of the FDCA, which reads: "The following acts and the causing thereof are prohibited. . . . The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505."[88]

The FDA interprets sections 404 and 505 to mean that a violation can only occur at the "moment of shipment in interstate commerce and not . . . [after] action taken subsequent to shipment in interstate commerce."[89] The FDA interpretation relies on the holding in *United States v. Phelps Dodge Mercantile Co.*[90] In *Phelps Dodge,* 150 cartons of spaghetti and 25 cartons of macaroni were shipped from Colorado to Arizona and stored there in the original packages for over two years. During storage, the food became adulterated. Pursuant to section 304(a) of the FDCA, which prohibited adulteration or misbranding of an article "when introduced into or while in interstate commerce," the FDA filed a libel.[91]

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88 21 U.S.C. § 331(d) (1970).

89 37 Fed. Reg. 16,503 (1972).

90 157 F.2d 453 (9th Cir. 1946), *cert. denied,* 330 U.S. 818 (1947).

91 A "libel" or "libel of information" is the instrument filed by the FDA which contains the charge (for alleged violations) brought against the manufacturer, pharmacist, or druggist. *See* 157 F.2d at 454-55.

The Court of Appeals for the Ninth Circuit held that food which becomes adulterated while stored in the original packages but after having been transported interstate is not adulterated "when introduced into" or "while in interstate commerce."[92] *Phelps Dodge* shocked the FDA. The original 1906 Pure Food and Drug Act had been interpreted to permit seizure for adulteration that occurred after interstate shipment. Although Congress, in enacting the 1938 Federal Food, Drug, and Cosmetic Act may have intended to incorporate the previous Act's authority, the court's decision in *Phelps Dodge* substantially diminished the agency's jurisdiction.[93]

Congress immediately revived section 304(a) by enacting the Miller Amendment, which added the words "while held for sale (whether or not the first sale)" to the provision.[94] But in the absence of similar congressional action in relation to section 505, the FDA feels bound by *Phelps Dodge.*[95]

At least one case has since questioned the validity of the *Phelps Dodge* interpretation.[96] In *United States v. Sullivan,*[97] a retail druggist in Columbus, Georgia, had purchased drugs from a distributor in Atlanta, Georgia, who received them from out of state. The retail druggist altered the labels on the drugs, thus misbranding them. While section 301(k), which prohibits alteration of labeling, did include the words "while held for sale," the Supreme Court did not in its decision limit itself to the words of section 301(k). According to the Court the FDCA was designed to safeguard "the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of

92 *Id.* at 455.

93 Kleinfeld, *Reflections on the Miller Amendment,* 4 FOOD DRUG COSM. L.Q. 43 (1949). For further discussion of *Phelps Dodge, see* Hutt, *Regulations of the Practice of Medicine under the Pure Food and Drug Laws,* 33 ASSOCIATION OF FOOD & DRUG OFFICIALS OF THE UNITED STATES 3, 18-19 (1969).

94 Act of June 24, 1948, Pub. L. No. 749, 62 Stat. 582.

95 In the 1972 Proposed Regulation, the FDA states that the Miller Amendment closed only the loophole for violations of § 502. There is no evidence that Congress ever considered extending such coverage to § 505. If § 505 is viewed purely as a preclearance procedure for new drugs, the "while held for sale" language would be nonsensical.

96 *See* Dunn, *House of Representatives Bill 4071,* 2 FOOD DRUG COSM. L. Q. 284, 290 (1947).

97 332 U.S. 689 (1948).

their delivery to the ultimate consumer."[98] It is this view of the Act which has led one commentator to say, "As long as the interstate origin of the article can be traced in its travels of sale and resale within a state, it appears that the government may extend its reach over that article."[99]

The language of *Sullivan* is not conclusive with respect to the scope of section 301(d). A strict interpretation of jurisdictional basis may still justify holding a limited view of the FDA's power. It is noteworthy, however, that the refusal of the FDA to argue that its power goes beyond the point where interstate commerce stops seems contrary to its previous recognition that such extended authority is necessary to protect the public health.[100]

Even assuming that the FDA is correct in claiming that such a limitation exists, its assertion in the 1972 Proposal, that once a drug is in the local pharmacy the physician may prescribe the drug as he sees fit, does not necessarily follow.[101] Section 301 specifically states that *causing* the in-

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98 *Id.* at 696.

99 Note, *The Interstate Ingredient of Section 304(a) of the Federal Food, Drug and Cosmetic Act*, 37 NOTRE DAME LAWYER 408, 414 (1962) [hereinafter cited as *Interstate Ingredient of Section 304(a)*].

100 During hearings on the Miller Amendment, the Association Commissioner of the FDA testified:

> Congress unquestionably has the authority to maintain these goods in a state of lily-white purity up to the time the interstate vehicle stops rolling but if that is all the authority Congress has it may be futile to exercise that authority because it cannot protect the consequences of the regulation by preventing the evil things happening to the goods after the interstate journey has ended. It seems to us to be a kind of negation of the beneficent effect of that authority while interstate transportation is in course, to say that nothing could be done to carry out the purpose of Congress and to bring it to fruition, the purpose being the protection of the ultimate consumer of goods from interstate sources.

Hearing Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce, on H.R. 3128 and H.R. 3147, 80th Cong., 1st Sess. 19 (1947), *quoted in Interstate Ingredient of Section 304(a), supra* note 99, at 414.

101 The proposed regulation stated in relevant part:

> (3) Once a new prescription drug has been shipped in interstate commerce intended for its approved use(s) under approved labeling, the Federal Food, Drug, and Cosmetic Act does not require a physician to file with the Food and Drug Administration an investigational new drug plan in order to lawfully prescribe the drug for an unapproved use, when such prescribing is done as part of the practice of medicine.

37 Fed. Reg. 16,503, 16,504 (1972).

troduction or delivery for introduction into interstate commerce of a drug in violation of section 505 is a prohibited act: if the physician orders the drug directly from an out-of-state manufacturer, section 505 would apply. Further, if the physician, by repeated prescriptions, causes the pharmacist to resupply constantly the pharmacy inventory, section 505 may extend to that physician notwithstanding the intermediate position of the pharmacist. However, if this were the case, the FDA's enforcement responsibilities would be enormous. Establishing the use intended by a recipient pharmacist, wholesaler, or distributor would prove quite difficult.[102]

The 1972 Proposal's interpretation of the jurisdictional limitation provides some insight into what the FDA had hoped to accomplish. In effect, the 1972 Proposal was directed at physicians who either order large quantities of a drug directly from the manufacturer or cause the pharmacist to order and reorder the drug. It avoided interference with the individual practitioner who uses a drug for an unapproved use on an occasional basis.[103] From the standpoint of the patient who receives a drug for an unapproved use, there is little rationale for such a distinction, but from the standpoint of the resources available to police the nation's physicians, a very practical rationale exists.

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102 Temple, *Legal Implications of the Package Insert*, 58 MED. CLINICS N. AM. 1151, 1158 (1974). *See* Campbell, *The Pharmacist's Responsibility to Determine Limitations on Prescribing*, 11 HOSPITAL FORMULARY 117 (1976); Mandl & Greenberg, *Legal Implications of Preparing and Dispensing Drugs under Conditions Not in a Product's Official Labeling*, 33 AM. J. HOSP. PHARMACY 814 (1976); Fink, *Some Legal Issues Presented in Clinical Pharmacy Practice*, 10 DRUG INTELLIGENCE & CLINICAL PHARMACY 445 (1976); Patterson, *Dispensing for FDA Nonapproved Uses*, NS8 J. AM. PHARMACEUTICAL A. 422 (1968).

103 *See generally* Fink, *Dispensing FDA-approved Drugs for Non-approved Uses*, 2 U.S. PHARMACIST 24 (1977). The Board of Trustees of the American Pharmaceutical Association has suggested that, in order to control improper prescriptions, some "consideration be given to a requirement that the physician indicate on each prescription order the use for which the drug is being prescribed for the individual patient." Letter from the American Pharmaceutical Association regarding 37 Fed. Reg. 16,503, filed with the Hearing Clerk of the Department of Health, Education, and Welfare (October 12, 1972) (copy on file with the Harvard Journal on Legislation).

C. *The Problems of Regulating Uses by Limiting Prescribing to Approved Indications*

In light of the jurisdictional limitation on the FDA's power discussed in the previous section, the impact of the 1972 Proposed Regulation, were it to be put into effect, can only be surmised. The great majority of physicians would probably be unaffected by the proposal. One recently proposed legislative solution, however, would influence the behavior of every physician: it would prohibit a physician from prescribing for any purpose other than those specifically included in the FDA-approved labeling.[104]

This proposed solution, like the 1972 Proposed Regulation, must have for its basic premise the belief that "a drug's labeling omits no information [known to the FDA] that is pertinent to the safe and effective prescribing by the physician."[105] However, a rigid reliance on the completeness of the drug's labeling is mistaken, first because of the process by which a drug's labeling is developed and revised, and second, because of the present rigid standards of efficacy. As a result, using a drug for nonapproved purposes is not synonymous with improper prescription.

1. The Package Insert

A drug's label is prepared through negotiation between the FDA and the manufacturer — the practicing physician is excluded. Only those indications for which the manufacturer submits data are considered for inclusion on the package insert.[106] The manufacturer is the applicant and the FDA the evaluator; the relationship can be characterized as adversarial.[107] Viewed in this perspective, it is the manufacturer's responsibility, not the FDA's, to submit supplemental or new

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104 S. 2697, 94th Cong., 1st Sess. §§ 301(s)-(v), 402(a)(17) (1975).

105 37 Fed. Reg. 16,503 (1972).

106 Rheinstein, *Drug Labeling As a Standard for Medical Care,* J. LEGAL MED. 22 (Jan. 1976).

107 *See* Review Panel on New Drug Regulation, Investigation of Allegations Relating to the Bureau of Drugs 672 (Apr. 1977) [hereinafter cited as Review Panel on New Drug Regulation].

NDAs for new indications.[108] Only those indications for which the manufacturer negotiates will be included on the drug's label. There is no guarantee that the manufacturer will attempt to achieve the inclusion of every potential use. On the contrary, there are a number of reasons why a manufacturer may choose not to negotiate for the inclusion of certain uses.

One reason is that a manufacturer may not deem the inclusion of an additional use worth the delay in marketing the drug that gaining FDA approval of that use may entail. The negotiation process between the FDA and the manufacturer of the drug tolmetin provides an example. In this case patients who were generally bedridden and stricken with rheumatoid arthritis (designated by the American Rheumatism Association as Functional Class IV) became "therapeutic orphans"[109] of the nonsteroidal anti-inflammatory drug. In a meeting between the manufacturer and the FDA regarding the drug's NDA, the agency stated that unless well-controlled and adequate clinical trials involving Functional Class IV patients were presented, the drug's labeling would have to reflect that the drug's safety and effectiveness were not established for these patients. The manufacturer later submitted data upon which the FDA's medical officer maintained the drug could properly be used by patients with rheumatoid arthritis. However, probably because the data had not been evaluated by higher-level authorities at the FDA, the warning that the drug was not being indicated for use with Class IV patients was retained in the drug's labeling. The manufacturer agreed to retain the warning rather than risk further delay in approval of the NDA.[110]

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108 S. FREDMAN & R. BURGER, FORBIDDEN CURES 156 (1976). However, "FDA officials . . . have been anxious to encourage secondary approval of certain drugs, such as propanolol for hypertension." *Id.* at 157.

109 The term "therapeutic orphan" here refers to those patients who would lose access to a drug because the drug's labeling does not refer to their particular disease. It may also refer to a person suffering from a disease for which there is no existing therapy. *See* American Academy of Pediatrics, Committee on Drugs, *"Therapeutic Orphans" and the Package Insert*, 46 PEDIATRICS 811, 811 (1970).

110 IND/NDA Study — Tolmetin, *supra* note 69, at 37-38.

Another reason why some uses are not included in a drug's labeling is that the manufacturer has chosen not to perform the required additional testing. Once the general preclinical data regarding safety have been generated, it would seem that there would be adequate incentives for the manufacturer to find multiple uses.[111] But the economic realities do not make this universally true. For example, lidocaine (xylocaine hydrochloride) received an NDA in 1949 for use as a local anesthetic. In 1950, the successful treatment of a cardiac arrhythmia with xylocaine was reported.[112] By 1965, the drug was reported in medical literature to be invaluable in the treatment of ventricular arrhythmias[113] and was in general use among cardiologists for that purpose.[114] In 1964, the manufacturer submitted an NDA based only on a review of the medical literature. Because the manufacturer was unwilling to accumulate new data through its own clinical trials, the FDA turned down the manufacturer's application.[115]

In both the tolmetin and xylocaine cases the uses of the drugs not approved by the FDA can hardly be characterized as improper. Yet neither use was included in the drug's labeling. Under the proposed legislative solution and, to a lesser extent, under the 1972 Proposed Regulation, those uses would be prohibited and patients would be denied effective treatment. Of course, the effect of the two proposals may be

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111 Ashford, Butler & Zolt, Comment on Drug Regulation and Innovation in the Pharmaceutical Industry 27 (Feb. 10, 1977), *reprinted in* 1 Review Panel on New Drug Regulation, Interim Reports C27 (May 31, 1977).

112 Southworth, McKusick, Pierce & Rawson, *Ventricular Fibrillation Precipitated by Cardiac Catheterization: Complete Recovery of the Patient After Forty-Five Minutes,* 143 J.A.M.A. 717 (1950) (a small amount of epinephrine and electric shock were also used).

113 Frieden, ANTIARRHYTHMIC DRUGS, *Part VII, Lidocaine as an Anti-Arrhythmic Agent,* 70 AM. HEART J. 713 (1965).

114 M. DIXON, DRUG PRODUCT LIABILITY, § 7.02 (1977).

115 Telephone interview with Mr. Jack Waterman, Department of Regulatory Affairs, Astra Pharmaceuticals (Nov. 17, 1977). Although the manufacturers' promotional activities would be prohibited until approval for treatment of ventricular arrhythmias by the FDA, the increased income generated by having an NDA in effect would not have offset the costs of the manufacturers' conducting their own clinical analysis. By 1967, the FDA recognized that xylocaine was so widely used for the nonapproved purpose that it dispensed with its adversarial role and probably for the first and only time invited the manufacturer to submit and resubmit an NDA for the use of the drug in cardiac arrhythmias based solely on the medical literature. The FDA approved the application in October 1969.

to strengthen the manufacturers' incentives to find multiple uses and gain FDA approval, because the proposals might cause physicians to prescribe less of a drug than they now do, since they can now legally prescribe for uses not mentioned in the drug's labeling. But regardless of any increase of manufacturers' incentives, marginal cases, where the manufacturer's incentive is still insufficient to insure the completeness of a drug's labeling, will continue to occur.

2. Standards of Efficacy

An indication may also fail to appear on the labeling because the studies that are undertaken fail to meet the statutory standard for approval. The standard is a rigorous one, as Congress apparently intended, requiring evidence of well-controlled and adequate studies demonstrating the drug's effectiveness.[116] However, it can be argued that the statutory standard is a higher standard than that of sound medical judgment, and it is more rigorous than the protection of the public health requires.

Two other factors have been suggested that diminish a manufacturer's incentive to conduct clinical trials: the relative rarity of the disease and the remaining life of the drug patent. *See* Rheinstein, *supra* note 106, at 23; D. SCHWARTZMAN, INNOVATION IN THE PHARMACEUTICAL INDUSTRY 162 (1976).

116 *See* note 65 and accompanying text *supra*. *See also* S. REP. NO. 1744, Part 2, 87th Cong., 2d Sess. 6 (1962); 21 C.F.R. § 314.111(a)(5)(ii)(c) (1977). In commenting on the regulations, the Supreme Court, in Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609 (1973), stated:

> The "substantial evidence" requirement reflects the conclusion of Congress, based upon hearings, that clinical impressions of practicing physicians and poorly controlled experiments do not constitute an adequate basis for establishing efficacy. This policy underlies the regulations defining the contours of "substantial evidence": "Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. . . ."

Id. at 630 (footnotes omitted). Elsewhere, the Court stated:

> Lower courts have upheld the validity of these regulations, and it is not disputed here that they express well-established principles of scientific investigation. Moreover their strict and demanding standards, barring anecdotal evidence indicating that doctors "believe" in the efficacy of a drug, are amply justified by the legislative history. The hearings underlying the 1962 Act show a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous.

Id. at 619 (footnotes omitted).

The inability to document well-controlled and adequate studies does not necessarily indicate that the drug is ineffective. In the past many drugs have been extensively used on the basis of observations made from uncontrolled studies. And such observations should not be disparaged as inherently unreliable.[117] The anecdotal observations of physicians are not entirely uncontrolled. What the physician believes would have happened had the drug not been administered is, in effect, a control.[118]

Even the FDA has, on occasion, recognized that approval of certain drugs may be based on evidence gathered from sources other than adequate and well-controlled studies. In an effort to implement the 1962 Drug Amendments, the FDA contracted with the National Academy of Sciences to review the efficacy of marketed drugs.[119] The guidelines for the

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117 Feinstein, *The Need for Humanized Science in Evaluating Medication*, 2 LANCET 421 (1972). Jenner's observations on the effect of his vaccination against smallpox and Huxham's observations that led to the proper treatment of scurvy were both the result of uncontrolled clinical experience. However, the widespread use of such dubious procedures as bloodletting and leeching directly illustrate that medical progress due to uncontrolled trials is probably the exception rather than the rule. The lack of reliability of uncontrolled trials is generally the result of four factors: (1) insufficient knowledge of the spontaneous course of disease, (2) random variation, (3) the placebo effect, and (4) the clinician's bias. H. WULFF, RATIONAL DIAGNOSIS AND TREATMENT 119, 122 (1976).

118 W. WARDELL & L. LASAGNA, REGULATION AND DRUG DEVELOPMENT 30 (1975).

119 *See Drug Efficacy, supra* note 62, at 209 n.153. The NAS-NRC review conducted by panels of experts established six categories for purposes of evaluating the effectiveness of each indication claimed for the drug. The categories were:

(A) *Effective.*

(B) *Probably effective.* Additional evidence required to consider effective. Remedy could be additional research or modification of claims or both.

(C) *Possibly effective.* Little evidence of effectiveness, but possibility of additional evidence should not be ruled out.

(D) *Ineffective.* No acceptable evidence to support claim of effectiveness. (When available data clearly indicate a drug ineffective, the panels should specifically cite that fact.)

(E) *Effective, but....* Effective for claimed indication but not approved form of treatment because better, safer or more conveniently administered drugs available.

(F) *Ineffective as a fixed combination.* Combination drugs for which there is no substantial reason to believe that each ingredient adds to the effectiveness of the combination.

Id.

review permitted the consideration of data other than that derived from well-controlled and adequate studies.[120]

In certain unusual cases the FDA has approved a drug before it determined that there were adequate and well-controlled studies demonstrating the drug's effectiveness. Propranolol, a drug originally marketed for use in cardiac arrhythmias and idiopathic hypertrophic subaortic stenosis,[121] was approved for use in angina pectoris to "protect the agency's credibility."[122] L-Dopa, a highly significant advancement in the management of Parkinson's disease, was approved before the completion of all trials because of the importance of the drug.[123]

In fact, the inability to document well-controlled and adequate studies often follows from the difficulties of conducting such studies.[124] There are many factors that influence the suc-

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120 In its Final Report the National Academy of Science stated that "in the deliberations of the Panels issues will almost certainly arise as to considerations, other than factual evidence, that should be weighed in arriving at judgments on effectiveness. ... The informed judgment and experience of the members of the Panels are valid evidence contributory to the final decision on the efficacy of a drug." NATIONAL ACADEMY OF SCIENCE, DRUG EFFICACY STUDY, FINAL REPORT TO THE COMMISSIONER OF FOOD AND DRUGS (1969), *cited in* WARDELL & LASAGNA, *supra* note 118, at 28.

121 *See* note 47 *supra.*

122 H.R. REP. NO. 787, 94th Cong., 2d Sess. 21 (1976). Dr. J. Richard Crout testified before the House Committee on Government Operations:

> I would say there was considerable pressure all of us felt. ... The fact is that propranolol, since about 1968, was being used for the treatment of angina beyond — as its major use and that we felt it not good medicine to have the drug in wide use for another couple of years, with no information going to the doctors about that use, with it, in a sense, outside the regulatory system merely because of our inability to have some gumption on the long-term short-term issue. So we think that the proper way to get the drug back into the regulatory system in this country was to grab hold of that indication.
>
> I feel quite strongly about that. I think that is a posture we are going to have to take on a number of other drugs that have similar problems.

Use of Advisory Committees by the Food and Drug Administration: Hearings Before the Subcomm. on Intergovernmental Relations of the House Comm. on Government Operations, 93d. Cong., 2d Sess. 250 (1974).

123 *See* WARDELL & LASAGNA, *supra* note 118, at 41.

124 Consider, for example, the difficulties of assessing the effectiveness of drug therapy in the treatment of angina pectoris. The condition is a subjective complaint: any response to treatment is likewise subjective, making the evaluation of the treatment extremely difficult. Accurate assessment is also made difficult by the numerous variables that influence the development of angina. The placebo effect is of special concern when dealing with any coronary disease.

cess of a clinical trial.[125] The factors include the heterogeneity of the clinical population,[126] a patient population of "sufficient size,"[127] observer error,[128] and the failure of the patient to comply with the prescribed procedure.[129] Any one of these could invalidate an otherwise sound study.[130]

The difficulties of developing evidence of efficacy were noted by the National Academy of Sciences in its review.[131] For many drugs the information submitted by manufacturers

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The design of the study may influence the conclusion reached as to a drug's effectiveness. To assess the effectiveness of a drug, it should be administered so that its effect peaks when the patient's angina develops. Studies which use an arbitrary schedule of medication might lead the investigator to conclude that the drug was ineffective when in fact the drug would be effective if administered at the appropriate time.

Finally, a drug's apparent ineffectiveness may be the result of insufficient dosage or a failure to consider the drug in combination with another drug. Logue & Robinson, *Medical Management of Angina Pectoris,* 46 CIRCULATION 1132-33 (1972).

125 *See* WARDELL & LASAGNA, *supra* note 118, at 29.

126 It has been suggested that the difficulties in establishing well-controlled and adequate studies for the drug propranolol, *see* notes 47 to 49 and accompanying text *supra,* are due in part to the fact that populations of patients with arrhythmias, hypertension, or angina pectoris are extremely heterogeneous. Subsets within the patient populations studied may respond differently from the overall population. Thus, while the results of the entire patient population studied may fail to indicate a statistically significant effect, individuals within the subset may benefit from the drug. Morrelli, *Propranolol,* 78 ANNALS INTERNAL MED. 913, 915 (1973). The difficulty thus lies in the proper identification of the subset population.

127 One commentator has advanced the following hypothetical situation to illustrate the limitations on statistical analysis caused by varying patient populations: assume three patients with pernicious anemia were fed a pound of raw liver daily and three other patients received no treatment; the three patients who received the treatment were cured, the other three died; although the treatment is today known to be effective in the treatment of pernicious anemia, statistical analysis would indicate that the results could have occurred by chance alone — the reason being the patient population is too small. H. WULFF, *supra* note 117, at 142.

128 *See* Finkel, *Factors Influencing Clinical Research Success,* in 11 PRINCIPLES AND TECHNIQUES OF HUMAN RESEARCH AND THERAPEUTICS 33 (1976).

129 Mumford, *The Responses of Patients to Medical Advice,* in UNDERSTANDING HUMAN BEHAVIOR IN HEALTH AND ILLNESS 405 (R. Simons & H. Pardes ed. 1977).

130 Because of these difficulties, it has been suggested that a negative trial should not be considered important evidence against a drug. It is argued that "several well done positive trials by responsible investigators should be taken as evidence of efficacy, even in the face of a few negative trials, although a large number of the latter would obviously make one wonder about the general utility of the drug or the way in which it was being studied." WARDELL & LASAGNA, *supra* note 118, at 29. While such a policy may be appropriate for evaluating conflicting efficacy data, since the harm from a non-efficacious drug may not severely endanger the public, a similar policy for evaluating conflicting safety data would seem inconsistent with the protection of the public's health.

131 *See* note 119 *supra.*

was based on "uncontrolled observations and testimonial-type endorsements." Moreover, there was a veritable dearth of solid evidence in the medical literature, though many of these drugs were in "good standing" in medical practice. The Academy concluded:

> There is every reason to believe that industry is aware of the need for, and seeks to obtain, the best scientific endorsement of its products. The failure, therefore, must be attributed to the difficulty that industry has in commanding the needed clinical facilities and the service of experienced investigators. This is not a fault of industry alone, but rather is a reflection of a serious gap in the programing and management of the national effort in therapeutic research.[132]

Establishing a drug's effectiveness for a particular indication is more difficult for a new indication of a drug already on the market than for a new indication of a drug never before permitted on the market, primarily because of the burden of finding investigators. A controlled clinical trial would necessitate allocating certain patients to a control population. When a physician believes that a drug is effective because of its widespread use in medical practice, the conflict between the patient's therapeutic needs and the needs of the experimental trial poses ethical problems which may deter a physician from acting as an investigator.[133] And it may be difficult for a manufacturer to recruit other investigators to conduct the trials if the drug in use has also been widely used for an indication not specifically approved on the label. To establish a use which appears to be widely accepted in medical practice is to many at least uninteresting, if not a waste of time.

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132 NATIONAL ACADEMY OF SCIENCES, DRUG EFFICACY STUDY: FINAL REPORT TO THE COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION 13 (1969). The panel evaluated over 2,800 drugs. About 7 percent of the drugs were found ineffective for all claimed indications. Furthermore, about 15 percent of all claimed indications were totally without support. Most drugs were classified as "possibly effective" or "probably effective." *See Drug Efficacy, supra* note 62, at 210.

133 *See generally* C. FRIED, MEDICAL EXPERIMENTATION: PERSONAL INTEGRITY AND SOCIAL POLICY 50-56 (1974); Fletcher, HUMAN EXPERIMENTATION: ETHICS IN THE CONSENT SITUATION, 32 L. & CONTEMP. PROB. 620 (1967); New York Academy of Sciences, *New Dimensions in Legal and Ethical Concepts for Human Research*, 169 ANNALS N.Y. ACAD. SCI. 293 (1970).

The problem posed by nonapproved uses, when a marketed drug is used with knowledge that its efficacy has not met the FDA's standards, can not be resolved until the FDA's standards themselves are reviewed. If, for example, the FDA were to adopt standards that correlate better with the standards set by medical practice,[134] nonapproved uses of a drug could more rationally be condemned.

Congress is currently reviewing the present drug laws.[135] While the present emphasis is directed, in part, toward revising the requirements of efficacy,[136] the relationship between efficacy standards and nonapproved uses also deserves consideration.

3. Requiring INDs for Nonapproved Uses

The 1972 Proposed Regulation and the proposed legislative solution would prohibit a physician, within the FDA's jurisdiction, from prescribing for any use not specifically listed on the package insert. This would require a physician who wishes to comply with this prohibition, yet prescribe for an unapproved use, to have an IND in effect.

The use of a drug under an IND is limited to patients who are part of a "bona fide scientific investigation to determine whether or not the drug is safe and effective for use."[137] Under an IND, the investigator is required to conduct controlled clinical trials; the basic element of such a trial is that

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134 The degree to which the efficacy standards of the FDA and of the medical profession differ can be demonstrated by the so-called "drug lag." From 1962 to 1971, approximately four times as many drugs were introduced in Britain as in the United States, and many of the drugs which failed to meet the FDA's standards for efficacy were widely accepted by British physicians. *See* R. CAMPBELL, DRUG LAG: FEDERAL GOVERNMENT DECISION MAKING (1976); Wardell, *Introduction of New Therapeutic Drugs in the United States and Great Britain: An International Comparison*, 14 CLINICAL PHARMACOLOGY AND THERAPEUTICS 773 (1973); Peltzman, *The Benefits and Costs of New Drug Regulation* in REGULATING NEW DRUGS 113 (R. Landau ed. 1973).

135 During the 95th Congress, several bills were introduced to overhaul the drug amendments of the FDCA. *E.g.*, S. 1831, 95th Cong., 1st Sess., 123 CONG. REC. S11,568 (daily ed. July 11, 1977); S. 2040, 95th Cong., 1st Sess., 123 CONG. REC. S13,952 (daily ed. Aug. 5, 1977); S. 2755, 95th Cong., 2d Sess., 124 CONG. REC. S3873 (daily ed. March 16, 1978) (endorsed by the Carter Administration).

136 9 WASH. DRUG & DEVICE LETTER 1 (Dec. 19, 1977).

137 21 C.F.R. § 312.1(d)(6) (1977).

the investigator selects patients for the study and allocates them randomly to two groups — a treatment group and a control group.[138]

These conditions would make it impossible for a physician to use the drug in a therapeutic rather than investigational context.[139] The physician would not want to subject the patient to a controlled clinical trial.[140] Present regulations on the use of INDs make no distinction between a physician who wishes to use the drug therapeutically and a manufacturer who wishes to develop the drug for commercial purposes.[141] While requiring INDs may curb some drug misuse, it may deprive a patient of important therapy.

III. Total Withdrawal and Limited Distribution: Alternative Approaches of the 1972 Proposed Regulation

The 1972 Proposed Regulation summarily listed several alternatives the FDA might pursue when confronted with a nonapproved use of a drug that might endanger the public health.[142] The most drastic of these alternatives included revoking approval of the underlying NDA and limiting the distribution of the drug. The FDA has attempted to implement both strategies.

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138 H. Wulff, *supra* note 117, at 134.

139 There is some evidence that INDs are approved in certain cases without even a pretense of use in controlled clinical trials. For example, after withdrawing approval for phenformin, the FDA stated that any physician still wishing to prescribe the drug could apply for an IND. 39 FDC Reports at T & G 1 (Oct. 24, 1977). In addition, the FDA has at times issued "compassionate" INDs to make a drug available where there is no other existing therapy. Telephone interview with Roger Eastep, Department of New Drug Evaluation, FDA (Nov. 17, 1977).

140 B-Z. Taber, Providing New Drugs 51 (1969). *See* text accompanying note 133 *supra*.

141 The physician would be required to submit an IND just as the manufacturer who wants the IND to accumulate data for a future NDA. No separate procedure exists for the private physician. However, the physician can obtain a "letter of authorization" from the manufacturer of any drug for which an NDA has been approved for other purposes. Since the basic animal toxicology data would be accumulated regardless of the drug's actual use, such a letter would allow the physician to forego all preclinical studies and to incorporate by reference those studies performed by the drug's manufacturer. Telephone interview with Roger Eastep, Department of New Drug Evaluation, FDA (Nov. 17, 1977).

142 The following alternative courses of action were listed in the 1972 Proposed Regulation:

A. *Total Withdrawal*

The FDA's power, through the Secretary of HEW, to revoke an NDA and thereby remove a drug from the market is granted by section 505(e).[143] In relevant part, that subsection states that the "Secretary shall . . . withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved. . . ."[144] On its face, this provision seems inapplicable to the problem of nonapproved uses: a showing that a drug is unsafe under conditions of use *not* a part of the initial application would not, it appears, permit the invocation of this power to withdraw. This interpretation is supported by the construction of the "safety clause"[145] in

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(1) Revision of the package insert may be required to add a specific contraindication or warning against the unapproved use.

(2) The manufacturer may be required to obtain and submit the available data with respect to the unapproved use, or to sponsor clinical trials to determine the safety and effectiveness of the drug for the unapproved use.

(3) If substantial evidence of safety and effectiveness is available, revision of the package insert may be permitted or required to add the unapproved use as an approved use and to state the conditions under which the drug is safe and effective for that use.

(4) Revision of the package insert may be required to state that a prescription for the drug should not be refilled.

(5) Revision of the package insert may be required to state that the drug should be distributed only through specified channels (e.g., hospital pharmacies) and/or should be prescribed, dispensed, or administered only by physicians with specified qualifications.

(6) The investigational new drug authority, as well as the new drug approval authority, may be invoked to impose a requirement that the drug may be distributed only through specified channels and/or may be prescribed, dispensed, or administered only by physicians with specified qualifications.

(7) The package of the drug dispensed to the patient may be required to contain a package insert containing appropriate information for the safe and effective use of the drug by the layman.

(8) The approval of the new drug application may be revoked.

37 Fed. Reg. 16,504-05 (1972).

143 21 U.S.C. § 355(e) (1970).

144 *Id.* § 355(e)(1).

145 "Safety clause" refers to the phrase, "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," in 21 U.S.C. § 355(d) (1970).

American Pharmaceutical Association v. Weinberger.[146] There the court stated:

> The term "safe" is used in conjunction with the phrase "for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." When taken in this context, a determination of whether a drug is "safe" is premised on the drug's use in the "prescribed, recommended, or suggested" manner. Thus the context of the statute indicates that the term "safe" was intended to include only the inherent safety of the drug when used in the manner intended.[147]

An interpretation of section 505(e) consistent with this would preclude that provision's use in combatting the problem of nonapproved uses.

Notwithstanding the language of the FDCA, the Secretary has exercised his section 505(e) powers in a case where improper prescription posed a danger to public health. That case concerned the drug phenformin, an oral hypoglycemic used in the treatment of diabetes. This drug was indicated for adult-onset diabetics who were neither insulin-dependent nor able to reduce caloric intake. Soon after the drug was marketed in 1959, the FDA became aware of reports of fatal lactic acidosis among patients receiving the drug. From 1974 to 1976, the FDA received reports, through its voluntary reporting system, that 190 phenformin patients suffered from lactic acidosis. By 1976, the FDA had altered the drug's labeling four times to include relevant warnings. And in January 1977, the FDA further revised the labeling to limit the drug's indication to those patients whose symptomatic diabetes was unresponsive to diet and to other drugs. A "Dear Doctor" letter was sent to physicians by the manufacturer to warn them further of the dangers.[148] Despite these measures, the

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146 377 F. Supp. 824 (D.D.C. 1974), *aff'd per curiam, sub nom.* American Pharmaceutical Ass'n v. Mathews, 530 F.2d 1054 (D.C. Cir. 1976).

147 *Id.* at 828.

148 The regulatory history of phenformin is revealed in both the plaintiff's memorandum in support of and the government's memorandum in opposition to plaintiff's motion for preliminary injunction. Forsham v. Califano, 442 F. Supp. 203 (D.D.C. 1977). *See* 42 Fed. Reg. 23,170 (1977). *See also* Bengtsson, Karlberg & Lindgren, *Lactic Acidosis in Phenformin-Treated Diabetics,* 191 ACTA MEDICA SCANDINAVIA 203 (1972).

Secretary of HEW felt that the situation warranted more drastic action: acting pursuant to the imminent hazard clause contained in section 505(e), he suspended the NDA for phenformin on July 25, 1977.[149]

The Secretary recognized that a small patient population, numbering at most a few thousand, could benefit from the drug.[150] However, he determined that without a change in the existing distribution system, phenformin could not effectively be restricted to the relatively small number of patients whose special circumstances justified exposure to its risks.[151] In effect, the Secretary felt that if the FDA had simply altered the labeling so as to approve uses in only those few patients, physicians would continue to use the drug for conditions beyond those permitted in the labeling.[152] As a conse-

149 Department of Health, Education, & Welfare, in re New Drug Application for Phenformin, NDA 11-624; NDA 12-752; NDA 17-126; NDA 17-127, Order of the Secretary Suspending Approval (July 25, 1977) [hereinafter cited as Secretary's Order]. The imminent hazard provision permits the Secretary to suspend approval of an NDA temporarily, thereby removing the drug from the market for a period, when the drug represents an "imminent hazard to the public health." If this provision is invoked, however, the Secretary must grant the manufacturer an expeditious hearing. The issue at the hearing is whether the evidence of clinical experience not contained in such applications or not available until after such applications were approved shows that such drugs were not shown to be safe for use under the conditions of use on the basis of which the applications were approved. 21 U.S.C. § 355(e)(2) (1970); 42 Fed. Reg. 23,170 (1977).

150 This group can be defined as follows:

> 1) those who have difficulty administering insulin to themselves . . . and have no one available to assist them; or 2) those . . . whose occupations are such that they cannot be allowed to run the risk of hypoglycemic reaction to insulin (a shock reaction that may cause unconsciousness), and who also meet all of the following conditions:
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> (a) they have symptoms in addition to high blood sugar, such as excessive water intake and urine volume, changing vision, or genital and urinary tract infections;
>
> (b) they cannot use sulfonylureas (the only other oral anti-diabetic drug) . . .;
>
> (c) they do not have other conditions such as kidney impairment or cardiovascular diseases which increase the risk of lactic acidosis; and
>
> (d) their symptoms are controlled by a treatment program that includes phenformin.

Secretary's Order, *supra* note 149, at 13. It was argued that the drug's labeling as of January 1977, and the criteria defining who receives the drug outlined in the Secretary's order were in essence identical. *See* Plaintiffs' Memorandum in Support of a Preliminary Injunction at 3, Forsham v. Califano, 442 F. Supp. 203 (D.D.C. 1977).

151 Secretary's Order, *supra* note 149, at 55.

152 Statement of FDA Commissioner Donald Kennedy, Food and Drug Administration Ad Hoc Professional Meeting (Oct. 18, 1977).

quence, phenformin was withdrawn from the market for all patients.[153]

Although the FDA's authority to act as it did in the case of phenformin appears questionable, its motivation for considering the drug's safety in relation to nonapproved but prevalent uses is understandable. The FDA may be concerned that if it is limited to considering the safety of a drug only in relation to the approved uses, the language and contents of the drug's labeling would become critical. And since a drug's labeling can very often be written by a manufacturer so narrowly as to minimize any risk of withdrawal, regardless of the drug's overall safety, the FDA's power of withdrawal would become ineffective as a means of protecting the public from nonapproved uses.[154]

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153 The manufacturers of phenformin refused to agree either to a limited distribution system or to the FDA's definition of the proper patient population. *See* Government's Memorandum in Opposition to Plaintiffs' Motion for Preliminary Injunction and in Support of Government's Motion for Summary Judgment, Forsham v. Califano, 442 F. Supp. 203 (D.D.C. 1977) (plaintiffs unsuccessfully challenged the Secretary's imminent hazard order as "arbitrary and capricious").

154 The FDA, in its brief in American Pharmaceutical Ass'n v. Weinberger, *decided sub nom.* American Pharmaceutical Ass'n v. Mathews, 530 F.2d 1054 (D.C. Cir. 1976), discussed in the text accompanying note 146 *supra* and in notes 156 to 166 *infra*, gave several examples of how such an interpretation would limit its authority to protect the public. The first example given was thalidomide, an effective and beneficial tranquilizer. Its sole known risk is its power to cause birth defects when taken by pregnant women. If its labeling limited its use to men and to women not of childbearing age, the FDA would have to approve the drug's NDA as it would be "safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 355(d)(1) (1970). Of course, as a prescription drug there would be physician supervision of thalidomide's use. But the drug would still be available in all pharmacies and therefore there would be no guarantee that pregnant women did not take the drug in ignorance of the drug's hazard or of their own pregnancy.

A second example is methotrexate, which has been approved for use in cancer therapy and for severe, disabling psoriasis. Because of misuse, resulting in several deaths, the FDA has already revised the drug's labeling to add strongly worded warnings about the hazards of the drug. The FDA has intimated that, should the misuse continue, it would consider withdrawing the drug's NDA or limiting methotrexate's distribution. Neither of these options would be available under an interpretation of the FDCA which limits the FDA's consideration to the safety of the drug when used in the manner suggested on the drug's labeling. Reply Brief for Appellants at 6, American Pharmaceutical Ass'n v. Weinberger, *decided sub nom.* American Pharmaceutical Ass'n v. Mathews, 530 F.2d 1054 (D.C. Cir. 1976).

The FDA has claimed that it withdrew approval for injectable methamphetamine as well as the use of methadone as a cough suppressant not because the drugs were

Total withdrawal, however, seems an unsatisfactory solution to the problem of misuse. Withdrawal of a drug that has value to a certain patient population because the drug may be misused by a larger population in effect imposes an unfair hardship on those patients who could use the drug safely and profitably. Unfortunately, it appears that in cases like phenformin, the FDA presently has no effective remedy for widespread misuse other than total withdrawal.

B. *Limiting Distribution*

A related but less drastic measure suggested by the 1972 Proposed Regulation is the imposition of restrictive distribution schemes for certain drugs.[155] This approach to the problem would restrict access to a drug by specifying which outlets to the consumer are permitted to receive and distribute the drug. However, the FDA's only notable attempt at limiting the distribution of a drug was rebuffed in *American Pharmaceutical Association v. Weinberger.*[156]

That case involved regulations promulgated by the FDA that would have restricted the distribution of methadone for analgesic use.[157] The regulations allowed physicians to prescribe methadone for non-addicted out-patients,[158] because, as the FDA acknowledged, there are instances in which methadone would be the "drug of choice" for treating a patient in severe pain.[159] But manufacturers were prohibited from shipping the drug except to approved maintenance treatment programs, approved hospital pharmacies,[160] and

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unsafe when used in accordance with the labeling instructions, but because the drugs have a serious potential for misuse. Other reasons given for removal of injectable methamphetamine were risk of dependency and availability of safer and equally effective drugs. 38 Fed. Reg. 4250 (1973); 37 Fed. Reg. 26,790, 26,807 (1972).

155 *See* note 142 *supra.*

156 377 F. Supp. 824 (D.D.C. 1974), *aff'd sub nom.* American Pharmaceutical Ass'n v. Mathews, 530 F.2d 1054 (D.C. Cir. 1976).

157 21 C.F.R. § 130.44 (1973), *recodified at* 21 C.F.R. § 310.505 (1977), 39 Fed. Reg. 11,680 (1974).

158 21 C.F.R. § 130.44(f)(2)(i) (1973), *recodified at* 21 C.F.R. § 310.505(f)(2)(i) (1977), 39 Fed. Reg. 11,680 (1974).

159 21 C.F.R. § 130.44(f)(3)(i) (1973), *recodified at* 21 C.F.R. § 310.505(f)(2)(i) (1977), 39 Fed. Reg. 11,680 (1974).

160 21 C.F.R. § 130.44(j)(i) (1973), *recodified at* 21 C.F.R. § 310.505(j)(i) (1977), 39 Fed. Reg. 11,680 (1974).

those community pharmacies "in remote areas or in certain exceptional circumstances where there are no approved hospitals. . . ."[161]

The FDA argued that a drug must conform to the conditions which the agency requires as part of the new drug approval process. Those conditions, which usually deal with when, how, to whom, and in what quantity the drugs should be administered, are normally included in the package insert. For a drug which is subject to extensive diversion and misuse, however, adherence to those conditions would not assure that the drug is "safe for use" unless the distribution of that drug could also be controlled. Restricted distribution, the FDA concluded, could be considered a "condition" for the safe use of such a drug.[162]

The district court did not agree with the FDA's argument. It held that restrictions on distribution were "controls" and that the only "controls" permitted by the FDCA were those expressly stated in section 505(d)(3).[163] In addition, it construed the word "safe" to "include only the inherent safety of the drug when used in the manner intended."[164]

The Court of Appeals affirmed without opinion. Judge McGowan, in a concurring opinion, agreed with the lower court's interpretation of the word "safe" but dismissed the lower court's other reasons in a footnote.[165] He concurred in

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161 21 C.F.R. § 130.44(f)(4) (1973), which is no longer in the regulations. 21 C.F.R. § 310.505(j)(i) (1977), however, permits alternate methods of distribution in such areas.

162 Brief for Appellants at 21, American Pharmaceutical Ass'n v. Weinberger, *decided sub nom.* American Pharmaceutical Ass'n v. Mathews, 530 F.2d 1054 (D.C. Cir. 1976).

163 21 U.S.C. § 355(d)(3) (1970) reads: "If the Secretary finds . . . the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity . . . he shall issue an order refusing to approve the application."

164 377 F. Supp. at 828.

165 Regarding "controls," Judge McGowan stated:

> The first theory is that the explicit grant of authority in 21 U.S.C. § 355(d)(3) (1970) to consider "the methods used in, and the facilities and *controls* used for, the manufacture, processing, and packing of [a] drug" (emphasis supplied) as a basis for denying a new drug application creates a negative implication that the FDA lacks authority to consider the adequacy of *controls* on distribution of drugs after their production . . . . The apparent applicability of a canon of statutory construction is by itself a

the result largely because he recognized that the FDA's power was finite. If the FDA had the authority to implement post-marketing restrictions to assure the safe use of drugs, it could, by administrative regulation, promulgate its own regulatory scheme, possibly as complex as the Controlled Substances Act. Judge McGowan could not believe Congress intended to grant the FDA such sweeping authority.[166]

American Pharmaceutical Manufacturers v. Weinberger is not the last word on the FDA's authority under the present Act to invoke post-marketing controls. The FDA has established a system of post-marketing surveillance for the drug L-Dopa, which has been widely acclaimed and used for the treatment of patients with Parkinsonism. The FDA is convinced of the drug's safety and efficacy for short-term use, but studies on long-term use are not yet available. The FDA granted the drug conditional approval and instituted a Phase IV post-marketing surveillance system requiring the manufacturer to keep records on patients receiving the drug.[167]

Phase IV surveillance is currently limited to L-Dopa. For other drugs in less special circumstances, it appears that the

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thin reed to stand on; here, reliance on that canon obscures the fact that the controls on distribution contained in the proposed regulations are entirely different in nature from the controls on manufacture discussed in § 355(d)(3).

530 F.2d at 1055 n.1.

Regarding the encroachment upon the Controlled Substances Act's jurisdiction, he stated, "Whatever the limits of the FDA's authority under its own enabling legislation, there is simply an inadequate basis for concluding that the Controlled Substances Act implicitly repealed any authority that the FDA might possess to regulate the channels of drug distribution." *Id.*, citing 21 U.S.C. § 902 (1970) ("Nothing in this chapter . . . [the Controlled Substances Act] . . . shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act").

166 530 F.2d at 1056.

167 21 C.F.R. § 310.303 (1977) permits the FDA to promulgate rules requiring special long-term studies for drugs that "because of the nature of the condition for which they are intended, must be used for long periods of time — even a lifetime." The FDA used this provision to require long-term studies of L-Dopa. 21 C.F.R. § 310.304 (1977). In a few other instances, the FDA has required pharmaceutical companies to conduct additional studies as a condition of approval of an NDA. *See* Review Panel on New Drug Regulation, Interim Reports, Vol. III, Expansion of the FDA's Statutory Authority in the Postmarketing Period for New Drugs F1 (May 31, 1977); IND/NDA Study — Tolmetin, *supra* note 69.

FDA has accepted the judicial pronouncement that control of distribution is beyond its authority. That acceptance is not only implicit in its failure to institute other limited distribution schemes; it may also be implicit in its submission to Congress of a bill that would grant the FDA the power to limit the distribution of drugs.[168]

The FDA's underlying assumption in asserting the need for distribution requirements to curb improper prescription must be based on the belief that such behavior can be better controlled in certain institutions. Hospitals do have an important responsibility in structuring drug use review and adverse drug-reaction programs.[169] In addition, Medicare regulations require that hospitals have a utilization review program which may locate and correct the existing overuse, misuse, or underuse of services.[170] The existence of hospital drug review procedures undoubtedly exerts pressure on the hospital physician which the individual practitioner is not subject to.[171] However, if review is the only safeguard necessary to assure proper prescription, any physician, whether hospital-based or not, who is willing to be subjected to such review should be permitted access to those drugs that would require FDA control.

Compared with the two alternatives — total withdrawal or total approval — the FDA's suggestion that it be permitted to limit the distribution of certain drugs to certain hospitals or types of pharmacies would give the FDA added flexibility

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168 9 WASH. DRUG & DEVICE LETTER 1 (Dec. 9, 1977). Other legislation has been introduced that would permit such postmarketing controls, S.2697, § 405(a), 94th Cong., 1st Sess., 121 CONG. REC. 37,559 (1975). *See also* H.R. 11,617, § 104 (1976) *reprinted in Drug Safety Amendments of 1976: Hearings Before the Subcomm. on Health and Environment of the House Comm. on Interstate and Foreign Commerce*, 94th Cong., 2d Sess. 5 (1976).

169 *See* JOINT COMM. ON ACCREDITATION OF HOSPITALS, ACCREDITATION MANUAL FOR HOSPITALS 111, 145 (1976); Muller & Westheimer, *Formularies and Drug Standards in Metropolitan Hospitals*, 40 HOSPITALS 97 (1966). *See generally* F. Gross & W. Inman, DRUG MONITORING (1977).

170 STEWART, CLUFF & PHILP, *supra* note 12, at 21. The only specific requirement for drug monitoring under present Medicare and Medicaid regulations is for long-term care facilities. These institutions must require their pharmacists to review patient drug therapy at least once a month. 42 C.F.R. § 405.1127 (1974).

171 Wolfe, *The Social Responsibility of the Physician in Prescribing Mind-Affecting Drugs*, in SOCIAL ASPECTS OF THE MEDICAL USE OF PSYCHOTROPIC DRUGS 57 (R. Cooperstock ed. 1974).

in controlling the misuse of drugs. However, by limiting access to needed drugs in this manner, the FDA would be unfairly burdening those patients who do not have ready access to the institutions permitted to dispense controlled drugs. It can be argued in response that many persons who live in areas underserved by such approved institutions could go outside the community for medical care. But "there probably are geographic limits beyond which available services cannot usually be 'exported' or dispensed."[172] Thus, limiting distribution, like total withdrawal and the prohibition of nonapproved uses, would be at best a trade-off between the patients who would benefit from the prevention of drug misuse and the patients who would suffer from lack of access to efficacious drugs.

IV. MISBRANDING: THE SQUEEZE PLAY

Following the release of the 1972 Proposed Regulation, the FDA attempted a different approach to the improper use problem. It charged a physician who was widely prescribing a drug for a nonapproved use with misbranding.[173] While this approach is ingenious, the practice strains both the literal interpretation and the meaning of section 502, the misbranding provision of the FDCA.

A. *Section 502*

One of the acts prohibited in section 301 of the FDCA is the adulterating or misbranding of a drug.[174] Section 502 describes the various circumstances which will cause a drug

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172 R. FEIN, THE DOCTOR SHORTAGE: AN ECONOMIC DIAGNOSIS 72 (1967).

173 *See* note 184 and accompanying text *infra*.

174 21 U.S.C. § 331(a) (1970). That section reads: "The following acts and the causing thereof are hereby prohibited: . . . The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." Related prohibited acts found in that section include 21 U.S.C. § 331(c) (1970) (prohibiting the receipt or delivery in interstate commerce of any misbranded or adulterated food, drug, device, or cosmetic) and 21 U.S.C. § 331(k) (1970) (prohibiting, *inter alia*, the alteration and mutilation of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic while such article is held for sale after shipment in interstate commerce which results in such article being adulterated or misbranded).

to be deemed misbranded. Section 502(a) provides that a drug is misbranded if its labeling is false or misleading.[175] In addition, section 502(f) states that a drug is misbranded if its labeling fails to provide adequate directions for use under which a layman, with no medical background or assistance from a physician, can use the drug in a safe and intelligible manner,[176] or if it fails to warn against use in certain pathological conditions, by certain patient populations, or in unsafe amounts.[177] The purpose of these misbranding provisions is "to provide effective safeguards for the public in their use of such articles, by requiring that all drugs shipped in interstate commerce be labeled in such fashion that the consumer thereof shall be given all information reasonably necessary for the intelligent use of the drug in self-medication."[178]

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175 21 U.S.C. § 352 (1970), which states that "A drug or device shall be deemed to be misbranded — (a) If its labeling is false or misleading in any particular." The determination of whether such labeling is misleading must take into account whether the labeling fails to reveal material facts. 21 U.S.C. § 321(n) (1970) states:

> If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as customary or usual.

176 *See* 21 C.F.R. § 201.5 (1977). *See generally* Alberty Food Products v. United States, 194 F.2d 463, 464 (9th Cir. 1952).

177 21 U.S.C. § 352 (1970), which reads:

> A drug or device shall be deemed to be misbranded— . . .
>
> . . . .
>
> (f) Unless its labeling bears
>
> (1) adequate directions for use; and
>
> (2) such adequate warnings against
>
> use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: PROVIDED, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

178 *See* H. TOULMIN, THE LAW OF FOODS, DRUGS AND COSMETICS § 24.3 (1962), *citing* United States v. Various Quantities of Articles of Drugs, 83 F. Supp. 882, 885 (D.C. 1949).

Prescription drugs were initially subject to section 502 in its entirety. However, the Durham-Humphrey Amendments of 1951,[179] by adding section 503(b)(2), specifically exempted prescription drugs from section 502(f), which includes the "adequate directions for use" requirement.[180] But the court in *United States v. "Amodril Spancap"* has interpreted the section 503(b)(2) exemption as applying "solely at the time the drug is dispensed to the patient."[181] Thus, prescription drugs remain subject to the requirements of section 502(f) until that time.

Notwithstanding this interpretation of section 503(b)(2), prescription drugs are not typically held to the requirements specified in section 502(f), because section 502(f) itself permits the Secretary to waive the requirement of "adequate directions for use" when such directions are "not necessary for the protection of the public health."[182] A waiver is granted if the prescription drug meets certain conditions, among which is that the manufacturer include with the drug (in the package insert) information which would enable physicians licensed by law to administer the drug for safe use and for the purpose for which it is intended, including all purposes for which it is advertised and represented.[183]

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179 Act of Oct. 26, 1951, Pub. L. No. 215, 65 Stat. 648. *See* H.R. REP. NO. 700, 82d Cong., 1st Sess. (1951); S. REP. NO. 946, 82d Cong., 1st Sess. (1951).

180 21 U.S.C. § 353(b)(2) (1970) reads:

> Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p) of said section if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (l) of this subsection.

181 *See* United States v. An Article of Drug . . . Amodril Spancap, [1975 Transfer Binder] FOOD DRUG COS. L. REP. (CCH) ¶ 38,009, at 38,035 (S.D. Fla. 1974) (upholding FDA's interpretation of § 503(b)(2) exemption).

182 *See* note 177 *supra*.

183 21 C.F.R. § 201.100(c)(1)-(d)(1) (1977).

B. *Improper Prescription and Drug Use as Misbranding*

In one notable case the FDA has successfully maintained that the improper prescription of a human drug may result in a violation of section 502(f). In *United States v. An Article of Drug * * * Diso-tate,*[184] the FDA sought a preliminary injunction to prevent the defendants from administering disodium edetate (EDTA), calcium disodium edetate, and other chelating agents for the treatment of arteriosclerosis and related diseases.

EDTA's labeling states that the drug is indicated for use in the "emergency treatment of hypercalcemis [sic] and for the control of ventricular arrhythmias and heart block associated with digitalis toxicity. . . ."[185] The labeling also states that the drug is contraindicated for arteriosclerosis and warns that the drug should only be used when the clinical condition is severe enough, such as for the emergency treatment of hypercalcemia, to justify this aggressive type of therapy.[186] In the case at hand, in disregard of the labeling's warning, the defendant, a physician, used EDTA in the treatment of arteriosclerosis and actively advocated such a use.[187]

On the basis of the defendant's actions, the court concluded that EDTA had become misbranded. It stated that a prescription drug can be marketed only if it meets the re-

184 [1976-1977 Transfer Binder] FOOD DRUG COS. L. REP. (CCH) ¶ 38,086 (E.D. La. 1976).

185 *Id.* at 38,286.

186 *Id.* at 38,286. *See* 35 Fed. Reg. 437, 438 (1970).

187 The defendant was notorious for his use of EDTA in arteriosclerosis. He was on the staff of Columbia General Hospital in Alabama. After treating several patients with the drug for arteriosclerosis, the hospital drug committee voted to prohibit the use of the drug. The defendant resigned. He then became associated with Atlanta West Hospital in Georgia and began treating patients with EDTA therapy. After a general walkout by the professional staff in protest of the defendant's actions, the defendant again resigned. The defendant then purchased Meadowbrook Hospital. At a press conference the defendant stated that "he is a leading authority in EDTA use in arteriosclerosis . . .; he has treated over 8,000 such patients with over 160,000 doses of EDTA . . .; Meadowbrook attracts patients from all over the nation because it uses EDTA for arteriosclerosis . . .; use of the drug in disregard of the labeling contraindications and in a manner inconsistent with the uses for which the drug is approved is the doctor's choice." Plaintiff's Memorandum in Support of Opposition to Motion to Dismiss at 4-5, United States v. An Article of Drug . . . Diso-tate, *supra* note 184.

quirements of the FDA's labeling regulations.[188] One requirement is that the labeling contain information that would allow practitioners to "use the drug safely and for the purposes for which it is intended. . . ."[189] The court held that EDTA's labeling did not meet the FDA's requirements because it did not contain adequate directions for use in arteriosclerosis, which was the defendant's intended use here.

The misbranding charge brought in this case is, in the FDA's parlance, an example of a "squeeze play." The "squeeze" results because misbranding can occur in two ways:[190] it can occur either if the drug's labeling is "false and misleading" or if that labeling does not contain adequate information for every use of the drug.[191] A physician who prescribes for a nonapproved use is caught in a dilemma: any effort to avoid a misbranding charge brought on one ground subjects him to a misbranding charge brought on the other ground.

At the heart of the dilemma lie two principles. First, a drug's labeling must include a statement of every purpose for which a drug is intended to be used.[192] Second, adequate information for use (*e.g.*, how and to whom the drug is to be administered) must be listed in the labeling for every intended use of the drug.[193] It follows from these that if an intended use is not listed, or if adequate information for that use is not given in the labeling, the drug is misbranded.[194] However, the

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188 United States v. An Article of Drug . . . Diso-tate, *supra* note 184, at 38,287.

189 *Id.*

190 These are not the only ways that misbranding occurs. For other ways, *see* 21 U.S.C. § 352(a)-(n) (1970).

191 *See* notes 175 & 176 *supra*.

192 *See* United States v. Device Labeled "Cameron Spitler, Etc.," 261 F. Supp. 243, 245 (D. Neb. 1966). *Cf.* V.E. Irons, Inc. v. United States, 244 F.2d 34, 44 (1st Cir.), *cert. denied*, 354 U.S. 923 (1957); United States v. Hohensee, 243 F.2d 367, 370 (3d Cir.), *cert. denied*, 353 U.S. 976 (1957).

193 21 C.F.R. § 201.100 (1977) lists the information to be included in the package insert for all prescription drugs exempted from § 502(f) of the FDCA. This listing of "adequate information for use" must be distinguished from the "adequate direction for use" requirement of § 502(f). The latter is for the patient; the former is for the doctor.

194 *See* United States v. El-O-Pathic Pharmacy, 192 F.2d 62, 77 (9th Cir. 151); United States v. Grayce, Inc., 126 F. Supp. 6, 9 (N.D. Ind. 1954); 21 C.F.R. § 201.100 (c)(1) (1977) (quoted at note 6 *supra*).

drug is still misbranded if the one who intends the use adds that use, or the adequate information for such a use, to the label.[195] Because the added use or information had not been approved by the FDA, it would make the label "false and misleading."[196]

It is important to note, regarding this process, that a drug has an "intended use" because some person in the chain of distribution intends the drug to be used in the treatment of a particular disease or in a particular manner.[197] Therefore, anyone from the manufacturer to the physician may have an intended use. What use is intended by any particular person can be inferred from a variety of sources including newspaper articles, magazines, advertisements, oral representations, and speeches.[198]

The *Diso-tate* case provides an example of this process. There, the physician's intended use was determined, through the promotional literature that he distributed, to be arteriosclerosis. Because the drug's labeling did not contain adequate information for use in the treatment of arteriosclerosis, the drug was misbranded. If the physician had, without FDA approval, added to the labeling adequate

195 It is assumed that the addition is made without FDA approval. Such approval for the desired use could — indeed, it should — be sought, but this would mean a long delay, since the entire FDA investigatory process would have to precede approval.

196 *See* note 175 *supra.*

197 Only if a person who intends an alternative use has a legal responsibility to provide adequate information for the new use can the decision in the *Diso-tate* case be supported. This position is supported by 21 C.F.R. § 201.128 (1977), which states:

> The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller *is required to supply adequate labeling in accordance with the new intended uses* (emphasis added).

The Court in the *Diso-tate* case did not specifically assert this link in presenting its decision, but without this link the decision is unjustified. The labeling of the drug complied with the FDA's notice for all forms of EDTA when shipped in interstate commerce. *See* 35 Fed. Reg. 437 (1970); 39 Fed. Reg. 26,056 (1974). It could not have provided adequate information for use in treatment of arteriosclerosis because the drug, as the labeling stated, was specifically contraindicated for this use.

198 United States v. An Article . . . Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969); United States v. Millpax Inc., 313 F.2d 152, 154 (7th Cir.), *cert. denied*, 373 U.S. 903 (1963); Nature Food Centers Inc. v. United States, 310 F.2d 67, 69 (1st Cir. 1962), *cert. denied*, 371 U.S. 968 (1963).

information for use in arteriosclerosis, the drug would still have been misbranded because the label would be false and misleading, as arteriosclerosis is not an FDA-approved use for EDTA.

However, the FDA's labeling requirements for prescription drugs are intended to provide adequate information for use only to the physician;[199] under section 503 prescription-drug labeling is not required to provide adequate directions for the patient.[200] Yet, in the *Diso-tate* case, it was the physician who changed the original intended use and failed to provide the adequate information for the new use. Since the information need not have been directed to the patient in this case, the court's decision amounted to the imposition of the nonsensical requirement that the physician provide *himself* with adequate information.[201]

A recent court decision regarding the scope of the section 503 exemption may make the *Diso-tate* court's decision appear more rational. In *Pharmaceutical Manufacturers Association v. FDA* (the *PMA* case),[202] the plaintiff challenged the FDA's regulations requiring labeling directions to patients when estrogen, a prescription drug, was dispensed. The court agreed with the plaintiff's argument that section 503 on its face grants an exemption to prescription drugs from the "adequate directions for use" requirements, but it ultimately ruled for the FDA.

The FDA could not single out a statutory provision to support its argument. It cited sections 505, 502(a), and 201(n) for the proposition that drugs must be safe and their labeling not misleading,[203] and then argued that the cited provisions overrode the negative implication of section 503's exemption.[204]

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199 *See* note 183 and accompanying text *supra.*

200 *See* note 180 and accompanying text *supra.*

201 If the physician were promoting a new use among physicians, the result requiring him to provide adequate information for the new use would be logical.

202 [1977-1978 Transfer Binder] FOOD DRUG COS. L. REP. (CCH) ¶ 38,130 (D. Del. 1977).

203 *See* notes 175 to 178 and accompanying text *supra.*

204 40 Fed. Reg. 15,394 (1975). Neither the FDA nor the court in the *PMA* case relied on § 502(f) in defending the use of patient inserts. The plaintiff in that case, however, argued that the § 503(b)(2) exemption of prescription drugs from § 502(f)

Section 503's exemption has two purposes: it prevents self-diagnosis and self-treatment by the patient, and it protects the pharmacist who relies "in good faith on the directions for use and warnings provided by the manufacturer or physician."[205] The court agreed with the FDA's assertion that section 503 was not intended to diminish the FDA's continued role in requiring wide dissemination of information that certain prescription drugs are hazardous. Thus, perhaps physicians who change the intended use are meant to provide adequate information regarding that use, including warnings that the use is not FDA-approved, to the patient.

Even if the charge of misbranding can be maintained against a physician in the face of section 503's exemption, the wisdom of doing so is questionable. The consequence of the FDA's approach in the *Diso-tate* case is that any use of a drug other than those specifically listed in its labeling could be susceptible to a charge of misbranding. However, the propriety of such action rests on the questionable assumption that the labeling always represents the proper standard of medical care.[206] A slightly better approach to the problem might be for the FDA to limit its use of the misbranding sanction to cases in which a physician has prescribed in disregard of a warning or in disregard of the drug's labeling where it has specifically stated that the drug was contraindicated, as in the *Diso-tate* case. However, since many warnings on drug labels may be "unsubstantiated, unexplained, and frivolous,"[207] this modified approach too would do little to cure the deficiencies of the FDA's use of the misbranding sanction.

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was evidence of congressional intent that those drugs need not carry information for consumers. Brief in Support of Motion for Preliminary Injunction at 24-37, Pharmaceutical Manufacturers Ass'n v. FDA, *supra* note 202.

205 [1977-1978 Transfer Binder] FOOD DRUG COS. L. REP. (CCH) ¶ 38,130, at 38,462.

206 For the reasons why the package insert should not be treated as establishing the proper standard for medical care, *see* notes 106 to 115 and accompanying text *supra*.

207 Archer, *A Guide Into Chaos: Resist It*, 227 J.A.M.A. 1397, 1398 (1974).

C. *Patient Labeling*

Until recently, the FDA had not considered the possibility of using the patient insert as a mechanism for deterring improper use.[208] But in 1976, the FDA announced that it would develop a general policy regarding the use of patient labeling.[209] Following that announcement, the FDA's use of the patient insert to accompany prescription drugs was upheld in the *PMA* case.[210]

Patient labeling can accomplish three important purposes.[211] First, it can serve to increase patient autonomy. In instances where the risk-benefit assessment fails to yield a clear answer as to a drug's therapeutic value, involving the patient in the decision-making process may contribute to the quality of the care that is delivered. Second, patient labeling can convey warnings that will assure greater safety and educate the patient toward proper compliance with the therapeutic regimen. Third, it can help to curb the improper prescription of drugs by physicians.

However, developing an insert that is effective in dealing with this problem is not an easy task. If the physician dispenses the insert with the drug, unwarranted inferences of improper prescription in the insert could create needless tension between doctor and patient. In any case, patient apathy, especially among the poorly educated, may limit the insert's usefulness. Unfortunately, empirical evidence may show that it is the disadvantaged or apathetic patients who are the most vulnerable to receiving improperly prescribed drugs.[212]

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208 Review Panel on New Drug Regulation, *supra* note 107, at 451.

209 *Hearings on Competitive Problems, supra* note 7, at 14,589.

210 Pharmaceutical Manufacturers Ass'n v. FDA, *supra* note 202.

211 *See generally* Ryan, *The FDA and the Practice of Medicine*, 297 NEW ENG. J. MED. 1287 (1977); Letter from R. Dorsey to the Editor, *Patient Package Inserts*, 298 NEW ENG. J. MED. 573 (1978) (reply to Ryan); Fink, *Therapeutic Liabilities: Package Insert*, 6 DRUG THERAPY 140 (1976); Agresta, *Package Inserts for Patients — Asking for Trouble?* CURRENT PRESCRIBING, Mar. 1977, at 17; Morris, *Patient Package Inserts: A New Tool for Patient Education*, 92 PUB. HEALTH REP. 421 (1977).

212 Wolfe, *supra* note 171, at 57. *See generally* Joubert, *Patient Package Inserts: Toward a Rational Package Insert*, 18 CLINICAL PHARMACOLOGY & THERAPEUTICS 663 (1975).

Whether requiring patient package inserts will actually have any beneficial effects is not clear. The FDA itself has recognized that "with the present state of knowledge it is impossible to predict accurately the influence that patient labeling will have or adherence to agreed medication regimens."[213]

If patient labeling will be required of only some prescription drugs, then those drugs that are prone to abuse and misuse must receive priority. However, it is likely that many patients will develop psychosomatic side-effects following extensive disclosure.[214] As one commentator has stated, "Most of the remedies . . . to reduce iatrogenesis include a further increase of medical controls. These so-called remedies generate second-order iatrogenic ills. . . ."[215]

V. Disapproving Particular Uses: A Proposal

A. *General Principles*

This article has analyzed several potential solutions to the improper prescription problem and has found them lacking, first because they ignore the therapeutic needs of patients unaffected by improper prescriptions and second, because each solution would result in considerable interference with the practice of medicine. An alternative proposal to control improper prescription which does not suffer these faults must therefore be developed. One solution is to permit the FDA to disapprove particular uses of a drug.

With the exception of withdrawal and limited distribution, the approaches previously discussed rely on the package insert and the uses approved therein to discriminate between the patients allowed to have access to the drug and the patients to be denied access. Yet under every proposal advanced to date, the patient population to be denied access includes patients who would benefit from the drug involved. This criticism most clearly applies to the withdrawal ap-

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213 42 Fed. Reg. 37,639 (1977).

214 Reply Brief in Support of Motion for Preliminary Injunction at 7, Pharmaceutical Manufacturers Ass'n v. FDA, *supra* note 202 (quoting Brief of American Society of Internal Medicine in Support of Motion to Intervene as Plaintiff at 3, Pharmaceutical Manufacturers Ass'n v. FDA, *supra* note 202).

215 I. Illich, Medical Nemesis: The Expropriation of Health 271 (1976).

proaches,[216] but it applies as well to those approaches which rely on the approval of uses in the package insert. In the latter approaches, many proper uses are never approved for reasons other than the drug's safety and efficacy for those uses.[217] A more refined determination of access is needed, one which would grant or deny access based on the propriety of the use intended. Such a factor is incorporated in the proposal to disapprove particular uses; that is, a use which represents a danger to a patient's health could be disapproved and thus prohibited.

It is also important that any solution to the problem involve only a minimum of interference with medical practice and judgment. The legislative history of both the Food, Drug, and Cosmetic Act and the 1962 Drug Amendments makes it clear that Congress did not intend to regulate medical judgment.[218] Statements such as the following, concerning the FDA's function, indicate the congressional intent. "[T]he . . . [FDCA] should not interfere with the professional function of the physician. FDA clearance would assure physicians that a drug *effectively* produces certain physiological actions, but the physician, not the FDA, would determine whether these specific physiological effects would be *useful or beneficial* with respect to particular patients."[219] The cholesterol-lowering drugs provide an example of the distinction drawn here. These agents effectively lower blood cholesterol, a physiological action.[220] But each physician will have to decide whether this effect is desirable for the treatment of any particular disease, *e.g.*, for the treatment of cardiovascular disease.[221]

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216 *See* notes 150 to 153 and accompanying text *supra*.

217 *See* notes 106 to 115 and accompanying text *supra*.

218 The sponsor of the 1938 Federal Food, Drug, and Cosmetic Act, in response to the concerns of the medical community that the Act would interfere with the "prerogatives of the doctor," stated that the revised bill "makes certain that the medical practitioner shall not be interfered with in his practice." 78 CONG. REC. 2728 (1934) (statement of Senator Copeland); C. DUNN, FEDERAL FOOD DRUG AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD 90 (1938).

219 S. REP. NO. 1552, 87th Cong., 2d Sess. 1998 (1962) (emphasis added).

220 A. GOTH, MEDICAL PHARMACOLOGY 441 (1974).

221 Conference on the Philosophy and Technology of Drug Assessment, *The*

This congressional view of the FDCA and the FDA's function is somewhat unrealistic. The FDA cannot accurately evaluate all drugs on the basis of their physiological action, for not all drugs have effects independent of any particular patient. Because most drugs are safe only for specific patient-populations, the FDA can fulfill its statutory obligations only by specifying that group of patients for which the drug is safe. In doing so, the FDA is, in effect, substituting its judgment for that of the medical community. In addition, FDA decisions regarding the availability of specific drugs for medical use also have an enormous impact on the medical profession. Consequently, some interference with medical practice must occur if the safety and efficacy of drugs is to be assured.

Nonetheless, congressional intent should be effectuated as much as possible. Proposals which would prohibit all nonapproved uses involve maximum, not minimum, interference with medical practice by severely restricting a physician's choice of uses. A more appropriate solution would remove from the physician's consideration only demonstrably harmful uses.

This less restrictive approach would, in addition, have a greater chance of surviving judicial scrutiny. There is unquestionably some judicial recognition of a state-licensed physician's constitutional right to be free from federal intrusion.[222] Whether derived from the substantive due process protection of liberty or from the right of privacy, the "professional judgment" of the physician has been safeguarded by the courts.[223] Since a constitutional right is involved, the

Philosophy of Evidence, in 3 PHILOSOPHY AND TECHNOLOGY OF DRUG ASSESSMENT 45 (J. Cooper ed. 1971).

222 Linder v. United States, 268 U.S. 5, 18 (1925) ("direct control of medical practice in the State is beyond the power of the federal government"); Schlessing v. United States, 239 F.2d 885, 886 (9th Cir. 1956) (the agency "has no jurisdiction or authority to attempt to regulate the practice of medicine"). *See* Dent v. West Virginia, 129 U.S. 114, 122-23 (1889); Doe v. Bolton, 410 U.S. 179, 196-97 (1973).

223 It may be that the physicians' "professional judgment" receives no protection in and of itself. As the court in the *PMA* case recognized, physicians may have only the "derivative rights which have been accorded to physicians in order to secure a patient's right to secure the treatment of his or her choice. These derivative rights are limited by the patient rights from which they spring." [1977-1978 Transfer Binder] FOOD DRUG COS. L. REP. (CCH) ¶ 38,130, at 38,459 n.7.

FDA would be well advised to exercise its regulatory authority cautiously in order to avoid an unfavorable judicial response.

B. *Implementation of the Disapproval Process*

1. The Process

An explanation of the proposed disapproval process requires consideration of the standard for disapproval, the allocation of burdens of proof during judicial review, and the means of enforcement available to achieve compliance with a disapproval.

An appropriate standard would permit the disapproval of a particular use of a drug only if there is a reasonable belief that harm will occur from that use.[224] "Harm" generally refers to safety alone, but in certain instances, it should also refer to an interaction of safety and efficacy. The use of ineffective but superficially harmless drugs in life-threatening situations where effective drugs are available should come within the meaning of "harm."[225] This standard requires affirmative evidence that the drug has the potential for harm in the particular use being considered. The allegation that a drug has not been shown to be safe should not be sufficient to justify disapproval, although it is presently sufficient to deny the approval of or to withdraw an NDA.[226]

Implicit in establishing a standard for disapproval are two questions: How is "harm" to be measured? And how much

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224 This suggested standard is a strict one. It is similar to the standard set by the imminent hazard clause in § 505(e)(4) of the FDCA; 21 U.S.C. § 355(e)(4) (1970). Contrasted with the safety clauses, the imminent hazard clause is an extraordinary provision; it allows withdrawal even before the holding of an administrative hearing. Because the normal hearing provision is bypassed, the imminent hazard provision requires a greater showing of damage than the safety clause. For withdrawal, the safety clause requires only that the drug no longer be shown to be safe; it can thus be viewed as precautionary in protecting the public health. The imminent hazard clause, while generally not requiring a crisis situation, can be invoked only if a substantial likelihood exists that serious harm will occur. [1977-1978 Transfer Binder] FOOD DRUG COS. L. REP. (CCH) ¶ 38,130, at 38,453

225 *See* Comment, *Government Regulation of Health Care, Drugs of Questionable Efficacy*, 14 SAN DIEGO L. REV. 378 (1977).

226 21 U.S.C. § 355(e)(2) (1970).

"harm" is enough to prompt disapproval? The FDA has answered questions similar to these with respect to the effectiveness of drugs,[227] but no such answers exist with respect to the safety of drugs.[228] While it has been argued that the determination of safety is inherently discretionary or judgmental,[229] HEW's analysis of the drug phenformin suggests that guidelines for safety may not be impossible to establish. The order which banned phenformin articulated the specific criteria used to assess the harm posed by that drug.[230] The order suggests that harm can be measured by the number of deaths per thousand patients who used the drug. The FDA estimated that the incidence of death due to lactic acidosis in phenformin users was between 0.125 and 2 deaths per 1,000 patients annually,[231] and the Secretary's order contrasted this incidence with the incidence of death from other drugs — for example, death resulting from penicillin anaphalaxis occurred in approximately 0.02 patients per 1,000 treated.[232] The FDA's calculation of the sufficiency of the harm in the phenformin case, which resulted in the drug's withdrawal, must also have included a determination of the benefits to be derived from the use of the drug. The fact that these benefits may not be quantifiable, as the corresponding risks are, poses a problem, but there is no alternative to balancing benefits and risks.

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227 21 C.F.R. § 314.111(a)(5) (1977).

228 *See* Memorandum of Ciba-Geigy Corporation in Support of its Request for a Hearing in Connection with the Proposed Withdrawal of the New Drug Applications for Phenformin Hydrochloride at 52, FDA Docket No. 77N-0150 (July 19, 1977). The FDA admits that neither the Act nor any existing FDA regulations provides concrete guidelines for determining "safety." Bureau of Drugs' Memorandum In Opposition to Manufacturers' Requests for a Hearing Before a Public Board of Inquiry at 3, FDA Docket No. 77N-0150 (August 26, 1977).

229 *Id.*

230 Secretary's Order, *supra* note 149, at 36.

231 *Id.* at 42.

232 *Id.* at 43-44. Such quantification is not without difficulties. It is a mere estimate of the risk posed by such a drug, and morbidity rather than mortality may be more significant for proper regulatory action. Furthermore, the benefit derived from a drug may defy the objective measurements applicable to risks. As the Order stated, the incidence calculations "reflected many assumptions about the size of the population . . ., the correctness of diagnosis and the accuracy of reporting." *Id.* at 45.

The proper allocation of the burden of proof[233] requires special attention in light of the large degree of scientific uncertainty and controversy that surrounds many of the potential toxicities of human drugs.[234] The approval and withdrawal provisions can provide examples of ways to allocate the burden of proof.

The New Drug Provisions have always placed the burden of proof on the manufacturer of a new compound.[235] In contrast, the withdrawal provisions, prior to 1962, required the FDA to show that the drug was unsafe.[236] In 1962, Congress amended these provisions to require only that the FDA establish that the new drug was no longer shown to be safe.[237] This charge leaves the FDA with an easier burden than it had before, but even under this less stringent standard, the FDA has the initial burden, which requires the FDA to produce some

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233 The term "burden of proof" here is synonymous with the "burden of nonpersuasion." J. WIGMORE, 9 EVIDENCE § 2485 (3d ed. 1940).

234 For a discussion of the proper allocation of the burden of proof in the face of scientific uncertainty, especially in environmental litigation involving toxic chemicals, *see* Williams, *Law and the Environment*, 3 OTAGO L. REV. 372,383(1975); Hoffman & Swartz, *Environmental Law*, [1974/1975] ANN. SURVEY AM. L. 641,659 (1975); Krier, *Environmental Litigation and the Burden of Proof*, in LAW AND THE ENVIRONMENT (M. Baldwin & J. Page ed. 1970); NATIONAL ACADEMY OF SCIENCES, DECISION-MAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT 86 (1975); Ashford, Legal and Socio-Economic Implications of Chemical Carcinogens, *reprinted in Toxic Substances Control Act: Hearings Before the Subcomm. on Consumer Protection & Finance of the House Comm. on Interstate & Foreign Commerce*, 94th Cong., 1st Sess. 165 (1975); Case Note, *Environmental Defense Fund, Inc. v. EPA*, 25 CATH. U.L. REV. 178, 184 (1975); Gelpe & Tarlock, *The Uses of Scientific Information in Environmental Decision Making*, 48 S. CAL. L. REV. 371, 384 (1974).

235 Allocating the burden to the manufacturer, although not specifically set forth in the FDCA, is supported by the Administrative Procedure Act (APA). Section 7(d) of the APA, 5 U.S.C. § 556(d) (1970), states "Except as otherwise provided by statute the proponent of a rule or order has the burden of proof." Since the statute requires the manufacturer to petition for approval of an additive, the manufacturer is the proponent of such a regulation.

The situation may be different when a product suspected of being hazardous is already on the market. The FDA is the proponent of the regulation withdrawing approval of an NDA. The burden thus shifts to the FDA under the APA. *See* Bell v. Goddard, 366 F.2d 177, 181 (7th Cir. 1966); USV Pharmaceutical Corp. v. Secretary of Health, Education, and Welfare, 466 F.2d 455, 461 (D.C. Cir. 1972), *aff'd*, 412 U.S. 655 (1973).

236 Federal Food, Drug and Cosmetic Act, ch. 675, § 505(e), 52 Stat. 1040 (1938).

237 21 U.S.C. § 355(e)(2) (1970). The previous standard, requiring that the government show the drug to be unsafe, remains in the Act as an alternate provision. 21 U.S.C. § 355(e)(1) (1970).

evidence to warrant its suspicion that harm will occur from use of a drug.[238]

If the FDA is given the same burden for the disapproval process as it has for the withdrawal process — it must show initially that the manufacturer has not shown that harm will not occur — the use of the disapproval process would be properly restricted.[239] Such restriction would prevent unnecessary interference with medical practice. A more stringent burden, requiring the FDA to demonstrate that a particular use is unsafe, could be imposed. But requiring the more demanding standard may drastically overburden the FDA; it would be forced to extensively test the large number of drugs thought to present a hazard.

The final element of the disapproval process to be considered is the means available to the FDA to enforce its actions. The FDA, with its resources limited and presently devoted in many directions, could not be expected to enforce any scheme that involved the monitoring of every physician in the nation. But direct action of this sort by the FDA may not be necessary.

Each disapproval of a use must be communicated to the practicing physician, and the communication must be accompanied by sufficient emphasis to bring the importance of the disapproval to the physician's attention. The package insert

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238 On nearly identical facts two courts of appeals disagreed on whether the FDA had met its initial burden. The Seventh Circuit in Bell v. Goddard, 366 F.2d 777 (7th Cir. 1966), upheld the FDA's order withdrawing approval of the petitioner's NDA under § 505(e); the court found that the use of the chemical DES in poultry production was unsafe. At the time of *Bell,* DES was a known carcinogen. 366 F.2d at 180. While residues were found in the slaughtered chickens, there was no evidence that the residues were in fact DES. In upholding the FDA order, the Court placed no requirement on the FDA to characterize those residues or establish that the residues, in addition to the drugs, were carcinogenic.

However, such a requirement was placed on the FDA in Hess & Clark, Division of Rhodia, Inc. v. FDA, 495 F.2d 975, 993 (D.C. Cir. 1974). The court in *Hess & Clark* reviewed the orders of the FDA withdrawing approval of DES implants for use in cattle and held that the FDA had failed to meet its statutory burden under the general safety clause theory. The withdrawal in *Hess & Clark* was brought pursuant to the post-1962 statute requiring only a showing that the substance was no longer shown to be safe. Ironically, *Bell* was brought under the predecessor statute imposing the much more stringent requirement that the government prove the drug to be unsafe.

239 If the FDA meets its burden, the manufacturer must then prove that no reasonable belief that harm will occur could exist.

is not the proper vehicle for this task, because it already lists many warnings that would divert attention from the significance of the disapproved use. Rather, an official compendium of disapproved uses distributed to every physician is required.[240]

If the disapprovals are adequately communicated and emphasized, and a respect for the FDA's prudent use of the process is developed, a significant degree of compliance will voluntarily result. Many physicians will comply largely because of a concern for their patients' health and welfare. However, others will comply because of the threat of adverse publicity from the FDA, the fear of which motivates much of the compliance with present FDA regulations and rulings.[241]

An additional motivating factor is the fear of medical malpractice litigation. Increased attention has recently focused on the status of package inserts as evidence of the standard of care in medical malpractice litigation.[242] If the FDA stresses the importance of its disapproval statements because of their scientific reliability, these statements could also become important evidence in establishing the standard of care in such litigation.

2. Limitations

The proposed disapproval of particular uses is not without problems of its own. Both the proposed FDA approval of uses and disapproval of uses restrict the uses of drugs from which a physician may choose, but they do restrict in opposite ways: the former does so by recommending a specific group of uses, while the latter does so by eliminating a specific group. Instead of approving uses, therefore, the FDA could

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240 S. 629, 95th Cong., 1st Sess., 123 CONG. REC. S2320 (daily ed. Feb. 4, 1977), would establish a national compendium of drugs.

241 Pines, *Regulatory Letters, Publicity and Recalls*, 31 FOOD, DRUG, COSM. L.J. 352 (1976); Lambert, *Recalls, Regulatory Letters and Publicity — Quasi-Statutory Remedies*, 31 FOOD DRUG COSM. L.J. 360 (1976).

242 *E.g.*, Comment, *Package Inserts for Prescription Drugs as Evidence in Medical Malpractice Suits*, 44 U. CHI. L. REV. 398 (1977).

achieve substantially the same result, the same specific group of uses, by disapproving uses. Yet, it is just this sort of interference with medical practice which is sought to be avoided by the adoption of the disapproval process.

It must be recognized that broad authority to disapprove may, in some cases, be necessary. For example, in the case of an extremely toxic drug, regarded as unsafe in most circumstances, adequate public protection would require disapproval for all indications except in life-threatening situations. It is hoped that the standard for disapproving uses will strike the proper balance between drugs requiring wide disapproval and those drugs not subject to such a need. Requiring the FDA to establish that it reasonably believes harm will occur in all but a few uses imposes a burden difficult to meet except in a situation in which the FDA is confronted with an extremely hazardous compound.

A second difficulty with disapproval arises because propriety of use, although a more refined standard than that used for approval, may not be sufficient alone in all cases. There are circumstances in which patients may benefit from an otherwise improper use if the drug is used in conjunction with other therapies and precautions. For example, the safety of amphetamines in the treatment of obesity is controversial in view of the drug's addictive potential. But if the drug is used in association with a weight reduction regimen and in such a fashion as to minimize drug habituation, the use is less controversial and potentially quite proper.[243] Unfortunately, in cases such as this, where additional restrictions may be necessary to meet the needs of patients threatened by improper prescription who could benefit from the use, the additional restrictions would further blur the distinction between approving uses and disapproving uses, and would constitute a major interference with medical practice.

The third difficulty is that, for many drugs, disapproval of particular uses would not occur until after the drug is on the

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243 H. CONN, CURRENT THERAPY 447 (1978).

market. While preclearance testing may uncover some conditions for which the drug is unsafe, in many instances such dangers will only become evident after the drug is widely used. An effective monitoring procedure to detect improper use is therefore required. But, at present, the FDA must rely on voluntary reports of adverse drug reactions, a system which has obvious limitations.[244] However, Congress is presently considering proposals which would grant conditional approval to new drugs for a limited period of time, to provide a period for adequate observation for potential misuse.[245] In any case, when information on misuse is received, the disapproval of particular drug uses is the most appropriate measure to take.

The final difficulty is that the disapproval procedure appears to require new legislation. Although total withdrawal is currently permitted, no provision in the FDCA specifically grants the necessary authority for disapproval. Partial withdrawal, *i.e.*, the removal of only certain indications, would seem a more moderate regulatory action than total withdrawal, one that could be inferred from the statute and permitted under the FDA's broad rulemaking authority. In addition, if each new indication of a drug is in fact treated as a statutory "new drug," withdrawal of a new drug under section 505(e) may permit disapproval for a particular indication.[246]

However, several implications of this line of reasoning are unacceptable. First, the treatment of a new use as a "new drug" results in requiring an NDA for each indication if that term is to have consistent meaning within section 505. This treatment, in turn, leads to approval of uses, an approach

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244 3 Review Panel on New Drug Regulation, Interim Reports E1 (May 31, 1977). *See* The Commissioner's Report of Investigation of Charges from Joint Hearings of the Subcomm. on Health of the Senate Labor and Public Welfare Comm. and the Subcomm. on Administrative Practice and Procedure of the Senate Judiciary Comm., Aug. 15-16, 1974, at 559 (Oct. 24, 1975).

245 A proposed Phase IV provides for a conditional period in the drug approval procedure, during which time an opportunity would exist for observation of misuse. WASH. DRUG & DEVICE LETTER, *supra* note 136, at 2.

246 *See* notes 76 to 87 and accompanying text *supra*.

earlier rejected. Second, if the procedure were derived from the present Act, without more, it would have to use the standards set out in the withdrawal provision and could not use the standard suggested here as most appropriate. Therefore, an effective disapproval procedure would require new and explicit legislation.

NOTE

TARGET MANAGEMENT AND TENDER OFFERS: PROPOSALS FOR STRUCTURING THE FIDUCIARY RELATIONSHIP

ROBERT S. OSBORNE*

As advertisements on the financial pages of current newspapers attest, the American economy is in the midst of a tender offer craze. The flurry of takeover activity has generated speculation and confusion among economists and investors, who question the health of the economy. Yet no one could be more confused than the individual who owns shares of the target company. Out of necessity, the individual shareholder turns to the target management for guidance in analyzing the offer.

Although Congress amended the securities laws in 1968 and 1970 to protect shareholders confronted with a tender offer bid, the guidance that an individual may expect from the target management may never be forthcoming. As Mr. Osborne points out, neither federal law nor state law requires the target management to evaluate the offer, to take a stand, or even to share information in the company files. When management adopts a tactical silence or offers perfunctory opposition, shareholders are left uninformed and unprotected. Mr. Osborne proposes to remedy this gap in the federal regulatory scheme by obligating target management to investigate the offer, to recommend a response, and to disclose material information during a minimum offer period.

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Introduction

A tender offer[1] for the shares of a company is a dramatic event in its corporate life.[2] The course of action that management adopts in responding to a takeover bid may be the single most important factor affecting the offer's success.[3] A tender offer frequently places the officers and directors of the target company in a "fiduciary dilemma," because the self-interest of the target's officers and directors will often diverge from that of the shareholders for whom they are fiduciaries.[4] The tender offer may thus crystallize the tension between managers and owners that is a common undercurrent in today's corporate world.[5]

Federal[6] and state[7] securities laws currently subject par-

1 The term "tender offer" is not defined by federal legislation. A tender offer is generally understood to refer to a public invitation made to all the holders of a class of stock of a corporation to sell their shares to the offeror at a particular price. Typically, the price offered represents a premium over the market price, and the opportunity to tender is limited to a period of about two weeks. *See generally* Note, *The Developing Meaning of "Tender Offer" Under the Securities Exchange Act of 1934,* 86 HARV. L. REV. 1250 (1973); Aranow & Einhorn, *Essential Ingredients of the Cash Tender Invitation,* 27 BUS. LAW. 415 (1972); Comment, *Regulation of Contested Cash Tender Offers,* 46 TEX. L. REV. 915 (1968). The proposed Federal Securities Code defines a tender offer as "an offer to buy a security, or a solicitation of an offer to sell a security, that is directed to more than thirty-five persons," with certain specified exceptions. ALI FED. SEC. CODE § 299.68 (Proposed Official Draft 1978).

Although the term "tender offer" is often used to cover exchange offers as well as cash tender offers, this Note deals only with cash tender offers. *See* note 18 *infra.*

2 *See generally* Fleischer & Mundheim, *Corporate Acquisition by Tender Offer,* 115 U. PA. L. REV. 317, 354 (1967); Krasik, *Tender Offers: The Target Company's Duty of Disclosure,* 25 BUS. LAW. 455, 470 (1970).

3 A study of 18 cash tender offers made during the first 6 months of 1967 revealed that only 2 of the 10 contested offers succeeded, while all of the 8 uncontested offers were successful. Comment, *Economic Realities of Cash Tender Offers,* 20 ME. L. REV. 237, 243, 247 (1968); *see* Note, *A Proposal for Affirmative Disclosure by Target Management During Tender Offers,* 75 COLUM. L. REV. 190, 206 (1975) [hereinafter cited as *Affirmative Disclosure*].

4 Management's position after a takeover is usually insecure. The offeror often makes a tender offer because it perceives that the target's financial difficulties are attributable to incumbent management, which it intends to replace after the acquisition. Gulf & W. Indus., Inc. v. Great Atl. & Pac. Tea Co., 476 F.2d 687, 697 (2d Cir. 1973) (deposition of Charles Bluhdorn, president of Gulf & Western Industries).

5 *See generally* W. CARY, CASES AND MATERIALS ON CORPORATIONS 229-34, 237-49 (4th ed. 1969).

6 The provisions of primary significance in this Note are §§ 14(d) and 14(e) of the Securities Exchange Act of 1934, 15 U.S.C. § 78n(d), (e) (1976) [hereinafter cited as the Exchange Act]. Section 13(d) of the Exchange Act, 15 U.S.C. § 78m(d) (1976), which requires disclosure by a person or group acquiring beneficial ownership of more than 5 percent of a company's stock, is also of importance to the offeror and target companies in tender offer contests.

7 *See, e.g.,* DEL. CODE ANN. tit. 8, § 203 (Supp. 1978); MASS. GEN. LAWS ANN. ch.

ticipants in tender offers to extensive regulation. Management of the target company may nevertheless avoid regulation and the responsibilities of disclosure by responding to a tender offer with either "tactical silence"[8] or "knee-jerk" opposition.[9] If management makes either of these responses, the shareholders will often be unable to make a reasoned decision in considering the tender offer. Thus, as this Note will suggest, the present legislation does not reach far enough in structuring the appropriate relationship between the managers of target corporations and their shareholders.

Although the Williams amendments of 1968 and 1970 (Williams Act)[10] did much to bring security and integrity to takeover contests, the legislation studiously avoided placing affirmative obligations on the managers of tender offer targets.[11] In passing the Williams Act, Congress decided correctly that the disruption caused by a takeover bid calls for the imposition of unusual burdens to protect the interests of shareholders and the integrity of the securities markets.[12] Since the decision to regulate has been made, the regulatory scheme should fulfill its objectives as effectively and effi-

110C, §§ 1-13 (West Supp. 1977). Twenty-one other states had takeover legislation as of 1976. *See* Wilner & Landy, *The Tender Trap: State Takeover Statutes and Their Constitutionality,* 45 FORDHAM L. REV. 1, 3 (1976).

8 *See, e.g.,* A & K R.R. Materials, Inc. v. Green Bay & W.R.R., 437 F. Supp. 636, 641 (E.D. Wis. 1977), where it was alleged that "the defendant violated a fiduciary duty to its shareholders to inform them or permit them to be informed of the A & K tender offer . . . ." The court rejected the claims both under a common law standard of ordinary care and diligence, and under federal tender offer legislation. *Id.* at 646.

9 *See* Flom, *Forcing a Friendly Offer,* 32 BUS. LAW. 1319, 1319 (1977); *see, e.g.,* Humana, Inc. v. American Medicorp, Inc., [1977-1978 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 96,286 (S.D.N.Y. 1978). Humana claimed that a knee-jerk response was made when "the Medicorp directors gave only perfunctory consideration to the benefits of the offer and announced new dividends solely as a tactical response to Humana's proposal." *Id.* at 92,824. The court rejected this claim but did issue a preliminary injunction restraining Medicorp "from disseminating materially false and misleading statements concerning Humana's offer." *Id.* at 92,833.

10 Act of July 29, 1968, Pub. L. No. 90-439, 82 Stat. 454 (adding Exchange Act §§ 13(d)-(e), 14(d)-(f), 15 U.S.C. §§ 78m(d)-(e), 78n(d)-(f) (1976)); Act of Dec. 22, 1970, Pub. L. No. 91-567, 84 Stat. 1497 (amending Exchange Act §§ 13(d)-(e), 14(d)-(e), 15 U.S.C. §§ 78m(d)-(e), 78n(d)-(e) (1976)).

11 "The failure of the statute to require incumbent management to make a statement regarding the offer was not inadvertent." E. ARANOW & H. EINHORN, TENDER OFFERS FOR CORPORATE CONTROL 220 n.2 (1973) [hereinafter cited as ARANOW & EINHORN].

12 *See* H.R. REP. No. 1711, 90th Cong., 2d Sess. 3-6, *reprinted in* [1968] U.S. CODE CONG. & AD. NEWS 2811, 2813.

ciently as possible. In order to effect Congress' intent to protect the interests of shareholders,[13] incumbent management should be required to respond to a tender offer by disclosing material information about the target company,[14] by investigating the business practices and intentions of the offeror,[15] and by making reasoned recommendations to the shareholders.[16] In addition, to facilitate the performance of these duties, federal law ought to require that tender offers remain open for a minimum period of several weeks.[17]

This Note first discusses the existing federal tender offer provisions and their counterparts in state corporation laws. It then examines some inadequacies of the federal regulatory scheme, especially with respect to the fiduciary dilemma of target management. Finally, the Note proposes ways in which federal legislation could provide additional shareholder protection.

I. INCUMBENT MANAGEMENT'S OBLIGATIONS UNDER EXISTING LAW

A. *Federal Regulation of Tender Offers*

Until 1968, federal law did not specifically regulate cash tender offers, although it did provide for extensive corporate disclosure in other contexts.[18] Senator Harrison Williams (D., N.J.), sponsor of the amendments to the Securities Exchange Act of 1934 (Exchange Act), which closed this gap, emphasized the need for increased disclosure of information to shareholders: "Today, the public shareholder in deciding

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13 *Id.*

14 *See* text accompanying notes 122 to 128 *infra.*

15 *See* text accompanying notes 138 to 148 *infra.*

16 *See* text accompanying notes 129 to 137 *infra.*

17 *See* text accompanying notes 149 to 163 *infra.*

18 The House committee reporting on the bill proposed by Senator Williams noted that "in both the exchange offer and the proxy fight . . . information is filed with the Securities and Exchange Commission and is subject to statutory requirements and sanctions." H.R. REP. NO. 1711, *supra* note 12, at 2-4, *reprinted in* [1968] U.S. CODE CONG. & AD. NEWS at 2813. Exchange offers are subject to the registration provisions of the Securities Act of 1933, 15 U.S.C. §§ 77a-77aa (1976). Proxy contests are regulated by § 14 of the Exchange Act, 15 U.S.C. § 78n(a)-(b) (1976). In 1970 exchange offers were made subject to § 14(d) of the Exchange Act. Pub. L. No. 91-567, § 4, 84 Stat. 1497 (1970). In addition, recent antitrust legislation imposes a 15-day notification period and requires limited target filing before con-

whether to reject or accept a tender offer possesses limited information. No matter what he does, he acts without adequate knowledge to enable him to decide rationally what is the best course of action. This is precisely the dilemma which our securities laws were designed to prevent."[19] Although the Williams Act contains no preamble or official statement of purpose, it is apparent that the primary goal of federal tender offer regulation was to protect shareholders by providing them with the information necessary to make a rational investment decision.[20]

1. Shareholder Interests Protected by the Williams Act

Congress' goal in enacting the Williams Act, to protect investors, was complicated by the fact that a tender offer splits shareholders into two broad classes with somewhat differing interests.[21]

The first class of stockholders is interested only in the price

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summation of certain tender offers involving large corporations. Antitrust Improvements Act of 1976, Pub. L. No. 94-435, § 201, 90 Stat. 1390 (adding Clayton Act, § 7A, 15 U.S.C. § 18a (1976)) (effective Sept., 1978).

19 113 CONG. REC. 24,664 (Aug. 30, 1967) (statement of Senator Williams). Before the legislation was passed, "shareholders to whom a tender offer was directed often found themselves making a decision as to whether or not to tender without the benefit of an adequate factual foundation upon which to ground that decision." Broder v. Dane, 384 F. Supp. 1312, 1318 (S.D.N.Y. 1974).

20 The bill was "designed to make the relevant facts known so that shareholders have a fair opportunity to make their decisions." H.R. REP. NO. 1711, *supra* note 12, at 4, *reprinted in* [1968] U.S. CODE CONG. & AD. NEWS at 2813.

Although the protection of investors was the primary objective, the requirement of full disclosure in the tender offer context may produce other beneficial effects. *See generally* Schoenbaum, *The Relationship Between Corporate Disclosure and Corporate Responsibility,* 40 FORDHAM L. REV. 565, 575-78 (1972). An increase in available information promotes the allocational efficiency of the stock markets and brings the price of various investments into line with their actual values. *See Affirmative Disclosure, supra* note 3, at 204-05. In addition, the proper functioning of the securities exchanges may depend as much on investor confidence in their integrity as on substantive investor protection. *See* ARANOW & EINHORN, *supra* note 11, at 69. The requirement of disclosure may also have a salutary impact upon the actual conduct of corporate insiders: "By opening matters to public scrutiny, societal standards as to what is permissible conduct will actually be raised, thereby constituting a check on the manner in which a corporate manager may handle other people's money." Schoenbaum, *supra,* at 578.

Disclosure, therefore, is intimately connected not only with shareholder protection but also with ensuring the free functioning of the investment markets and checking the potential for insider abuse.

21 *See* 1 A. BROMBERG, SECURITIES LAW: FRAUD § 6.3 (121), at 116.2 (1974).

of the offer. This class includes those shareholders who tender and those who sell in the open market at prices which have been inflated by the offer.[22] They need no information about the offeror[23] except whether it has adequate financing for the purchase of tendered shares.[24] However, these shareholders do need current information about the target company and the value of its securities, in order to evaluate the adequacy of the offering price. This information is most efficiently obtained from the target's management.[25]

A second class of investors is more interested in the "credentials" of the offeror than in the price of the offer. This class includes shareholders who retain their investment and those who tender their shares in a partial tender offer, but have only a pro rata portion of them accepted.[26] The second class also includes holders of other debt and equity securities of the target corporation.[27] Shareholders in this class continue to have an investment in the company, either intentionally or unintentionally. The drafters of the Williams Act recognized that minority shareholders have cause for concern: "[T]he offeror may obtain sufficient stock to guarantee

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22 Arbitrageurs may also be included in this group, since they are not interested in investment but buy in the market at inflated prices in order to tender for the full offer price. *See* Henry, *Activities of Arbitrageurs in Tender Offers,* 119 U. PA. L. REV. 466 (1971); ARANOW & EINHORN, *supra* note 11, at 173-91.

23 *See* Brudney, *A Note on Chilling Tender Solicitations,* 21 RUTGERS L. REV. 609, 617 (1967): "As sellers, the offerees, of course, have no concern with the identity or background of the buyer or his allies or financial backers, or with their plans for the company."

24 *Id.* at 618 n.21.

25 *See Affirmative Disclosure, supra* note 3, at 191-92; 1 A. BROMBERG, *supra* note 21, § 6.2 (410), at 114.2. *See also* Great Western United Corp. v. Kidwell, 577 F.2d 1256, 1286 (5th Cir. 1978) ("Incumbent management is more likely to possess information about the current value of the target than is the offeror"), *prob. juris. noted,* 47 U.S.L.W. 3463 (U.S. Jan. 9, 1979) (No. 78-759).

26 In a partial tender offer, the offeror makes an offer for some specified number of shares which is less than the number of target shares outstanding at the time of the bid. If more than the specified number of shares are tendered, the offeror must return the excess shares to the tendering shareholders on a pro rata basis, pursuant to § 14(d)(6) of the Exchange Act, 15 U.S.C. § 78n(d) (1976).

Those shareholders who cannot sell all their shares pursuant to the offer may be able to sell the balance of their shares in the open market, but not at the premium paid for shares accepted in the tender offer. Hayes & Taussig, *Tactics of Cash Takeover Bids,* HARV. BUS. REV., Mar.-Apr., 1967, at 148 ("Whether or not the bid is successful, stockholders cannot expect the value of the shares they have retained to perform well in the after-market, at least in the near term").

27 *See* 1 A. BROMBERG, *supra* note 21, § 6.3(121), at 116.2.

itself permanent control of the corporation, and to eliminate whatever influence the public shareholders may previously have had in the management of their company, and indeed perhaps prevent another takeover bidder who might be a better entrepreneur from coming in."[28] Of even greater concern to minority stockholders is the possibility that the offeror will follow a successful tender offer with a cash-out merger,[29] which will eliminate these shareholders completely.[30] This second class of investors, therefore, needs disclosures about the offeror's past record of business performance and about its plans for the target company if control is acquired.[31]

Since shareholders do not know in advance into which category they will fall, they need information about both the target and the bidder in order to make an informed decision on which class to enter. The federal legislation is intended to elicit information that will be of use to both classes of the target's security holders.[32]

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28 *Hearings on S. 510 Before the Subcomm. on Securities of the Senate Comm. on Banking and Currency,* 90th Cong., 1st Sess. 180-81 (1967) (statement of SEC Chairman Cohen); *see* H.R. REP. NO. 1711, *supra* note 12, at 3-6, *reprinted in* [1968] U.S. CODE CONG. & AD. NEWS at 2812.

29 In a cash-out merger, minority shareholders receive only cash for their securities, while the controlling shareholder receives equity in the surviving corporation. *See generally* V. BRUDNEY & M. CHIRELSTEIN, CASES AND MATERIALS ON CORPORATE FINANCE 614-21 (1972).

30 *But see* Singer v. Magnavox Co., 380 A.2d 969 (Del. Sup. Ct. 1977). In *Magnavox,* the offering company, a subsidiary of North American Philips Corporation, obtained 84 percent of the voting stock of the target, Magnavox. The offeror and the parent company then planned to use a statutory merger to cash out the minority. The Delaware court allowed damages for the second step, on the theory that statutory mergers may not be used for the sole purpose of eliminating minority interests. *Id.* at 978. If it is read broadly, the *Magnavox* holding supports barring the second step in many situations. *But cf.* Weiss, *Tender Offers and Management Responsibility,* 23 N.Y.L.S. L. REV. 445, 458 (1978) (*Magnavox* does not require target management to seek injunction against offer at first step).

31 The offeror is required to disclose information about its plans pursuant to § 14 (d) of the Exchange Act, 15 U.S.C. § 78n(d) (1976), which is triggered by the making of the tender offer.

32 Commonwealth Oil Ref. Co. v. Tesoro Petroleum Corp., 394 F. Supp. 267, 273 (S.D.N.Y. 1975) (emphasis added):

> [I]t must always be remembered that the protections of the Williams Act extend to all shareholders of the target company — *both those who intend to divest themselves of ownership and those who do not.* Both groups must be assured full, fair and adequate disclosure so that their decision to tender or retain their shares will be predicated upon a knowledgeable and informed evaluation of the alternatives.

2. The Williams Act Provisions

The drafters of the Williams Act did not intend that the offeror bear the sole responsibility for providing information to investors during tender offers. The Williams Act was designed to avoid tipping the balance of advantage in favor of either the offeror or the target company,[33] and its drafters envisioned at least voluntary participation by incumbent management in the disclosure process.[34] In testimony before the Senate subcommittee reporting on the legislation, for example, then Securities and Exchange Commission (SEC) Chairman Manuel F. Cohen noted that "one important potential protection to security holders is an opportunity for management to furnish any information at its disposal pertinent to the merits of the offer before the security holder responds to it."[35] Thus, both the substantive problem which federal regulation was intended to address and the comments of those who were responsible for the legislation suggest that a burden of disclosure should have been placed upon target management. The final legislation, however, does not cast target management in the role of an information broker.

Target responses to tender offers are governed by section 14(d)(4) of the Exchange Act,[36] which authorizes the SEC to adopt rules relating to solicitations or recommendations, and by section 14(e),[37] which prohibits fraudulent statements in

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33 Senator Williams stated: "I have taken extreme care with this legislation to balance the scales equally to protect the legitimate interests of the corporation, management, and shareholders without unduly impeding cash takeover bids." 113 CONG. REC. 854 (1967).

34 H.R. REP. NO. 1711, *supra* note 12, at 4, *reprinted in* [1968] U.S. CODE CONG. & AD. NEWS at 2813. "[The bill] is designed to require full and fair disclosure for the benefit of investors while at the same time providing the offeror and management equal opportunity to fairly present their case."

35 *Hearings on S. 510, supra* note 28, at 19.

36 15 U.S.C. § 78n(d)(4) (1976). Section 14(d)(4) states that "[a]ny solicitation or recommendation to the holders of such a security to accept or reject a tender offer or request or invitation for tenders shall be made in accordance with such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors."

37 15 U.S.C. § 78n(e) (1976). Section 14(e) states:

> It shall be unlawful for any person to make any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made, in the light of the circumstances under which they are made, not misleading, or to engage in any fraudulent, deceptive, or

connection with any tender offer. Although it is authorized to regulate recommendations, the SEC has until recently operated under its original emergency rules rather than establish "a comprehensive regulatory framework specifically designed for tender offers."[38]

The Commission's rule 14d-4[39] requires any person who makes a recommendation to file a schedule 14D.[40] If management comments on the offer, it must disclose the reasons for its recommendation,[41] any arrangements or understandings it may have with the offeror,[42] the identity of persons retained to make solicitations or recommendations and the terms of their employment,[43] and information as to insider trading in the previous six months in the securities for which the offer is made.[44] Filings under rule 14d-4 may be perfunctory.[45] In any event, they do not necessarily furnish the information which shareholders most need from the management of their corporation — information about operations which

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manipulative acts or practices, in connection with any tender offer or request or invitation for tenders, or any solicitation of security holders in opposition to or in favor of any such offer, request, or invitation. The Commission shall, for the purposes of this subsection, by rules and regulations define, and prescribe means reasonably designed to prevent, such acts and practices as are fraudulent, deceptive, or manipulative.

38 SEC Rel. No. 34-13787 (July 21, 1977), [1977-1978 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 81,256, at 88,373. In this release the SEC adopted the new schedule 14D-1, the first of a series of new regulations proposed in SEC Rel. No. 34-12676 (Aug. 2, 1976), [1976-1977 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 80,659, pursuant to § 14(d) of the Exchange Act, 15 U.S.C. § 78n(d) (1976).

39 17 C.F.R. § 240.14d-4 (1977).

40 17 C.F.R. § 240.101 (1977).

41 17 C.F.R. § 240.14d-101 (1977) (item 1(b)). The current SEC proposals for new rules include a schedule 14D-4, which is to be filed by any person making a recommendation. Item 4 of that schedule requires disclosure of "the reasons for and *bases* of such solicitation or recommendation." SEC Rel. No. 34-12676 (Aug. 2, 1976), 2 FED. SEC. L. REP. (CCH) ¶ 24,284F (emphasis added). Compliance with this rule apparently would require disclosure of facts supporting a "reason" such as the inadequacy of the price. *See also* Note, *The Williams Act: An Evaluation of the Early Returns*, 23 VAND. L. REV. 700, 709 (1970).

42 17 C.F.R. § 240.14d-101 (1977) (item 2(b)).

43 *Id.* (item 3).

44 *Id.* (item 5).

45 A "canned" release may be prepared in advance and filed as soon as any offer is made. *See* Brown, *The Scope of the Williams Act and Its 1970 Amendments*, 26 BUS. LAW. 1637, 1644 (1971); Fleischer, *Defensive Tactics in Tender Offers*, 9 REV. SEC. REG. 853 (1976).

the shareholders could use to evaluate the adequacy of the price offered for their stock.

Once the incumbent management makes a public response to the offer, it becomes subject to the restrictions of section 14(e) of the Exchange Act,[46] which requires management, if it speaks at all, to disclose all facts in its possession that are material to the offer. Section 14(e), which is similar in concept to section 10(b) of the Exchange Act,[47] has been read broadly and may require significant disclosures from target management. For example, it has been held that the subject company may not simply characterize the offer as "quite inadequate" and an attempt to gain control at "bargain-basement prices."[48] If it does make such a statement, the target corporation must also reveal any potentially damaging material facts, such as its own recent negotiations for a transaction at a similar price.[49] On the other hand, courts are sensitive to the fact that the participants in a takeover bid work under the stress of short time periods, and the applicable standards of materiality may be relaxed, with respect both to what facts must be disclosed and to what facts may be omitted.[50]

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46 15 U.S.C. § 78n(e) (1976). The text of § 14(e) is set out at note 37 *supra.*

47 15 U.S.C. § 78j(b) (1976). As with liability under § 10(b) and rule 10b-5, the key factors affecting § 14(e) liability are materiality and culpability. Chris-Craft Indus., Inc. v. Piper Aircraft Co., 480 F.2d 341, 362 (2d Cir. 1973), *cert. denied,* 414 U.S. 910 (1975). Just as § 14(e) is not triggered if management is silent, in the absence of a prior statement which becomes misleading "no case has yet held that there generally is any liability [under rule 10b-5] for the mere withholding of material, inside information when no one trades or tips." R. JENNINGS & H. MARSH, JR., CASES AND MATERIALS ON SECURITIES REGULATION 950 (1977); *see* Financial Industrial Fund, Inc. v. McDonnell Douglas Corp., 474 F.2d 514 (10th Cir. 1973). Unlike § 10(b), however, the tender offer provision needs no enabling rule but operates of its own force.

48 Emhart Corp. v. USM Corp., 403 F. Supp. 660, 662 (D. Mass.), *vacated on other grounds,* 527 F.2d 177 (1st Cir. 1975); *see* Royal Indus., Inc. v. Monogram Indus., Inc., [1976-1977 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 95,863, at 91,144 (C.D. Cal. 1976); Humana, Inc. v. American Medicorp, Inc., [1977-1978 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 96,286, at 92,833 (S.D.N.Y. 1978).

49 Emhart Corp. v. USM Corp., 403 F. Supp. 660, 662 (D. Mass.), *vacated on other grounds,* 527 F.2d 177 (1st Cir. 1975).

50 *See, e.g.,* Electronic Specialty Co. v. International Controls Corp., 409 F.2d 937, 948 (2d Cir. 1969) (Friendly, C.J.): "They act quickly, sometimes impusively, often in angry response to what they consider, rightly or wrongly, to be low blows by the other side. Probably there will no more be a perfect tender offer than a perfect trial." *See also* Missouri Portland Cement Co. v. Cargill, Inc., 498 F.2d 851, 874 (2d Cir.), *cert. denied,* 419 U.S. 883 (1974).

Although allowance must be made for the heat of the contest, a broad reading of materiality[51] for the purposes of section 14(e) could make the statute a powerful tool for compelling disclosure from the target management. Some courts have expressed the sound view that it is the total mix of information available to the shareholders that is relevant in deciding what constitutes a material omission.[52] These courts have recognized the value of statements from target management and have held that target disclosures can "cure" defects in statements made by an offeror.[53] These holdings may be based in part on the realization that the target is an opposing faction which possesses both the incentives and resources necessary to challenge and to elaborate upon the offeror's initial assertions.[54]

As a practical matter, the "cure" cases do more than hold that target management's actions may save the offeror from contravening section 14(e). Although the cases do not place an affirmative burden on the target to cure the defects in the offeror's statements, management must perhaps either speak up or accept its adversary's evaluation of the situation. Indeed, should management subsequently try to enjoin the

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51 *See, e.g.*, TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438 (1976). In that case, the court formulated a broad materiality standard for the purposes of SEC rule 14a-9. The court stated: "An omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote." *Id.* at 449.

52 *See, e.g.*, Spielman v. General Host Corp., 402 F. Supp. 190 (S.D.N.Y. 1975), *aff'd*, 538 F.2d 39 (2d Cir. 1976). *See generally* Shevitz & Taylor, *Curing Tender Offer Disclosures*, 9 REV. SEC. REG. 965, 967 (1976).

53 Spielman v. General Host Corp., 402 F. Supp. 190 (S.D.N.Y. 1975), *aff'd*, 538 F.2d 39 (2d Cir. 1976). The court of appeals noted that curing was particularly important and appropriate when the omission related to facts about the target company rather than the offeror. *Id.* at 194-95.

Other courts have disagreed, and it has been said that "it would emasculate the purposes of the Williams Act to allow the offeror to look to the target company to remedy the offeror's own material deficiencies in disclosure .... That duty cannot be shifted to the shoulders of others." Sonesta Int'l Hotels Corp. v. Wellington Assocs., 483 F.2d 247, 255 (2d Cir. 1973). *See also* Shevitz & Taylor, *supra* note 52, at 967: "A different rule would invite irresponsibility by the offeror, who could expect that his omissions and half-truths would be 'corrected' by his opponent."

54 *See* Broder v. Dane, 384 F. Supp. 1312, 1318 (S.D.N.Y. 1974) (dictum contrasting contested tender offer with management attempt in *Broder* to buy up shares in order to go private).

offer, its initial failure to correct the offeror's statements could be evidence that alleged misstatements or omissions by the offeror were not material.[55]

Section 14(e) has an important limitation, however, in that the target, unlike the offeror,[56] may choose to avoid entirely the material information requirements by not making a recommendation with respect to the tender offer. Although some non-verbal defensive actions may be the equivalent of a recommendation,[57] target management can employ a wide range of defenses which do not trigger section 14(e).[58] This gap in the regulation is an anomaly in light of Congress' original understanding of the Williams Act as a balanced regulatory scheme that would involve both target and offeror in the disclosure process.[59]

B. *State Regulation of Tender Offers*

The belief that the relationship between managers and shareholders should be left to state corporation law[60] may account for the reluctance to place a federal affirmative

55 *Cf.* General Time Corp. v. Talley Indus., Inc., 403 F.2d 159, 162 (2d Cir. 1968), *cert. denied,* 393 U.S. 1026 (1969) (in a proxy contest, management's "failure to correct [insurgents'] alleged misstatements or rectify claimed omissions is some evidence that it does not regard them as material . . .").

56 The offeror must make a public filing upon announcing the tender offer. Exchange Act § 14(d)(4), 15 U.S.C. § 78n(d)(4) (1976).

57 *See* SEC v. Madison Square Garden Corp., [1969-1970 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 92,649 (S.D.N.Y. 1970), where the SEC charged that an attempt by a third party to drive the market price of the target's shares above the tender offer price constituted a recommendation against the offer. The action ended in a consent decree. *Id.; cf.* Butler Aviation Int'l, Inc. v. Comprehensive Designers, Inc., 307 F. Supp. 910, 914 (S.D.N.Y. 1969) (offeror artificially inflated market price of shares before offering to exchange them for those of target), *aff'd,* 425 F.2d 842 (2d Cir. 1970). *But cf.* Humana, Inc. v. American Medicorp, Inc., [1977-1978 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 96,286, at 92,833 (S.D.N.Y. 1978) (target management increased dividend rate); Anaconda Co. v. Crane Co., 411 F. Supp. 1210 (S.D.N.Y. 1975) (allegation that target made acquisition in order to raise antitrust claim as defense to tender offer).

Management will also have to make disclosures if it responds to the tender offer by purchasing its own shares. Exchange Act § 13(e), 15 U.S.C. § 78m(e) (1976).

58 *See Affirmative Disclosure, supra* note 3, at 203, 207; Fleischer, *supra* note 45, at 855 ("The most critical and effective defensive tactic is being incorporated in, or subject to, a state takeover statute"); ARANOW & EINHORN, *supra* note 11, at 265; Comment, *Economic Realities of Cash Tender Offers,* 20 ME. L. REV. 237, 249 (1968) (in 10 contested cash offers made in 1967, defensive mergers were employed 7 times).

59 *See* notes 33 to 35 and accompanying text *supra.*

60 *See* 1 ADVISORY COMM. ON CORPORATE DISCLOSURE, REPORT TO THE SECURITIES

disclosure burden on target management. Former SEC Chairman Cohen expressed this belief in describing the limits of the federal law:

> We have certain anti-fraud provisions and theoretically under those provisions a case can be made that directors have an obligation to take certain steps in connection with a purchase or sale of shares. I do not think that view has as yet been accepted under our Federal Statutes. You are now in an area of what I would consider conventional Company Law which is really outside the jurisdiction of the S.E.C. as such.[61]

This view apparently has not changed with the enactment of the Williams Act; affirmative obligations of fiduciaries are still to be found, if anywhere, in the corporation laws of the states. The relevant rules developed in the common-law cases and the state statutes will be surveyed in this section.

1. Common-Law Fiduciary Duties

The traditional view at common law has been that a decision to sell or purchase shares of a corporation is a matter which concerns only the parties to the transaction.[62] Under this theory, management does not have a duty to respond to a shareholder's request for information about the worth of the company's stock.[63] In a leading case, *Broffe v.*

AND EXCHANGE COMM'N 305 (1977) (Comm. Print No. 95-30) [hereinafter cited as ADVISORY COMM. REPORT]:

> The Commission's function in the corporate disclosure system is to assure the public availability in an efficient and reasonable manner on a timely basis of reliable, firm-oriented information material to informed investment and corporate suffrage decision-making. The Commission should not adopt disclosure requirements which have as their principle objective the regulation of corporate conduct.

See Swanson, *S. 510 and the Regulation of Cash Tender Offers: Distinguishing St. George from the Dragon,* 5 HARV. J. LEGIS. 431, 504-05 (1968).

61 19 *Minutes of Evidence Taken Before the Company Law Comm. of the British Bd. of Trade* ¶ 6640, at 1471 (1961) (statement of SEC Chairman Cohen). The "antifraud provisions" mentioned are Exchange Act § 10(b), 15 U.S.C. § 78j(b) (1976), and rule 10b-5. Exchange Act § 14(e), 15 U.S.C. § 78n(e) (1976), had not yet been enacted.

62 *See, e.g.,* Abelow v. Midstates Oil Corp., 41 Del. Ch. 145, 151, 189 A.2d 675, 678 (Sup. Ct. 1963).

63 *See* Broffe v. Horton, 172 F.2d 489, 494 (2d Cir. 1949); Klink, *Management's Role in Recommending For or Against an Offer,* 39 ANTITRUST L.J. 325, 325 (1970). The absence of a duty is conditioned on a lack of self-dealing, *see* Andersen v. Albert & J. M. Anderson Mfg. Co., 325 Mass. 343, 90 N.E.2d 541 (1950) (refusal of directors to accept offer for treasury stock solely to maintain control of corporation).

Horton,[64] the court noted that the shareholder, who was an inactive director of the corporation, "was an experienced man in that particular business who knew how to inform himself and to form his own opinion as to values."[65] The company president was therefore "under no duty of disclosure"[66] concerning lucrative government contracts which greatly increased the actual value of the shares, and of which the shareholder was ignorant.[67]

The common-law courts have begun to relax the traditional rule by involving management in proxy challenges and takeover bids in certain situations. Some courts have been willing to allow the use of corporate funds to repurchase stock in order to avert a clear threat to the subject company from the business methods of an insurgent.[68] Moreover, cases have indicated that the making of misleading statements during opposition to a tender offer violates general fiduciary duties as well as the Williams Act,[69] and that any position

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64 172 F.2d 489 (2d Cir. 1949).

65 *Id.* at 494.

66 *Id.; see* Mairs v. Madden, 307 Mass. 378, 30 N.E.2d 242, 244-45 (1940).

67 The shareholder sold for $43.57 per share; all of the shares in the corporation were sold shortly thereafter for $321 per share. 172 F.2d at 492.

68 *See* Kors v. Carey, 39 Del. Ch. 47, 55, 158 A.2d 136, 141 (Ch. 1960); Cheff v. Mathes, 41 Del. Ch. 494, 504, 199 A.2d 548, 554 (Sup. Ct. 1964). "*Kors* and *Cheff* stand clearly for the proposition that directors of a Delaware corporation, once convinced that control is threatened by an outside interest which arguably would advocate some change classifiable with any verisimilitude as 'policy,' can decide a priori that such change would not be in the best interests of all the shareholders." Israels, *Corporate Purchases of Its Own Shares — Are There New Overtones?* 50 CORNELL L.Q. 620, 624 (1965). *See also* Kaplan v. Goldsamt, 380 A.2d 556, 568-69 (Del. Ch. 1977).

Such expenditures have not been permitted, however, when the goal was simply to perpetuate the control of present management, rather than to protect the corporation from injury. Bennett v. Propp, 41 Del. Ch. 14, 20-21, 187 A.2d 405, 408-09 (Sup. Ct. 1962); *see* Petty v. Penntech Papers, Inc., 347 A.2d 140, 143 (Del. Ch. 1975). In other words, such expenditures are valid only if management's motivation is "the maintenance of . . . proper business practices." Condec Corp. v. The Lunkenheimer Co., 43 Del. Ch. 353, 364, 230 A.2d 769, 776 (Ch. 1967) (dictum). *Compare* Singer v. Magnavox Co., 380 A.2d 969 (Del. Sup. Ct. 1977) (management forbidden by fiduciary duties from using statutory merger to freeze out minority shareholders) *with* Tanzer v. International Gen. Indus., Inc., 379 A.2d 1121, 1125 (Del. Sup. Ct. 1977) (merger genuinely advanced business purposes of the majority stockholder and therefore held not to violate the rule of *Singer*).

69 *E.g.,* Emhart Corp. v. USM Corp., 403 F. Supp. 660, 662 (D. Mass.), *vacated on other grounds,* 527 F.2d 177 (1st Cir. 1975) (dictum).

which management does take must be based upon direct investigation or professional consultation.[70]

Northwest Industries, Inc. v. B. F. Goodrich Co.,[71] represents a further departure from the traditional rule. In "persuasive dictum,"[72] the court stated that "management has the responsibility to oppose offers which, in its best judgment, are detrimental to the company or its stockholders."[73] The *Northwest Industries* dictum has been neither rejected nor approved by other courts. Indeed, it appears that the management of a target has never been required either to disclose information relevant to the offer[74] or to investigate the offeror[75] when a takeover bid was presented to the shareholders. Where potential fiduciary obligations have been recognized, moreover, considerable deference has been given to the business judgment of the target's managers, who must respond to the exigencies of a crisis situation.[76]

The dictum in *Northwest Industries* may indicate that common-law courts will continue to take exception to the spirit of *Broffe v. Horton*[77] and will impose greater duties on the target in takeover situations.[78] It is clear under present

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70 *E.g.*, Condec Corp. v. The Lunkenheimer Co., 43 Del. Ch. 353, 364, 230 A.2d 769, 776 (Ch. 1967) (no evidence that an investigation had taken place).

71 301 F. Supp. 706 (N.D. Ill. 1969) (applying New York law).

72 ARANOW & EINHORN, *supra* note 11, at 222.

73 301 F. Supp. at 712-13. The court further defined management's responsibility: "In arriving at such a judgment, management should be scrupulously fair in considering the merits of any proposal submitted to its stockholders. The officers' and directors' informed opinion should result from that strict impartiality which is required by their fiduciary duties."

74 *See* A & K R.R. Materials, Inc. v. Green Bay & W.R.R., 437 F. Supp. 636, 641-42 (E.D. Wis. 1977) (refusal to produce a shareholder list is not itself a violation of § 14(e)).

75 Controlling shareholders may be required to investigate a purchaser of control when there are facts, such as an excessively high premium, which indicate an improper motive for the purchase. *See* Gerdes v. Reynolds, 28 N.Y.S.2d 622, 651-54 (Sup. Ct. 1941); Insuranshares Corp. v. Northern Fiscal Corp., 35 F. Supp. 22, 25 (E.D. Pa. 1940). This limited duty of investigation has not been extended to management.

76 *See* United States Smelting, Ref. & Mining Co. v. Clevite Corp., [1969-1970 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 92,691, at 99,046-47 (N.D. Ohio 1968).

77 *See* ARANOW & EINHORN, *supra* note 11, at 222.

78 *See, e.g.*, E. ARANOW, H. EINHORN & G. BERLSTEIN, DEVELOPMENTS IN TENDER OFFERS FOR CORPORATE CONTROL 80 (1970):

> Even though 14(e) does not appear to require that a target's management respond to an offer, in certain circumstances, some form of response may be

law, however, that if a disclosure duty is to be imposed on target companies, it will not be sufficient simply to rely upon the existing decisions under the state common law of corporations. Further developments in this area are likely to evolve slowly, because most tender offer litigants bring actions under the federal statutes and allege state fiduciary violations as an afterthought.[79]

2. State Tender Offer Legislation

In the wake of the enactment of the Williams Act in 1968, which reflected a federal recognition that inadequate disclosures were being made in tender offers, many states have added takeover sections to their corporation statutes.[80] The motivating philosophy, however, has been one of local interest rather than shareholder protection. One authority on tender offers notes that these statutes are "thinly disguised as legislation for the protection of investors," and "cannot in any practical sense be viewed as anything more than attempts to protect incumbent management and local industry."[81]

The protective provisions which the statutes offer to local businesses include, among others, lengthy pre-offer notice periods[82] and minimum offer durations.[83] Many of the state statutes also allow target management to waive the

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required under general fiduciary principles. If a target's management knows that a tender offer price is unfairly low, or that the offeror has a history of bad management or a policy of making "raids" on the assets of successfully acquired targets, managers might be required, as part of their obligation to protect the interests of their shareholders, to inform the shareholders of these facts.

79 *See, e.g.*, Emhart Corp. v. USM Corp., 403 F. Supp. 660, 662-63 (D. Mass.), *vacated on other grounds*, 527 F.2d 177 (1st Cir. 1975), where the court was willing to find a breach of fiduciary duties but the individual directors had not been joined as defendants.

80 By 1976, 23 states had passed takeover statutes. Wilner & Landy, *supra* note 7, at 3.

81 ARANOW & EINHORN, *supra* note 11, at 172.

82 *E.g.*, MASS. GEN. LAWS ANN. ch. 110C, § 2 (West Supp. 1977) (30 days); DEL. CODE ANN. tit. 8, § 203(a)(1) (Supp. 1978) (20 to 60 days).

83 *E.g.*, MASS. GEN. LAWS ANN. ch. 110C, § 7 (West Supp. 1977) (60 days); DEL. CODE ANN. tit. 8, § 203(a)(2) (Supp. 1978) (20 days).

statutory burdens in the event that a "friendly" offer is received.[84] These provisions give the target an excessive measure of discretion in determining the course of the tender offer. The offeror's one-sided burden of disclosure, which at the federal level has arguably been a device to provide shareholders with the information necessary to an evaluation of the offer's merits, has at the state level become a weapon which the incumbent management may, at its option, use to delay and defeat the offer.[85]

The local-interest character of the takeover statutes has prompted several commentators and courts to question their constitutionality.[86] In a recent case, *Great Western United Corp. v. Kidwell*,[87] the district court held that the Idaho law both violates the commerce clause and is preempted by the Williams Act. *Kidwell* was affirmed by the Fifth Circuit in August 1978.[88] This decision reflects the court's recognition that state takeover statutes have frustrated the congressional intent to avoid "tipping the balance of regulation either in favor of management or in favor of the person making the takeover bid."[89]

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84 *E.g.*, MASS. GEN. LAWS ANN. ch. 110C, § 1 (West Supp. 1977).

85 *See* ARANOW & EINHORN, *supra* note 11, at 172; Fleischer, *supra* note 45.

86 *See* Wilner & Landy, *supra* note 7; Note, *Commerce Clause Limitations Upon State Regulation of Tender Offers*, 47 S. CAL. L. REV. 1133 (1974). *But see* Vaughan, *State Tender Offer Regulation*, 9 REV. SEC. REG. 901 (1976).

87 439 F. Supp. 420 (N.D. Tex. 1977), *aff'd*, 577 F.2d 1256 (5th Cir. 1978). For related litigation, *see* Sunshine Mining Co. v. Great Western United Corp., [1977-1978 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 96,049 (D. Idaho 1977).

88 Great Western United Corp. v. Kidwell, 577 F.2d 1256 (5th Cir. 1978), *prob. juris. noted*, 47 U.S.L.W. 3463 (U.S. Jan. 9, 1979) (No. 78-759).

89 H.R. REP. NO. 1711, *supra* note 12, at 4, *reprinted in* [1968] U.S. CODE CONG. & AD. NEWS at 2813. *See* note 33 *supra;* Great Western United Corp. v. Kidwell, 577 F.2d 1256, 1279 (5th Cir. 1978), *prob. juris. noted*, 47 U.S.L.W. 3463 (U.S. Jan. 9, 1979) (No. 78-759). "Instead of relying upon *investors'* decisions after full disclosure, Idaho relies upon the business judgment of corporate directors with a fiduciary duty to their shareholders. Idaho's 'fiduciary approach' to investor protection may be one way to protect shareholders, but it is an approach Congress rejected," 577 F.2d at 1279 (emphasis in original).

An indirect challenge to a state takeover law attacked DEL. CODE ANN. tit. 8, § 203, which requires that the tender offeror prepare a statement containing information on the target company. This provision was held to be of insufficient importance to state interests to justify jurisdiction where the only contact with Delaware was plaintiff's incorporation in that state. Barker-Greene Co. v. Walco Nat'l Co., 428 F. Supp. 567, 572 (D. Del. 1977).

The proposed Federal Securities Code would preempt state tender offer legislation

II. THE GAP IN REGULATION

A. *Reasons for Silence: The Fiduciary Dilemma*

In most cases, target management will either support or oppose a tender offer.[90] The managers of the target might wish to remain silent for a number of reasons, however, none of which is consistent with the broad disclosure policies of the securities laws.

Target management is likely to speak out in situations where the tender offer threatens to undermine or displace management.[91] Yet, in making disclosure or taking a stand, management always incurs the risk of liability for misrepresentation.[92] Therefore, to the extent that incumbency protects management from effective challenge it will not be prompted to make a recommendation or to risk liability for misrepresentation.[93] When it is in management's interest simply to "weather the storm," the shareholders are deprived of guidance in evaluating the tender offer.

It may also be the case that target management favors the tender offer and has decided that silence will aid the offer's success. This silence may mean that management's neutrality has been purchased by the offeror[94] or that management is seeking to avoid disclosures concerning more attractive offers from companies which are suspected to be hostile to the incumbents.[95] Silence in either context is detrimental to the shareholders' interests.

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explicitly in all cases where fewer than 50 percent of equity holders of equity securities reside in a state or hold less than half the securities. ALI FED. SEC. CODE § 1904(c) (Proposed Official Draft 1978).

90 *See* Klink, *supra* note 63, at 3250: "As a practical matter, few managements have remained neutral in the face of a hostile takeover bid. Failure to take a position (the takeover of Jones & Laughlin by LTV is an example) is viewed by the market and by stockholders as tacit approval of the offer."

91 *See* note 4 *supra.*

92 *See* Exchange Act § 14(e), 15 U.S.C. § 78n(e) (1976).

93 *Affirmative Disclosure, supra* note 3, at 203.

94 Fleischer & Mundheim, *supra* note 2, at 357-59; *Affirmative Disclosure, supra* note 3, at 206-07.

Under current law, the filings required to accompany the offer must disclose any arrangements between the bidder and the target management. Schedule 13D, 17 C.F.R. § 240.13d-101 (1977) (items 6-7). If a position is taken with respect to the offer, target management must also disclose such an understanding or arrangement in item 2(b) of schedule 14D, 17 C.F.R. § 240.14d-101 (1977).

95 When one takeover bid is announced or rumored, the target normally is

Silence, however, is not always a sign that management has failed in its fiduciary duty.[96] For instance, the officers of the target corporation may believe that a change in control would improve the operational prospects of the company but they may also feel that the directors would vote to resist the offer in order to perpetuate their positions on the board.[97] Under such circumstances, the officers may attempt to prevent the matter from coming to a vote in order to avoid incurring any liability for corporate waste in carrying out the board's instructions to oppose the bid.[98] Although the officers would presumably be acting in the best interests of the shareholders, they would be frustrating the disclosure policies of the Williams Act. An assessment that a change in control will benefit the corporation is precisely the sort of information that shareholders need to know when confronted with a tender offer.

Finally, management may fail to respond to a tender offer even though it is opposed to the offer. For instance, the target corporation's affairs may be "in such bad shape that disclosure of the information required by the SEC to accompany a management statement would aid the offeror rather

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showered with proposals from other companies for mergers and competitive bids. Flom, *supra* note 9, at 1320; Klink, *supra* note 63, at 328; *e.g.*, United States Smelting Ref. & Mining Co. v. Clevite Corp., [1969-1970 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 92,691, at 99,034 (N.D. Ohio 1968).

The target may already have negotiated a merger or acquisition before the tender offer is made. In that case, the tendency to favor the friendly agreement already made may hinder objective evaluation of the competing offer. *Cf.* SEC v. Thermal Power Co., [1975-1976 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 95,265 (D.D.C. 1975) (summary of complaint), where the SEC charged that § 14(e) was violated because the target failed to disclose that the primary purpose of selling a controlling block of stock to a friendly company was to defeat a competing tender offer.

96 *See* Fleischer, *supra* note 45, at 858; *cf.* Anaconda Co. v. Crane Co., 411 F. Supp. 1210, 1213 (S.D.N.Y. 1975) (target press release said a position would be taken later: "Until that time it should not be assumed that the Anaconda management is sympathetic to the proposed offer").

97 *See* Swanson, *supra* note 60, at 504; *cf.* Fleischer, *supra* note 45, at 856 ("It would seem desirable to submit any bona fide offer to the board for its consideration").

98 This situation also raises the question of the officers' duty, if any, to present all proposals for "friendly" bids to the board of directors. *See* Fleischer, *supra* note 45, at 856.

than hinder him."[99] Similarly, if incumbent management is negotiating a defensive merger or a sale of the company at a price similar to that being offered, management may remain silent because it fears that premature disclosure would destroy the negotiations.[100] It may also be prudent for management to preserve a tactical silence in situations where the shareholders are widely scattered geographically and the offeror does not have access to a shareholder list.[101]

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99 Swanson, *supra* note 60, at 504. *Affirmative Disclosure, supra* note 3, at 207. Conversely, when the news is good, prompt disclosure may be an effective defensive tactic. *See* Fleischer & Mundheim, *supra* note 2, at 355 n.146.

If unfavorable news is revealed, shareholders may sell in the market instead of tendering. It has been estimated that over 50 percent of shares tendered come from arbitrageurs who have purchased from risk-averse investors. *See* O'Boyle, *Changing Tactics in Tender Offers,* 25 BUS. LAW. 863, 865-66 (1970); Henry, *supra* note 22, at 466.

A disclosure requirement in this context would give investors confidence in the open and fair operation of the securities markets. Investor confidence is weakened as long as management resorts to tactical silence to suppress disappointing information. *See* H.R. REP. NO. 1711, *supra* note 12, at 3, *reprinted in* [1968] U.S. CODE CONG. & AD. NEWS at 2812; *cf.* Copperweld Corp. v. Imetal, 403 F. Supp. 579, 608 (W.D. Pa. 1975) (management's delay of the offer by obtaining injunctive relief may violate obligation to shareholders whose interest is in the success of the takeover); Electronic Specialty Co. v. International Controls Corp., 296 F. Supp. 462, 469 (S.D.N.Y. 1968), *aff'd,* 409 F.2d 937 (2d Cir. 1969).

100 Swanson, *supra* note 60, at 504; *cf.* Emhart Corp. v. USM Corp., 403 F. Supp. 660, 662 (D. Mass.) (Williams Act violation found where recommendation against offer failed to disclose management's recent negotiations for a similar price), *vacated on other grounds,* 527 F.2d 177 (1st Cir. 1975).

101 Many shareholders may not be aware that a tender offer is being made for their shares. It has been held that the target company need not itself inform the stockholders that an offer is outstanding. A & K R.R. Materials, Inc. v. Green Bay & W.R.R., 437 F. Supp. 636 (E.D. Wis. 1977). This holding, which reflects a fear that a disclosure requirement would overburden the target company, *id.* at 644, misconstrues the congressional intent to balance the positions of tender offer contestants. The offeror and the target were intended to have equal opportunity to present their cases to the shareholders, but neither party was to be able to ensure their ignorance. *See* H.R. REP. NO. 1711, *supra* note 12, at 4, *reprinted in* [1968] U.S. CODE CONG. & AD. NEWS at 2813.

Furthermore, target management is currently under no direct obligation to deliver a list of shareholders to the offeror, although it may be required to do so if it uses the list for a defensive solicitation of the company's owners. *See* Mesa Petroleum Co. v. Aztec Oil & Gas Co., 406 F. Supp. 910 (N.D. Tex. 1976); *cf.* Applied Digital Data Systems, Inc. v. Milgo Electronic Corp., 425 F. Supp. 1163 (S.D.N.Y. 1977) (where target gave shareholder list to friendly offeror, it must also give it to hostile bidder). The SEC's proposed rule 14e-1 would require the target to give its shareholder list to the bidder upon filing of the offer and the bidder's promise to limit the use of the list. SEC Rel. No. 34-12676 (Aug. 2, 1976), [1976-1977 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 80,659, at 86,701.

In each of the situations described above — inertia, acquiescence, and opposition — target management maintains its silence because it possesses material, non-public information which it does not wish to disclose. Shareholders are thus deprived of information by which to evaluate the tender offer. If information in target management's possession is material to the value of the shares, and consequently to the adequacy of the price, the shareholders are no less in need of the facts than they are when management triggers Exchange Act section 14(e)[102] by taking a position for or against the offer.[103]

B. *Inadequacy of the Williams Act Regulatory Scheme*

In 1970, when the SEC requested the inclusion in section 14(e) of rulemaking authority,[104] it recognized the problem that target companies might deliberately avoid disclosure. Responding to Senator Williams' request for examples of the practices which the SEC might need to regulate, then SEC Chairman Hamer H. Budge expressed concern that "management of the target company in a tender bid may omit to make timely disclosure of its position in favor of or in opposition to such bid or changes in such position."[105] Notwithstanding the rulemaking power conferred by the 1970 amendment, the SEC has never actually required "timely disclosure" when the target has decided not to make a recommendation.[106] The failure of Congress and the SEC to take action in this area has left the federal regulatory scheme inadequate in three respects.

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102 15 U.S.C. § 78n(e) (1976).

103 *Affirmative Disclosure, supra* note 3, at 203.

104 The last sentence of § 14(e) of the Exchange Act, 15 U.S.C. § 78(n)(e) (1976), states: "The Commission shall, for the purposes of this subsection, by rules and regulations define, and prescribe means reasonably designed to prevent such acts and practices as are fraudulent, deceptive, or manipulative."

105 *Hearings on S. 3431 Before the Subcomm. on Securities of the Senate Comm. on Banking and Currency,* 91st Cong., 2d Sess. 12 (1970).

106 In fairness, it must be noted that even with its rule-making power the SEC may not have the authority to place an affirmative disclosure burden on management. *Cf.* Brown, *SEC Tender Offer Rules,* 9 REV. SEC. REG. 815, 815-16 (1976) (power of SEC to promulgate rules regarding stockholder lists and minimum offer duration). *But cf.* the SEC's proposals for new rules under § 14(e), discussed at note 101 *supra* and at notes 160 to 163 and accompanying text *infra.*

First, the federal legislation provides no resolution of the fiduciary dilemma discussed above.[107] Individual shareholders may be left ignorant of material information in management's possession and may thus be compelled to make an uninformed decision to tender or not to tender.

Second, the Williams Act falls squarely within the disclosure tradition and suffers from the limitations that afflict that tradition. Proponents of the disclosure model believe that if the facts are made available, investors are adequately protected and the securities markets allocate resources efficiently. The Advisory Committee on Corporate Disclosure recently stated the underlying theory as follows: "It would appear to be self-evident that the quality of any investment allocation decision, that is, the extent to which it maximizes return, will in large measure be determined by the quantity and quality of the information that is available concerning the potential investments which may be made."[108]

Disclosure is, however, not the only means, nor necessarily the most effective method, of protecting shareholders. Alternatives are plentiful. For example, the dictum in *Northwest Industries, Inc. v. B. F. Goodrich Co.*,[109] suggests that management should have an affirmative duty to resist a takeover bid that it has determined, after a good faith investigation, to be detrimental to the shareholders and to the corporation. State takeover statutes also go beyond simple disclosure. They typically provide for a period of several weeks during which the target may make inquiries concerning the background of the offeror and the possibility of receiving bids from other parties.[110] These alternatives cannot be adopted if the federal regulatory authorities continue their narrow adherence to the disclosure model.

A third problem with the Williams Act is that it seeks to achieve its goal of full disclosure in an inefficient manner.

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107 *See* text accompanying notes 90 to 103 *supra*.

108 1 ADVISORY COMM. REPORT, *supra* note 60, at xv.

109 301 F. Supp. 706, 712-13 (N.D. Ill. 1969); *see* text accompanying notes 71 to 73 *supra*.

110 *E.g.*, MASS. GEN. LAWS ANN. ch. 110C, § 2 (West Supp. 1977) (30 days); DEL. CODE ANN. tit. 8, § 203(a)(1) (Supp. 1978) (20 to 60 days).

Although the federal legislation set out to ensure full disclosure and to avoid tipping the scales toward the offeror or the target company,[111] the Williams Act is not a balanced and rationally divided model of disclosure. Instead, the Act requires the offeror to make information available not only about its own operations and plans but also about the performance of the target company. The offeror, however, is not likely to possess inside information concerning the target company;[112] it must piece together the best picture it can from information available in the target's SEC filings and other public sources.[113]

A more effective means of protecting shareholders is to require that the managements of the target and of the offeror provide material information according to some rational division of content.[114] An efficient disclosure policy would require the offeror to come forward with information as to its past business activity and its plans for the target if control is achieved.[115] Management of the target should likewise be required to furnish information about its current operations and its potential earning power whenever a tender offer is made. Each side should investigate the other and challenge the accuracy of the other's statements. Full development of material information through the responsive statements of the contenders would enable shareholders to make a fully informed decision whether to continue to invest in the company, to sell out in the open market, or to tender.

Within its limited framework of disclosure, then, the Williams Act, as it now stands, fails to effectuate Congress' determination that the investing public should receive all the material facts before responding to a tender offer. Those

111 *See* notes 33 to 35, 89 and accompanying text *supra.*

112 *See* note 25 *supra.*

113 To the extent that the offeror's own analysis of public financial data has enabled it accurately to appraise the target's desirability, it enjoys an advantage which is consistent with the integrity of securities markets and is ordinarily not thought to be prohibited by legislation. *See* Brudney, *supra* note 23, at 625; *cf.* SEC v. Texas Gulf Sulphur Co., 401 F.2d 833, 848-49 (2d Cir. 1968) (insiders not obligated to confer the benefit of superior financial analysis on outsiders, who must draw their own conclusions from the basic material facts), *cert. denied,* 394 U.S. 976 (1969).

114 *See Affirmative Disclosure, supra* note 3, at 191.

115 This information is required to be disclosed under present law. Exchange Act § 14(d)(4), 15 U.S.C. § 78n(d)(4) (1976).

material facts may never come to light if target management observes a tactical silence, even though the informational needs of the shareholders are no different when management avoids disclosure. While it is true that management will usually respond of its own accord,[116] silence should not be encouraged by the existence of a gap in the disclosure legislation.

C. *The Relevance of State Law*

The states have not adequately filled the gap in federal tender offer regulation. Instead of creating target management duties, which are thought to be an appropriate object of state corporation law,[117] state law has tipped the regulatory balance overwhelmingly against offerors.[118]

On the one hand, both the pre-offer notice periods and the minimum offer durations required by state laws[119] have the beneficial effect of ensuring that the managers and owners of the target company enjoy an adequate opportunity to investigate the credentials of the offeror, to evaluate the performance of the incumbents, and to seek higher prices from the offeror or alternative bidders. On the other hand, the requirement that an offer be announced to target management long before it becomes effective for shareholders is undoubtedly an unnecessary burden on the offeror. The states can achieve the same beneficial effects of their regulatory strategy by limiting the regulation of tender offers to the requirement that an offer remain open for a minimum period.

The states' experience with minimum offer periods has been useful to reformers of the federal laws. The A.B.A. Subcommittee on Proxy Solicitations and Tender Offers has recommended federal adoption of a longer offer period:[120]

116 *See* note 90 *supra.*

117 *See* text accompanying notes 60 to 61 *supra.*

118 *See* notes 111 to 115 and accompanying text *supra.*

119 *See* notes 82 and 83 *supra.*

120 There is currently no explicit minimum offer period in the federal legislation, but the 7 day withdrawal period, 15 U.S.C. § 78n(d)(5) (1976), and 10 day pro rata acceptance period if fewer than all shares are sought, 15 U.S.C. § 78n(d)(6) (1976), create effective minimum periods. *See* Petersen v. Federated Development Co., 416 F. Supp. 466, 475 (S.D.N.Y. 1976); notes 149 to 151 and accompanying text *infra.*

"Congress should borrow from the 'Brandeisian Laboratory' of state legislation some formulation fixing a longer minimum time that tender offers must remain open than the seven to ten days currently possible. When this is done, Congress should also preempt the state takeover laws."[121] State law is, therefore, relevant to federal regulation in that it provides useful models for improving the federal tender offer legislation.

III. PROPOSED MANAGEMENT OBLIGATIONS

A. *Affirmative Disclosure*

The most significant step that can be taken to fill the void in federal tender offer legislation is to place an affirmative disclosure burden on target management. That is, the target should be required to furnish material information available to it when a tender offer is made, regardless of whether target management makes a recommendation for or against the offer. This is not to suggest that management should have a continuing obligation to make an immediate disclosure of information which is material to the value of the company's stock,[122] but only that such disclosure should be required whenever a takeover bid, an extraordinary event, is in progress.

Once the duty of affirmative disclosure is created, the SEC should be called upon to define the scope of that duty through rulemaking. In determining what information must be disclosed by management, the overriding concern will be,

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121 ABA Subcomm. on Proxy Solicitations and Tender Offers, *State Takeover Statutes and the Williams Act*, 32 BUS. LAW. 187, 198-99 (1976). The subcommittee did not itself disapprove of provisions for pre-offer notification to the target or administrative agencies. However, to the extent that such provisions "are intended simply to furnish a greater overall period for review and response, it would be preferable, if necessary as a compromise, to accomplish that purpose by extending the minimum period within which an offer, once made, must remain open." *Id.* at 195.

122 *But cf.* Talesnick, *Corporate Silence and Rule 10b-5: Does A Publicly Held Corporation Have an Affirmative Duty to Disclose?* 49 DEN. L. J. 369, 405-12 (1973) (proposes legislating affirmative duty to disclose, but limiting civil sanctions to injunctive relief).

as it is generally in the federal legislation, the protection of investors. The conventional wisdom of securities law has been that only "hard" information, verifiable facts and figures, should be included in filings with the SEC and in communications with shareholders.[123] However, securities analysts and sophisticated investors consider "soft" information, such as management projections, to be highly relevant to the valuation of companies and their stock.[124] The SEC currently requires that offerors reveal, at the time the offer is filed, soft information concerning their future plans for the target.[125] Since investors will benefit, the SEC should also require that targets disclose soft information such as management projections and financial forecasts.

The burden of informing shareholders of the material facts need not be excessive. Companies now subject to the Exchange Act are required to file periodic reports under existing provisions.[126] In the rare event of a tender offer, past information would be available and could be updated.[127] In order to ease further the burden of full disclosure, the minimum offer period should be made sufficiently long to allow management

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123 There has been a growing general dissatisfaction with this rule. *See, e.g.,* 1 ADVISORY COMM. REPORT, *supra* note 60, at 344-98; Schneider, *Nits, Grits, and Soft Information in SEC Filings,* 121 U. PA. L. REV. 254 (1972); Kripke, *A Search for a Meaningful Securities Disclosure Policy,* 31 BUS. LAW. 293, 314 (1975).

124 Schneider, *supra* note 123, at 280; Kripke, *supra* note 123, at 314.

125 Schedule 13D, 17 C.F.R. § 240.13d-101 (1977) (item 4). *See* 1 A. BROMBERG, *supra* note 21, § 6.3(633), at 120.8.

The SEC has relaxed the ban on management projections in many SEC filings. SEC Rel. No. 33-5699 (Apr. 23, 1976), [1975-1976 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 80,461, at 86,200-03. Indeed, the SEC has recently decided to encourage corporate forecasts of future revenue and earnings by proposing a "safe-harbor" rule. Should its predictions prove false, a company would not be liable for making a false or misleading statement "if the statement: (1) was prepared with a reasonable basis; and (2) was disclosed in good faith." SEC Rul. No. 33-5993 (Nov. 7, 1978), [Current] FED. SEC. L. REP. (CCH) ¶ 81,757, at 81,043. *Cf.* Dolgow v. Anderson, 53 F.R.D. 664 (E.D.N.Y. 1971), *aff'd per curiam,* 464 F.2d 437 (2d Cir. 1972) (internal review procedures supported reasonableness and good faith of management's forecasts against claimed violation of rule 10b-5).

Some restraint should of course be exercised, and projections should be accompanied by a statement pointing out their "soft" nature and stating any underlying assumptions. 1 ADVISORY COMM. REPORT, *supra* note 60, at 358. While good faith judgments ought to be protected by a "safe-harbor rule," *id.,* excesses should trigger injunctive relief under § 14(e).

126 Exchange Act § 13(a)(2), 15 U.S.C. § 78m(a)(2) (1976).

127 *See* Krasik, *supra* note 2, at 460.

to compile the necessary data and to distribute it to the shareholders.[128]

B. *Management Recommendation*

Should the affirmative disclosure burden be adopted, management would rarely choose not to make a recommendation. However, there may be good reasons for management's reluctance to take a stand, especially where there are several offers outstanding.[129] Therefore, management should be required to recommend either acceptance or rejection of any bid, or to articulate its reasons for failing to make a recommendation.[130]

Target management's position on the tender offer is highly relevant to the individual shareholder's decision to tender or not to tender. An investor, particularly one without a great deal of sophistication in analyzing financial data, is likely to rely on management's view of the offer.[131] As one commentator has noted:

> [S]hareholders are likely to be confused by the total situation, and management is in the best position to explain the present position of the company and its prospects. While management may be biased, if it is required to state clearly

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128 *See* text accompanying notes 154 to 156 *infra.*

129 *See* note 95 *supra.* Management could satisfy the requirements of the proposed legislation by citing the difficulty of evaluating a multitude of competing offers as its reason for not making a recommendation.

130 This suggestion goes further than either the current law or the SEC's proposed rule. Management currently may make an initial response to a tender offer without triggering disclosure requirements. Rule 14d-2(f), 17 C.F.R. § 240.14d-2(f) (1977). If a sufficiently "bland" notice is released, *see* Anaconda Co. v. Crane Co., 411 F. Supp. 1210, 1215 (S.D.N.Y. 1975), which advises shareholders not to tender until management has completed studying the offer, a schedule 14D need not be filed. The subsequent communication must be made no later than 10 days before the offer expires. 17 C.F.R. § 240.14d-2(f) (1977).

Proposed rule 14d-4(c)(4) would require that management, once it has filed an initial statement, either make a subsequent recommendation or indicate its decision not to recommend. SEC Rel. No. 34-12676 (Aug. 2, 1976), [1976-1977 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 80,659, at 86,698. The flaw in the proposal is that there is no requirement that management make an initial statement, such as the statement that it is studying the offer.

131 *See* Chris-Craft Indus. Inc. v. Piper Aircraft Corp., 480 F.2d 341, 364-65 (2d Cir. 1973) (corporate insiders have special responsibility during battle for control because shareholders will rely heavily on insiders' representations), *cert. denied,* 414 U.S. 910 (1975).

> its reasons for its recommendation for or against a tender offer and if the statement of reason is limited by a "reasonable belief" test, the value of the information would far outweigh any possible harm.[132]

The dictum in *Northwest Industries, Inc. v. B. F. Goodrich Co.*,[133] suggested that management has a fiduciary duty to resist actively any takeover which it perceives, after good faith inquiry, to be detrimental to the interests of the corporation and its shareholders.[134] One commentator has gone even further and has suggested that a duty to resist in every case fits into the federal disclosure scheme because the clash of adversaries would promote the fullest development of material information.[135] This Note makes a more limited suggestion, and leaves any imposition of a duty to resist takeovers, in some or all circumstances, to state corporation law.[136] An obligation to oppose every tender offer, moreover, would be inconsistent with investor protection, since the success of the offer will often be in the best interests of the shareholders.[137] It is difficult, on the other hand, to imagine any injury flowing to shareholders from a requirement that management either make a recommendation or account for its decision not to do so.

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132 Krasik, *supra* note 2, at 460. The "reasonable belief" test asks whether a reasonable person "in management's position as of the date the prediction was made, could have had a reasonable belief that those predictions would come to pass." *Id.* at 465. This test is similar to the safe-harbor rule, which has been proposed for use in evaluating soft information. *See* note 125 *supra*.

Management could also protect itself by retaining an independent investment banker to evaluate the financial merits of the offer or offers and to give an opinion that would form the basis for management's recommendation. *See* Fleischer, *supra* note 45, at 862; Klink, *supra* note 63, at 328; 1 A. BROMBERG, *supra* note 21, § 6.3(633), at 120.8; *cf.* Gerstle v. Gamble Skogmo, Inc., 298 F. Supp. 66, 95 (E.D.N.Y. 1969) (person who is retained to express opinion on fairness of transaction must be absolutely impartial).

133 301 F. Supp. 706 (N.D. Ill. 1969) (applying New York law); *see* text accompanying notes 71 to 73 *supra*.

134 *Id.* at 712-13.

135 Barnhill, *The Corporate Raider: Contesting Proxy Solicitations and Take Over Offers*, 20 BUS. LAW. 763, 780 (1965).

136 *See* notes 60 to 61 and accompanying text *supra*.

137 Takeover bids may "serve a useful purpose in providing a check on entrenched but inefficient management." H.R. REP. NO. 1711, *supra* note 12, at 4, *reprinted in* [1968] U.S. CODE CONG. & AD. NEWS at 2813. *See generally* Brudney, *supra* note 23.

C. *Investigation of the Offeror*

Whether recommendations are required or permitted, the effective functioning of the regulatory model is threatened as much by "knee-jerk" opposition from entrenched management as by the latter's tactical silences.[138] Although there are many legitimate reasons for management's opposition to a particular takeover bid,[139] many targets anticipate the possibility that a tender offer will be made by preparing "canned" releases[140] and assembling a defensive staff well in advance.[141] Under present law, such perfunctory consideration of an offer and immediate employment of defensive tactics appear to be subject to virtually no judicial scrutiny.[142]

The frequency of knee-jerk resistance and tactical silences can be reduced by requiring incumbent management to undertake a reasonable investigation of the offeror before responding with defensive tactics or with a recommendation. Such a duty would be analogous to management's common-law duty to investigate insurgents before buying them out[143] or to controlling shareholders' duty to investigate purchasers

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138 *But see* Flom, *supra* note 9, at 1319: "[Targets' attitudes] have changed significantly from those of five or six years ago when the knee jerk reaction was particularly violent — when the attitude was, no matter who gets it, this guy can't get it."

139 *See* Note, *The Courts and the Williams Act: Try a Little Tenderness,* 48 N.Y.U. L. REV. 991, 995 (1973): "Legitimate reasons would include the nature and plans of the offeror, the target's improving prospects under present management, or the target's temporarily depressed security prices. Finally, although management may not be adverse [sic] to a takeover, it may decide that the particular price offered is inadequate."

140 Fleischer, *supra* note 45, at 853.

141 ARANOW & EINHORN, *supra* note 11, at 224; Cary, *Corporate Devices Used to Insulate Management from Attack,* 25 BUS. LAW. 839 (1970).

Brown, *supra* note 45, at 1644, notes:

> Because Rule 14d-4 would prohibit a target company management from recommending against a tender offer until a Schedule 14D has been filed, companies concerned about possible tender offers frequently draft a Schedule 14D in advance and, in some cases, have an agent in Washington duly authorized to complete and file the Schedule.

142 *See* Humana, Inc. v. American Medicorp, Inc., [1977-1978 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 96,286, at 92,824, 92,832-33 (S.D.N.Y. 1978).

143 *See generally* Condec Corp. v. The Lunkenheimer Co., 43 Del. Ch. 353, 230 A.2d 769 (Ch. 1967).

of control in some situations.[144] An obligation to investigate goes beyond the disclosure mandated by the federal scheme. It is nevertheless consistent with the general investor-protection objective of federal securities law, because management is more likely than the individual to have the expertise, resources, and motive to make a thorough investigation of the tender offeror.[145]

Besides protecting against "knee-jerk" opposition, the target's duty to investigate would produce two additional benefits. First, the quality of the recommendation, should target management be required to make one, would be improved. Second, the duty to investigate would directly promote disclosure of material information. Tender offer regulation should take advantage of the fact that each side has a practical incentive to probe into the practices of the other.[146] The target may discover and reveal facts which the offeror has not disclosed, since the judicial interpretation of the offeror's duty to disclose does not necessarily include all information which may be relevant from the standpoint of the target shareholder.[147] In general, it seems that statutory re-

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144 *See* Insuranshares Corp. v. Northern Fiscal Corp., 35 F. Supp. 22 (E.D. Pa. 1940); *cf.* Gerdes v. Reynolds, 28 N.Y.S.2d 622 (Sup. Ct. 1941) (board of directors' willful disregard of buyers' intention to waste assets of company held a breach of fiduciary duty to minority stockholders).

145 *Cf.* Chris-Craft Industries, Inc. v. Piper Aircraft Corp., 480 F.2d 341, 370 (2d Cir. 1973) (underwriter can be relied on to make thorough investigation since he has expertise and resources to do so and has a financial interest at stake), *cert. denied*, 414 U.S. 910 (1975). Similar factors suggest that management should be required to investigate an offeror for the benefit of the shareholders. Of course, management may employ an investment banker to ensure even greater expertise and objectivity. *See* note 132 *supra*.

The federal legislative scheme should not be bound by an original vision of disclosure which looked to more substantive regulation at the state level. The states have failed in the takeover situation to protect investors adequately and have actually frustrated the federal policy laid down by the Williams Act. *See* text accompanying notes 85 to 89 *supra*.

146 *See* H. K. Porter Co. v. Nicholson File Co., 482 F.2d 421, 424 (1st Cir. 1973).

147 *See, e.g.*, Missouri Portland Cement Co. v. H. K. Porter Co., 535 F.2d 388, 397 (8th Cir. 1976) (tender offeror need not disclose past policy of liquidating or selling assets of target company, nor is such policy a material fact). Although a past policy of liquidation need not be disclosed, any specific plans to liquidate the target corporation if control is achieved must be revealed in item 4 of schedule 13D, 17 C.F.R. § 240.13d-101 (1977). *Cf.* Gulf & W. Indus., Inc. v. Great Atl. & Pac. Tea Co., 476 F.2d 687, 696-97 (2d Cir. 1973) (offeror need not disclose "a well established practice

quirements work best when there is an adverse party lurking on the sidelines and ready to call "foul."[148]

D. *Minimum Duration of Offer*

The Williams Act does not explicitly require that tender offers remain open for any specified period of time, but the withdrawal[149] and pro rata[150] rights effectively impose a

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of eventually acquiring firms in which it initially purchased only a small percentage of the outstanding shares"; however, if offeror intends, when announcing its tender offer, to take control of the target, failure to disclose intent would violate § 14(e)).

Other information, such as compensation by the offeror of persons promoting the offer, must under current rules be revealed in filings with the SEC, 17 C.F.R. § 240.13d-101 (1977) (item 7), but need not be included in communications with the shareholders, 17 C.F.R. § 240.14d-1(c)(4) (1977).

148 Of course, the advantages that are present in an adversary system should also be available to ensure that target management fulfills the proposed duties of investigation, recommendation, and disclosure. The "obvious economic stake" which the offeror has in the outcome of the tender contest suggests that it should have standing to bring an action against the target management for breach of the proposed duties. H. K. Porter Co. v. Nicholson File Co., 482 F.2d 421, 424 (1st Cir. 1973).

The Supreme Court has recently held that "a tender offeror, suing in its capacity as a takeover bidder, does not have standing to sue for damages under the Williams Act," Piper v. Chris-Craft Indus., Inc., 430 U.S. 1, 42 n.28 (1977). The Court did not decide the more critical issue of an offeror's standing to sue for injunctive relief. *Id.* at 47 n.33. In Humana, Inc. v. American Medicorp, Inc., [1977-1978 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 96,286, at 92,824 (S.D.N.Y. 1978), the offeror was held to have such standing despite *Chris-Craft*.

Although the standing issue is beyond the scope of this Note, adoption of these proposals will be effective only if the offeror is given standing to challenge target action and to receive both injunctive and monetary relief.

149 Exchange Act § 14(d)(5), 15 U.S.C. § 78n(d)(5). Section 14(d)(5) states:

> Securities deposited pursuant to a tender offer or request or invitation for tenders may be withdrawn by or on behalf of the depositor at any time until the expiration of seven days after the time definitive copies of the offer or request or invitation are first published or sent or given to security holders, and at any time after sixty days from the date of the original tender offer or request or invitation, except as the Commission may otherwise prescribe by rules, regulations, or order as necessary or appropriate in the public interest or for the protection of investors.

150 Exchange Act § 14(d)(6), 15 U.S.C. § 78n(d)(6). Section 14(d)(6) states:

> Where any person makes a tender offer, or request or invitation for tenders, for less than all the outstanding equity securities of a class, and where a greater number of securities is deposited pursuant thereto within ten days after copies of the offer or request or invitation are first published or sent or given to security holders than such person is bound or willing to take up and pay for, the securities taken up shall be taken up as nearly as may be pro rata, disregarding fractions, according to the number of securities deposited by each depositor. The provisions of this subsection shall also apply to securities deposited within ten days after notice of an increase in the

minimum duration of seven days for all offers and of ten days for offers in which the offeror plans to accept fewer than one hundred percent of the tendered shares.[151] Many state statutes require a longer period,[152] and the New York Stock Exchange recommends a period of at least ten days for listed companies.[153]

Federal law should require a minimum offer period of several weeks. This minimum duration would have three salutary effects. First, target management would have enough time to fulfill its fiduciary obligations to investigate the offeror, disclose material facts about the target, and make its recommendation. In addition, extra time would provide third parties greater opportunity to make a better offer for the shares.[154] Finally, during the extended period, the original offeror might itself raise the offer price, in response either to competition or to prodding from the target.

The primary reason for extending the time is to avoid stampeding the target company into a hastily conceived reaction to the offer. As much as possible, management's response should be the product of objective decision making that takes into account the interests of the shareholders.[155] Preceding sections of this Note have suggested that target management be required to fulfill duties to conduct investigations, to disclose information, and to make recommendations. Full discharge of these additional obligations would be difficult under present legislation because of the practical

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consideration offered to security holders, as described in paragraph (7), is first published or sent or given to security holders.

See note 26 *supra.*

151 *See* Petersen v. Federated Development Co., 416 F. Supp. 466, 475 (S.D.N.Y. 1976).

152 *E.g.*, MASS. GEN. LAWS ANN. ch. 110C, § 7 (West Supp. 1977) (60 day minimum offer period); DEL. CODE ANN. tit. 8, § 203(a)(2) (Supp. 1978) (20 day minimum period).

153 N.Y. STOCK EXCHANGE COMPANY MANUAL A-180: "While it is desirable that a period of about 30 days be used, a tender offer should remain open for a minimum of 10 days, so that all stockholders, even though they may live at a distance, will have ample opportunity to learn of the tender offer and to tender their shares."

154 *See, e.g.*, E. ARANOW, H. EINHORN & G. BERLSTEIN, *supra* note 78, at 79.

155 *See* Small, *Defending Target Companies: General Perspectives*, 32 BUS. LAW. 1349, 1349 (1977).

time limits in effect during most tender offers.[156] If a higher standard of fiduciary conduct is to be imposed upon incumbents, the federal law should require a minimum offer period of several weeks.

Shareholder protection, of course, must not be bought at any price. A minimum period of several weeks might pose a detriment to target shareholders because it might deter potential offerors from making desirable tender offers.[157] It is difficult to assess the practical impact which the proposals here would have on corporate behavior, but it is unlikely that extension of the duration of tender offers would put an end to their employment as a means of acquisition. It seems probable that any deterrent effect of extending the offer period is more likely to be felt by a corporate "raider"[158] than it is by a company interested in acquiring an additional operation and productive investment. For the latter companies, "[t]he delay will mean [only] that you are not going to get quite the same bargain you might otherwise have gotten on a short-fuse tender or so-called 'Saturday night special.' "[159] The tactical maneuvering currently allowed should therefore be restricted in order to ensure that target management has an adequate opportunity to respond to the offer.

The SEC's proposals for rules under section 14(e) of the Exchange Act[160] would extend the minimum time period during which offers must remain open. Proposed rule 14e-2 requires that offers be held open for at least fifteen business days and

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156 *See* Gulf & W. Indus., Inc. v. Great Atl. & Pac. Tea Co., 476 F.2d 687, 696 (2d Cir. 1973) (management's proof of offeror's intent difficult "particularly where only limited discovery is possible, as in the case below due to the time limitations"); *cf.* Commonwealth Oil Ref. Co. v. Tesoro Petroleum Corp., 394 F. Supp. 267, 274 n.1 (S.D.N.Y. 1975) (management's limited time for responding to tender offer held relevant on question of materiality).

157 *See* Brown, *supra* note 106, at 816.

158 A "raider" is primarily interested in expansion and acquisition at cheap prices, rather than in building up the target company.

159 Flom, *The Role of the Takeover in the American Economy,* 32 BUS. LAW. 1299, 1299 (1977). A "short-fuse tender" or "Saturday night special" is a tender offer which comes as a surprise and catches the target off-guard. The target is unable to take effective defensive measures because of time limits on the offer. A "Saturday night special" takes its name from the fact that it is prepared after the closing of the market on Friday to prevent leaks and is announced on Monday morning.

160 15 U.S.C. § 78n(e) (1976).

for ten business days after any increase in the price or the dealer's fees.[161] The proposed rules in effect create an offer period comparable to that required by most state takeover statutes.[162] The minimum offer periods of state legislation, originally intended to give management greater opportunity to muster its defenses to thwart an offer, may thus have provided the model for a federal minimum period, which would be designed to allow management an opportunity to investigate and respond for the benefit of the shareholders.[163]

In view of the analysis suggested here, however, a minimum period is more than a measure to prevent fraud and manipulative acts; rather, it is an integral part of the disclosure scheme, necessary in order to impose investigative and disclosure obligations on management without tipping the balance of regulatory hardship. It would not be inappropriate to incorporate the minimum period into the legislation itself, as part of a thorough revision of the Williams Act.

Conclusion

Management's fiduciary dilemma during extraordinary corporate transactions will not be resolved entirely by more legislation. But a tender offer affects all shareholders and it is imperative that they be as fully informed as possible. The potential conflict of interest between managers and shareholders may lead to tactical silences or knee-jerk resistance, neither of which is consistent with the protective policies of the federal law.

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161 SEC Rel. No. 34-12676 (Aug. 2, 1976), [1976-1977 Transfer Binder] FED. SEC. L. REP. (CCH) ¶ 80,659, at 86,702. In addition, the present 7 day withdrawal period would be increased to 10 business days, or 7 business days after a competing bid is made. Proposed rule 14d-5, *id.* at 86,698.

Business days are defined as those days on which the SEC is open for business. The business day terminology may be confusing, *see* Brown, *supra* note 106, at 815, and should be replaced with a simpler 21 calendar-day requirement. *See, e.g.*, ALI FED. SEC. CODE § 606(e), at 242 (Proposed Official Draft 1978).

A second, and potentially more significant, problem with the proposed rule is that it is not clear that the rule-making provision in § 14(e) authorizes the SEC to promulgate a rule prescribing a minimum period. *See* Brown, *supra* note 106, at 816.

162 Brown, *supra* note 106, at 816.

163 *See* ABA Subcomm., *supra* note 121, at 195-99.

This Note therefore has proposed that the fiduciary relationship be regulated more directly by the federal securities laws. In making these proposals, the Note is "not pleading the cause of takeover bidders; on the contrary . . . , imposing disclosure duties upon management would 'make it much easier for *stockholders* to evaluate the offer on its merits.' "[164] Although there may never be a perfect tender offer, the federal regulation should operate as efficiently and effectively as possible.

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164 Piper v. Chris-Craft Indus., Inc., 430 U.S. 1, 34 (1977) (quoting testimony of SEC Chairman Cohen in *Hearings on S.510, supra* note 28, at 184) (emphasis in the original).

STATUTE

STATE REGULATION OF THE SITING OF LIQUEFIED NATURAL GAS FACILITIES

JOHN T. BUTLER*

Liquefied natural gas (LNG) offers substantial opportunities to ease this nation's energy problems. Its volatility, however, makes it extremely hazardous to property and life near LNG facilities. Mr. Butler examines the federal response to these hazards and legislation passed in three states to regulate LNG facility siting. Finding these approaches inadequate, Mr. Butler proposes a Model Statute that offers a framework for states to rationalize site selection within their jurisdictions.

Introduction

Liquefied natural gas (LNG) technology presently provides solutions to many of the United States' natural gas problems and promises to be even more useful in the future. Liquefied natural gas is natural gas in the liquid state. Because natural gas is a light, volatile hydrocarbon, its boiling point is quite low. Liquefying natural gas (liquefaction) requires reducing its temperature to below -260° Fahrenheit (-162° Celsius).[1] Since LNG must be kept at this low temperature in storage, special materials and technologies, known as cryogens, are necessary for its handling, and LNG is thus frequently referred to as a cryogenic liquid.

As a consequence of liquefaction, the volume occupied by a given mass of natural gas is reduced to one six-hundredth of its volume in the gaseous phase at atmospheric pressure, making it much more practical and economical to store natural gas as LNG than to store it in the gaseous state.[2] Its

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1 Drake & Reid, *The Importation of Liquefied Natural Gas,* SCIENTIFIC AM., April 1977, at 22 [hereinafter cited as Drake & Reid].

2 Increases in pressure can reduce the size of the container needed to store a given mass of gaseous natural gas. Limitations in container technology, however,

unique characteristics make LNG a vital link in our nation's energy supply.[3] Most frequently LNG technology is employed for water-borne transportation and peak shaving storage of natural gas. The volumetric reduction achieved by liquefaction makes long distance shipping economically feasible.[4] In addition, it permits local gas companies to store large supplies of natural gas in order to meet the excess consumer demand over pipeline supply during peak demand periods.[5]

There are, however, substantial safety hazards associated with LNG transportation and storage that require careful regulatory attention before LNG can be utilized on a wide scale. While there is some federal regulation of LNG facilities, a state in which such a facility may be erected would do well to supplement this federal effort with a program of its own.

This Note proposes a Model Statute by which a state could effectively regulate the siting of liquefied natural gas facilities. First, a brief description of the safety hazards associated with liquefied natural gas technology will be presented. Second, several extant legislative efforts to deal with these dangers will be reviewed. Finally, the Model Statute will be set forth with appropriate comments.

I. NEED FOR LNG FACILITY REGULATION

Since LNG is a highly volatile substance, the prospect of widespread utilization of LNG as an energy source raises several disturbing questions of public safety.

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make it impractical to achieve in this manner the sort of volumetric reduction possible with liquefaction. OFFICE OF TECHNOLOGY ASSESSMENT, TRANSPORTATION OF LIQUEFIED NATURAL GAS 8 (1977) [hereinafter cited as OTA STUDY].

3 *Safety Issues Concerning LNG Storage Facilities: Hearings Before the Special Subcomm. on Investigations of the House Comm. on Interstate & Foreign Commerce,* 93d Cong., 1st Sess. (1973) [hereinafter cited as *Safety Issues Hearing*].

4 *See* A. VAN HORN & R. WILSON, LIQUEFIED NATURAL GAS: SAFETY ISSUES, PUBLIC CONCERNS, AND DECISION MAKING, 17-22 (1976) [hereinafter cited as VAN HORN & WILSON]; Uhl & Giese, *LNG Export-Import System Economics,* PIPE LINE & GAS J., June 1973, at 41, 48.

5 It would be technically feasible to build pipelines large enough to carry sufficient gas for the peak season. However, to build gas extraction wells and pipelines large enough to accommodate peak season demand would leave idle very expensive equipment during the off-peak seasons. *See generally* Nelson, *Liquid Natural Gas Energy Center Decisions: Experience in the New England Area,* NEW ENG. J. OF BUS. & ECON., Fall 1974, at 41.

Although the LNG industry has a good safety record, there are serious risks to workers at LNG facilities and to people and property in adjacent areas. Most of these risks stem from the combustibility of natural gas and the potential for large fires fed by the great quantity of natural gas stored in an LNG facility. The risk of fire was demonstrated very early in the history of the LNG industry by a spill in Cleveland in 1944. In that accident, LNG spread through the streets and sewers and, when it vaporized, the resulting gas caught fire, killing 128 people.[6]

The risks of LNG storage far exceed those associated with gaseous natural gas storage for reasons besides the much larger quantities of gas. If a gaseous natural gas storage vessel were breached, the natural gas, being buoyant, would diffuse through the surrounding air and quickly become so diluted as to be unable to support combustion unless the leak was confined to a closed area. Because of this quick dilution, gaseous natural gas storage presents relatively few threats to property near the facility. Although fires might occur within the plant confines, these would principally concern the property owners immediately adjacent to the plant.

LNG presents a quite different risk. Because it is a liquid, LNG escaping from a storage vessel will flow downhill until it vaporizes. Even after it vaporizes the extremely cold natural gas will remain heavier than air for quite some time, forming a dense natural gas cloud that will hug the ground. Considering the large quantities of natural gas contained in a storage vessel, this cloud could become very large before diffusion safely dilutes the natural gas. Although estimates vary substantially, even the lower forecasts predict a cloud extending three to five miles downwind of a major LNG spill.[7]

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6 VAN HORN & WILSON, *supra* note 4, at 22. The spill resulted from a fracture in a brittle storage tank. In the early days of the LNG industry, the tanks were made of 3 percent nickel steel alloy which was extremely susceptible to such failures. *See* Foley v. Pittsburgh-Des Moines Co., 363 Pa. 1, 68 A.2d 517 (1949). Present day technology utilizes a nickel steel with much better cryogenic properties.

7 *See* OTA STUDY, *supra* note 2, at 66, figure 35. The upper estimates foresee a cloud extending up to 50 miles downwind before it is no longer flammable. Since these clouds may be "a few miles wide," VAN HORN & WILSON, *supra* note 4, at 32, many square miles could be covered by this cloud.

Within the area covered by the cloud, several undesirable consequences may occur. First, it is likely that the gas in the cloud will be ignited. The resultant fire will radiate dangerous amounts of heat within the cloud, and for a considerable distance outside as well, causing extensive property damage and personal injury or death.[8] Even if the cloud does not ignite, its natural gas concentration could be harmful and possibly even lethal to people breathing it.[9] Finally, contact with the LNG itself could result in severe cold burns.

Another safety hazard associated with LNG import facilities is the liquid-liquid vapor explosion, a phenomenon unique to cryogenic liquids. When LNG comes into contact with water, rapid heating and vaporization of the liquid occurs. The vaporization may be contained for a short period by the fluid properties of a liquid-liquid vapor interface, allowing pressure to build up. Upon escaping the containment, rapid expansion of the vapor at an explosive rate may occur. The ensuing detonation could in itself be harmful or could exacerbate the spill conditions, turning a small spill into a major catastrophe.[10]

For LNG plants to be acceptable within a community, these risks must be reduced. This objective can be attained through a comprehensive program with three components: 1) safe design; 2) personnel training; and 3) safe siting. The Model Statute presented in this Note deals particularly with the safe siting of LNG facilities, but maximum benefit from the statute requires continuing enforcement through a comprehensive program. Therefore, this Note will briefly discuss elements of safe design and the training of personnel and will then turn to an in-depth discussion of safe siting considerations.

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8 It is unclear exactly what level of heat flux is low enough to be safe. Even fairly high estimates of the maximum safe exposure level could still be encountered at a distance of over 500 feet from a moderate (150 foot radius) LNG pool fire. *Id.* at 43-45.

9 Although natural gas is not toxic, high concentrations in the air people breathe could cause asphyxiation by reducing the oxygen content in the air. OTA STUDY, *supra* note 2, at 7.

10 VAN HORN & WILSON, *supra* note 4, at 39-43.

A. *Safe Facility Design and Accident Contingency Responsibility*

In designing a safe LNG facility, attention must be paid both to reliable, accident-free, normal operation and to containment and safe dispersal of escaping LNG should an accident occur.[11] Among the measures taken to enhance safe operation are the use of special nickel-steel alloys which are suitable for use at cryogenic temperatures,[12] failsafe valving to prevent leaks,[13] maintenance of pure natural gas atmosphere inside storage vessels to eliminate explosion,[14] and dikes around facilities to stem the flow of escaping LNG.[15]

Since controllable accidents can develop into major disasters because of the failure of personnel, employees of LNG facilities must be trained to respond to an LNG accident. Because of the peculiar safety hazards created by LNG spills, local fire departments must be familiar with the properties of LNG and LNG vapor clouds and police and civil defense personnel must be prepared to evacuate nearby residents.

B. *Proper Siting of the Facility*

While careful facility design and proper safety training can substantially reduce the probability that a major LNG accident will occur, significant risks to those whose property is near the facility remain. It is still necessary to analyze carefully the proposed location of the facility, to generate and analyze alternatives, and to choose the most acceptable location. This process is called siting.

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11 Existing safety standards, both in the form of government regulation and industry codes, have been directed primarily at minimizing the risk of operational failure because large initial improvements in risk reduction can be made at low cost by designing a facility largely free of operational failure risks. *See generally* National Fire Protection Association Code, Standard 59A, 49 C.F.R. § 192.12 (1977).

12 OTA STUDY, *supra* note 2, at 9.

13 *See generally,* VAN HORN & WILSON, *supra* note 4, at 43; Drake & Reid, *supra* note 1, at 27.

14 Natural gas cannot burn in the absence of oxygen.

15 *See* 42 Fed. Reg. 20,776, 20,787-89 (1977) [hereinafter cited as OPSO Draft Guidelines].

A mathematical model that quantifies the risks and consequences of foreseeable accidents at alternative sites is necessary to determine the most acceptable location for a proposed facility.[16]

A proper siting model can be derived by evaluating alternative facilities with respect to four relevant factors:[17] 1) hazards from natural disasters; 2) number of people and value of property exposed to a potential accident; 3) impact on the local ecology; and 4) construction and operating costs.[18]

The first three factors are of considerable importance in governmental regulation of LNG facility siting. There is little direct economic incentive for a person proposing a facility to take these into account since they will frequently work against his interest in keeping down costs. The fourth factor is, of course, perfectly compatible with the economic interests of the facility owner and can be assumed to be self-enforcing.

The first factor, siting LNG facilities in order to avoid the worst natural hazards, is particularly important in certain parts of the country. The possibility of earthquakes in California requires detailed attention to the seismological characteristics of proposed sites.[19] Similarly, other areas of the country require sites that will reduce exposure to tornadoes, hurricanes, and floods.[20]

In addition to natural hazards, various manmade hazards, though uncommon and not directly connected with the LNG facility, should be considered in risk assessments of LNG facilities. While manmade risks, such as airplanes crashing into a facility, are always very small, they can be reduced further by such precautions as avoiding airport glide paths when siting the facilities.[21]

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16 *See* SCIENCE APPLICATIONS, INC., LNG TERMINAL RISK ASSESSMENT STUDY FOR LOS ANGELES, CALIFORNIA (1975).

17 The standard procedure for selecting foreseeable accidents is to select the "worst case scenario" and compute risk on the product of the consequences of this accident times its probability of occurrence. This may well underestimate the risk of more mundane but nonetheless serious accidents.

18 These and other criteria are discussed in OTA STUDY, *supra* note 2, at 64-66.

19 *Hearings on Liquefied Natural Gas before the Permanent Subcommittee on Energy,* California Assembly, July 1976 [hereinafter cited as *California Hearings*].

20 *See* OPSO Draft Guidelines, *supra* note 15, at §§ 193.113, .117.

21 *See* SCIENCE APPLICATIONS, INC., *supra* note 16.

The second factor considers the damage and injury that would result if a serious accident should occur. This is probably the factor most opposed to the facility owner's concern with low costs. It is usually desirable from a cost standpoint to have the LNG facility close to densely populated areas of gas consumers, however undesirable this may be from the standpoint of safety. Selecting the most favorable site according to the criteria of this second factor requires an intentional compromise with the desire to minimize costs. Therefore the facility owner will almost certainly vigorously resist any site proposals which are far from his customers, and the regulatory body should carefully attend to this consideration.

The third factor, minimizing ecological intrusion, may also be at odds with the second value favoring remote location. This conflict frequently divides groups that are normally allied, revealing a split between those who most want to protect human safety and those who most want to protect open spaces.[22]

Once the consequences of building at each proposed site have been quantified according to the three factors of concern to the regulatory agency, they must be compared in order to select the most acceptable site. When no single site is most advantageous along all three factors, decision theory offers two methods of comparing sites. The first approach begins by numerically weighing the relative importance of each factor. Then the attractiveness of each site can be determined by taking the sum of the values assigned to the site for each factor times that factor's relative weight. This results in a single value for each site which reflects both that site's characteristics and our value judgments of the relative importance of each characteristic. The second approach requires the decision maker to select the site valued most favorably along one predetermined factor, subject to the constraint that no more than a predetermined level of risk will be tolerated for each of the other factors.[23]

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22 *See California Hearings, supra* note 19.

23 This approach also requires a value judgment about the acceptable risk

One of the most useful byproducts of a comprehensive, quantitative safety analysis would be the resulting numerical assessment of the total risk to the public from each proposed facility. Such an assessment would provide a final check on the construction of unduly dangerous facilities if the regulating body were to reserve the right to deny approval to a facility that had been risk-minimized according to its siting criteria but was still unacceptably dangerous.

II. Survey of Existing and Proposed Regulatory Legislation

A. *Federal Regulation*

Responsibility for some aspect of federal LNG regulation rests with as many as twelve different agencies, commissions, and departments.[24] Two of these (the Federal Energy Regulatory Commission (FERC) and the Office of Pipeline Safety Operations (OPSO) of the Department of Transportation) affect state legislation because of the fairly intricate interaction between them and their state counterparts.

1. Federal Energy Regulatory Commission (FERC)

The FERC has jurisdiction over all interstate gas transmission under the Natural Gas Act of 1938 (Gas Act).[25] It is empowered by section 7 of the Gas Act to grant Certificates of Public Necessity and Convenience to interstate gas projects when it determines that these projects are appropriate.

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associated with the other factors. *See* H. Taha, Operations Research 597 *passim* (1971); E. Mishan, *Second Thoughts on Second Best,* Oxford Econ. Papers (1962).

24 OTA Study, *supra* note 2, app. B, at 96.

25 15 U.S.C. § 717a (1976). Under the Gas Act, the Federal Power Commission (FPC) was to have this authority. However, when the Department of Energy (DOE) was formed, the FPC was subsumed and redesignated as FERC. The enforcement powers and policies relevant to this Note are preserved intact within FERC by congressional mandate in the DOE enabling act. 42 U.S.C.A. § 7172 (West Supp. 1977). Certain ratemaking functions of the FPC have been reassigned to the Economic Regulatory Authority within DOE; these are not relevant here.

Because FERC is statutorily assigned the role formerly occupied by the FPC and because much of the available case law deals with the FPC, the following discussion of FERC will contain numerous citations to FPC material.

FERC's mandate within the federal system raises two significant questions with respect to state regulatory efforts: (1) What types of facilities qualify as "interstate" facilities such that the FERC has jurisdiction? and (2) When the FERC has jurisdiction, to what extent does its section 7 certification program preempt state authority?

"Interstate," as used by the FERC, is a term of art whose statutory definition is found in subsections 1(a)-(c) of the Gas Act and has been refined by extensive litigation. Of particular interest to the state regulation of LNG are judicial decisions which have held that the national importance of LNG is such that LNG is within interstate commerce even if all, or nearly all, the regasified gas or LNG is sold intrastate,[26] and that all the interim components in a pipeline distribution system between the wellhead and the local gas company are elements of interstate commerce.[27] The latter is important because it means that an LNG wholesaler who bought gas from a pipeline, liquefied it, and then sold the LNG to satellite LNG facilities owned by local gas companies would be interstate within the meaning of the Gas Act. It appears, however, that local gas companies and their peak shaving facilities are not interstate for FERC jurisdictional purposes.[28] Therefore, one would expect the FERC to assert jurisdiction over LNG import terminals, liquefaction plants owned by interstate pipeline companies, and LNG companies who sell interstate.

Once FERC jurisdiction is asserted, the question of federal preemption must be answered. Actually, the issue of preemption has two parts. The first and most important of these is whether the FERC intends to regulate the safety or merely the economic aspects of facilities within its jurisdiction. The current position seems to be that the FERC will contribute to OPSO decisions, but will not explicitly consider safety in its

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26 Distrigas Corp. v. Federal Power Comm'n, 495 F.2d 1057 (D.C. Cir.), *cert. denied*, 419 U.S. 834 (1974).

27 Distrigas of Mass. Corp. v. Federal Power Comm'n, 517 F.2d 761 (1st Cir. 1975).

28 *Id.*

own certification process.[29] It is likely that the FERC makes at least some implicit consideration of safety issues, given the terms of its section 7 certification procedure requiring a consideration of the public interest.[30] However, these implicit safety considerations will not preempt state regulation because judicial decisions have consistently upheld an interstitial residuum of state power where the federal government has not explicitly acted.[31]

The interstitial residuum concept also provides the states with some authority to regulate safety issues involved in siting even when the FERC has explicitly considered safety in its certification proceedings. The cases have consistently pointed to a power analogous to the zoning power which permits states and local governments to restrict the location of a federally certified facility. This power exists because of the residuum left by a federal decision too macroscopic to consider matters of local concern.[32]

There is one disturbing aspect of the interstitial residuum concept when it rests upon local concern rather than upon FERC failure to regulate explicitly safe siting. Such cases as *New York State Gas Corporation v. Town of Elma*[33] clearly support state power to require alternate siting of an FERC-certified facility where the site chosen is not in the best in-

29 For a discussion of views concerning the extent of the FPC's jurisdiction over safety issues, *see* Opinion of the Comptroller General of the United States, in *Safety Issues Hearings, supra* note 3; S. REP. NO. 94-852, 94th Cong., 2d Sess. 10-11, 38-42, *reprinted in* [1976] U.S. CODE CONG. & AD. NEWS 4697-4700, 4703; H.R. REP. NO. 94-1660, 94th Cong., 2d Sess. 7, *reprinted in* [1976] U.S. CODE CONG. & AD. NEWS 4682-83.

30 15 U.S.C. § 717f(a) (1976).

31 *See* Panhandle Eastern Pipeline Co. v. Public Serv. Comm'n of Ind., 332 U.S. 507 (1947). The Court stated that "Congress meant to create a comprehensive and effective regulatory scheme, complementary in its creation to those of the states and in no manner usurping their authority." 332 U.S. at 520. *But see* United Gas Pipeline Co. v. Terrebonne Parish Police Jury, 319 F. Supp. 1138 (E.D. La. 1970), *aff'd* 445 F.2d 301 (5th Cir. 1971) (Pipeline Safety Act preempts the regulation of "design, installation, inspection, testing, construction, extension, operation, replacement, and maintenance of pipeline facilities").

32 *See* Transcontinental Gas Pipe Line Corp. v. Hackensack Meadowlands Dev. Comm'n, 464 F.2d 1358 (3d Cir. 1972). The "local concern" rule derives from Pennsylvania Gas Co. v. Public Serv. Comm'n, 252 U.S. 23, 29-31 (1919). This case preceded the Gas Act and was responsible for the inclusion of the "local concern" exception therein. *See* H.R. REP. No. 709, 75th Cong., 1st Sess. 2 (1937).

33 182 F. Supp. 1 (W.D.N.Y. 1950).

terest of the locality. Yet, these and other cases make it clear that, when the FERC has certified a facility and the state is merely acting in the interest of its local concern, the state may not ban the facility or so relocate it as to render it economically infeasible.[34] If one assumes that these cases stand for the proposition that whatever other powers a state may have it cannot prevent the FERC from exercising its will in permitting a gas company to construct a facility, then this limitation on residual power may apply when as a matter of policy FERC decides not to regulate facility safety.[35]

Thus, one can see that the FERC has preempted economic and siting regulation of a large part of the LNG industry. It is not clear exactly what it leaves to the states, although two principles emerge. First, if the FERC explicitly considers safe siting in its certification proceedings, the state may still regulate the precise location of the facility and may prescribe conditions not inconsistent with those of the FERC. Secondly, if the FERC does not explicitly consider safe siting, the state may regulate siting more broadly and exercise authority over non-local safety issues. This authority may still stop short of a total ban on the FERC-certified facility as unsafe.

2. Office of Pipeline Safety Operations (OPSO)

OPSO was created by the Department of Transportation (DOT) in response to the Natural Gas Pipeline Safety Act of 1968 (Pipeline Safety Act).[36] The Pipeline Safety Act invested DOT with control over the safe design, construction, and operation of natural gas pipelines and related facilities. OPSO asserts jurisdiction which parallels that of the FERC. Thus, the same LNG facilities which are interstate for the purposes of the FERC are within the ambit of OPSO's authority.

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34 Although a state may not administratively ban a federally approved facility, it may have standing to challenge such approval in court if certification of a facility is too detrimental to local interests; *see* 15 U.S.C. § 717r (1976).

35 The language of New York State Gas Corp. v. Town of Elma, 182 F. Supp. 1 (W.D.N.Y. 1950), would seem to prevent an outright ban based on safety regulation as well as one based on the "local concern" authority of the states.

36 49 U.S.C. § 1671-84 (1976).

The Pipeline Safety Act does not explicitly confer on OPSO the power to regulate directly the siting of proposed natural gas facilities. Furthermore, OPSO has refused to assert direct authority over the siting of facilities, bolstering the negative implication suggested by the omission of such powers from the Pipeline Safety Act.[37]

Nevertheless, OPSO contends that by requiring more stringent safety standards when a facility is situated near a populous area, it achieves the same result as an explicit siting decision.[38] However, OPSO is woefully understaffed and cannot adequately enforce its standards on a continuing basis.[39]

Anticipating the difficulty in enforcing OPSO decisions, the Pipeline Safety Act established a program by which states can be certified to act as OPSO's agents for the purpose of inspecting natural gas facilities.[40] A substantial portion of the states' costs will be reimbursed by OPSO.[41]

In addition to acting as OPSO's agents, states may take advantage of this program to impose and enforce additional safety standards.[42] These standards can take the form of modification of OPSO's standards, subject to OPSO's approval, as they apply to intrastate facilities.[43] The state may also regulate safety and siting of interstate facilities when these areas have not been preempted by federal regulation or when they involve matters of peculiarly local concern.[44]

B. *State Regulation*

Many states control various aspects of LNG facility siting or operation, usually through their public utility regulating agencies. However, California, Massachusetts, and New York

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37 OPSO's proposed regulations take this factor into consideration. *See* Testimony of Joseph Caldwell (director of OPSO), in *Safety Issues Hearings, supra* note 3, at 174.

38 *Id.*

39 *Id.*

40 49 U.S.C. § 1674 (1976).

41 *Id.* § 1672. A state may charge a tariff to pipeline companies to help defray the cost of enforcing OPSO's interstate regulations; *see* Tenneco, Inc. v. Public Serv. Comm'n of W. Va., 489 F.2d 334 (4th Cir.), *cert. denied,* 417 U.S. 946 (1973).

42 49 U.S.C. § 1674 (1976).

43 *Id.*

44 *See* text accompanying notes 25 to 35 *supra.*

stand out for their efforts at comprehensive regulation. Twelve salient aspects of LNG facility siting regulation will be discussed, with reference to the manner in which these states handle each aspect. The California plan discussed here differs in some respects from the LNG regulation bill recently enacted by the California legislature. Although it was modified during the legislative process, the California plan is discussed here as originally proposed by Assemblyman Terry Groggin because it is more interesting analytically.[45]

1. Nature of the Organization Entrusted with Siting Regulation

Both California and New York regulate siting by providing additional authority in this area to extant departments or agencies. In the California plan, this is the Energy Resources Conservation and Development Commission (ERC).[46] In New York, both the Department of Environmental Conservation (DEC)[47] and the State Energy Office (SEO)[48] are involved. In

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45 The proposal which is analyzed here is AB 220, California Legislature, Regular Sess. 1977-1978 [hereinafter cited as Cal. Siting Bill].

The law as passed is SB 1081. It will add Chapter 10 to Division 2 of the Public Utilities Code and will amend § 30261 of the Public Resources Code. SB 1081 differs in the following ways from AB 220: 1) the decision authority is vested in the California Coastal Commission (CCC) instead of the Energy Resources Conservation & Development Commission (ERC); 2) the authority of the CCC extends only to issuing a permit for a single import LNG facility; 3) no forecast of demand and supply is required of permit applicants, though the ERC is required to provide the CCC with such demand information as required for decision making; 4) the CCC charges only a filing fee and does not levy surcharges to help defray its operational costs; and 5) rather than specifying criteria to be considered in making a discretionary decision on siting, SB 1081 specifies a list of minimum standards which a facility must meet.

SB 1081 is a compromise between AB 220 as originally proposed by California Assemblyman Terry Groggin and a natural gas industry sponsored bill, the original SB 1081. After being passed in its original form by the California Senate, SB 1081 was altered to incorporate substantially the philosophy of AB 220. AB 220 was then allowed to die in the Assembly and SB 1081, as modified, was passed by the Senate. Telephone conversation with Terry Stuart, Office of California Assemblyman Terry Groggin, September 27, 1978.

46 Cal. Siting Bill, *supra* note 45.

47 NY ENVIR. CONSERV. LAW § 23-1701 (McKinney Supp. 1978) [hereinafter cited as NY SITING STATUTE].

48 NY ENERGY LAW § 23-1727 (McKinney Supp. 1978) [hereinafter cited as NY ENERGY STATUTE].

contrast, Massachusetts created a new agency, the Energy Facilities Siting Council (EFSC), entirely separate from existing regulatory agencies.[49]

Expanding the scope of existing agencies has the advantage of not increasing the number of state agencies and may require fewer new personnel for the enforcement of the regulatory program. There are, however, two main objections to utilizing existing agencies. First, it is quite unlikely that a state will have an established agency with expertise in siting. If not, it is questionable whether any resources would really be saved by overlaying an entirely new function on an old agency. Secondly, existing energy regulatory agencies, such as public utilities commissions, are frequently concerned more with assuring an adequate supply of energy than with public health and safety.[50] Therefore, unless a state has an existing agency that has siting experience and is not controlled by the utility industry, that state should start with a clean slate and create a new agency.[51]

2. Extent of State Authority

The extent of federal preemption and state residual power over LNG siting is unclear. All three states provide their regulatory agencies with authority to the greatest extent that is not in conflict with federal regulation.[52]

This approach is well advised. The extent of federal preemption, and thus upper bounds on state authority, will be established in court challenges by the LNG industry. By not explicitly setting limits, the states avoid needlessly cutting short their programs, leaving loopholes through which those regulated could escape the force of the regulation.

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49 MASS. GEN. LAWS ANN. ch. 164, § 69H (West Supp. 1978) [hereinafter cited as MASS. SITING STATUTE].

50 *See generally* B. COLE, RELUCTANT REGULATORS (1978).

51 In this context, it is interesting to note that both New York and California entrusted their siting regulation to environmentally conscious, experienced agencies.

52 Cal. Siting Bill, *supra* note 46, at § 26570; MASS. SITING STATUTE, *supra* note 49, § 69; New York does not explicitly provide for this power, but it is implicit in the mandatory certification program, NY SITING STATUTE, *supra* note 47, § 23-1707.

3. Funding

For both economic and political reasons, it is important that a siting regulatory agency be funded from charges levied upon those it regulates. The price of the regulated product will not reflect the true cost of providing it if the regulating costs are borne by the state. Such a misallocation of costs can be both inequitable and inefficient. [53] Politically, user charge funding is important because it insulates the agency from some of the year-to-year pressure which opposition interest groups may bring to bear on the legislature.

Massachusetts and California rely heavily on filing fees for siting certificates and forecasts. In Massachusetts, the filing fee for a certificate may range up to $25,000 and for a forecast approval up to $125,000. Each gas company must file only one forecast, but a certificate is needed for each facility. No direct provision is made for determining exact fees within these limits.[54]

For siting certificates, California charges a filing fee which must be greater than $10,000, but the statute establishes no upper limit or guidelines by which to determine the fee. In addition, it collects a surcharge on all natural gas sold in California. The revenue (up to $20,000,000) is allocated to the agency.[55]

By contrast, New York meets the cost of its LNG regulatory activities by charging the owner of each facility for the cost of regulatory decisions and their implementation.[56]

Of the three approaches, California's seems best suited to isolating the agency from political pressure. A second concern is the agency's ability to contract for and accept OPSO financial assistance. Federal funding which eliminates some user-charges would introduce some over-consumption of LNG, but would nonetheless be welcome in states which, for

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53 This problem is discussed with respect to over-utilization of airport facilities in Levine, *Landing Fees and the Airport Congestion Problem,* 12 J.L. & ECON. 79 (1969).

54 MASS. SITING STATUTE, *supra* note 49, § 69H. These fees need not cover the agency's expenses, nor must they be limited to expenses.

55 Cal. Siting Bill, *supra* note 45, §§ 26620 & 26622.

56 NY SITING STATUTE, *supra* note 47, § 23-1715.

political reasons, are hard pressed to exact the full regulatory costs from general tax revenues or from gas companies and consumers.

All three states permit their siting agencies to contract with and accept the substantial subsidies available from the federal government.[57] Additionally, it is important for the state to provide specifically that its LNG regulatory agency shall be its agent in the OPSO enforcement program as it relates to LNG. Massachusetts discovered this the hard way. Its Department of Public Utilities was participating in the OPSO program before the EFSC was created and has exhibited considerable reluctance to share this federal funding assistance. Without explicit state instructions to the contrary, OPSO has continued to give its assistance exclusively to the DPU.

4. Site Certification Process

New York requires every proposed LNG facility to obtain a Certificate of Environmental Safety (CES). Before certifying a facility, the DEC holds an adjudicatory hearing to consider the following criteria: 1) risks to the public from the LNG facility; 2) the density of the population around the facility and its delivery routes; 3) the risk of an LNG accident; 4) size and coverage of a foreseeable vapor cloud resulting from an LNG accident; 5) the geographic location of the facility; 6) the design of the facility; 7) sources of supply for the facility; 8) the need for the facility; 9) the environmental impact; and 10) reasonable alternative sites or ways of meeting the area's energy needs.[58]

In California, any person who wishes to build an LNG facility capable of processing more than 23.0 mmcf per day or of storing more than 220 mmcf must obtain a site certificate from the ERC. After seeking comments from local officials, the ERC holds a public hearing near the site of the proposed facility. After announcing a preliminary decision, the ERC

57 Cal. Siting Bill, *supra* note 45, § 26601; MASS. SITING STATUTE, *supra* note 49, at § 69H; NY ENERGY STATUTE, *supra* note 48, § 5-105(11).

58 NY SITING STATUTE, *supra* note 47, § 23-1711.

conducts additional hearings and makes a final decision to grant or deny certification. In reviewing an application, the ERC must abide by the following criteria: 1) maximum public safety must be insured; 2) no facility may be built within one mile of any indigenous or working population or within six miles of an area with a population density greater than 0.1 person per acre; 3) no facility may be built where a hazard to vessel traffic would result; 4) the best construction and operating practices must be followed; and 5) no facility may be built in scenic, wildlife, or historical areas unless the ERC determines that no alternative exists.[59] The California criteria are noteworthy because they make concrete proscriptions rather than use the more discretionary "must consider" language. Additionally, the California Coastal Commission has the authority to prevent any facility from being built in the coastal zone.[60]

Massachusetts allows any person proposing to construct an LNG facility who is aggrieved or burdened by multiple state and local regulatory requirements to apply for a Certificate of Environmental Impact and Public Need (CEIPN). This certificate can override all other regulatory "stops." Considering an application, the EFSC must provide a public hearing and opportunity for written comment.[61] The EFSC considers the following criteria: 1) the facility's necessity to meet energy requirements; 2) environmental protection, public health, and safety; 3) the extent to which the facility fails to conform to other regulatory requirements and the burden which these place on the applicant; and 4) public interest, convenience, and necessity.[62] It is noteworthy that no explicit mention is made of alternatives to the proposed site, and, of the three states' decision criteria, those of

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59 Cal. Siting Bill, *supra* note 45.

60 *Id.* § 26574. This is an instance where siting authority approval is not an absolute override of other agencies' interests. Apparently California feels the coastal zones and the commission set up to protect their use are too important to allow their interest to be overridden.

61 The applicant is entrusted with giving notice, subject to EFSC supplementation.

62 MASS. SITING STATUTE, *supra* note 49, § 69K.

Massachusetts are the most amorphous and least subject to quantification.

5. "One-Stop" Powers

One of the keys to industry acceptance of a stringent regulatory program is the prospect that approval under the program will override all other regulation. This is usually called "one-stop" regulation and is an attractive *quid pro quo* for which a regulatory agency can demand and receive greater concessions from those regulated. Besides providing political bargaining strength, "one-stop" regulation is also appealing because it introduces efficiency and eliminates repetition in regulatory process. An example of the inefficiencies that "one-stop" can eliminate is the proposed Oxnard, California, LNG import facility which must receive over twenty separate state and local authorizations before operation can begin.[63]

Massachusetts and California both provide forms of "one-stop" override. In California, the ERC site certification process is mandatory and provides for automatic override of all other state, local, and, to the extent permissible, federal agency requirements.[64] In Massachusetts, participation in the site certificate program is voluntary; any facility owner may participate if he is aggrieved or burdened by the securing of other permits. The override is likewise discretionary: certification by the EFSC does not automatically override other agencies, but the EFSC has the power to grant an override at its discretion.[65] New York provides no "one-stop" benefits to the facility owner even though its site certificate program is mandatory.[66] As such, it merely adds another regulatory "stop" to the path travelled by the prospective facility owner.

6. Non-Conforming Facilities

Since some states may have existing LNG facilities which do not conform to newly promulgated regulatory criteria, they should consider how to deal with these facilities. It

63 VAN HORN & WILSON, *supra* note 4, 75-77.
64 Cal. Siting Bill, *supra* note 45, § 26570.
65 MASS. SITING STATUTE, *supra* note 49, § 69K.
66 NY SITING STATUTE, *supra* note 47, § 23-1707.

seems unjust to require existing facilities to shut down, but the continuing operation of unsafe facilities in the face of a regulatory program designed to prevent such risks is unsatisfactory.

Neither California nor Massachusetts statutes cover non-conforming facilities.[67] New York deals with existing facilities in a rather harsh manner. After a hearing which is required for all non-conforming facilities, the DEC may give permission to continue operating under specified safety conditions or may require discontinuance of operations. Discontinuance can be required of a facility which serves public needs that can be met otherwise or which, while serving public needs that cannot readily be met otherwise, unduly endangers public safety.[68]

7. Long-Range Forecasting

Long-range forecasting of demands for natural gas and LNG facilities is an important adjunct to a siting certification program because subjecting the public to the potential dangers of an LNG facility can be justified only if there is a demonstrated long-term need for such a facility.

Of the three states, New York has the weakest forecasting because it does not make agency approval of a gas company's long-range forecast a condition precedent to site certification.

California requires each company operating an LNG facility to file five-, ten-, and twenty-year forecasts based on a standard set of assumptions and data sources.[69] While certification does not explicitly depend upon approval of these

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67 In Massachusetts, because CEIPN certification is an optional, pre-construction program, existing facilities are not within its intended scope. In California, no provision is made because no LNG facilities now exist.

68 NY SITING STATUTE, *supra* note 47, § 23-1719.

69 The California forecasts must include the following information: 1) tabulation of estimated demand for gas and projected supplies for each of the following ten years and for the twentieth year; 2) existing supply sources and facilities; 3) projected future facilities; 4) analysis of the demand for gas by the various sectors of the economy, such as industrial, residential, and commercial; and 5) projected population and industrial growth. Within six months after the receipt of the forecasts, the ERC must publish a tentative summary of them and transmit this to the governor's office and to the legislature. Cal. Siting Bill, *supra* note 45, § 26550.

forecasts, the siting application requires reference to their projections. This provides the positive link between a company's announced long-range plans and its short-term projects which New York's program lacks.

Massachusetts requires a five-year forecast as a condition for EFSC action on any siting certificate application. Even a company not desiring a CEIPN must prepare a long-range forecast since it is a condition precedent to the issuance of any state or local permit for an LNG facility.[70]

After a forecast has been submitted, the EFSC must decide whether to accept, reject, or modify a company's forecast. This decision must consider the degree to which the forecast is consistent with state policies on health, environment, resource use, the state's need for gas at the lowest cost, and whether the projections made by the gas company are complete and accurate. This last consideration does not assure as much accuracy in forecasting as does California's standard assumption approach.

8. Generating Siting Alternatives

To evaluate adequately any proposed site, a regulatory agency must be able to compare it with alternatives. Consequently, some process for generating alternatives must be adopted. Requiring an applicant to suggest alternatives to his proposed site produces alternative sites of greatly varying acceptability. Obviously, the site which an applicant has chosen is optimal from his point of view. It is very tempting for him to propose only weak, "straw alternatives" to his first choice, in the hope that none of these will be accepted in its stead. Either guidelines regulating an applicant's generation of alternatives or some supplemental generation process, or both, is needed to provide the regulatory agency with a full range of choices.

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70 The forecast must specifically include the following: 1) description of existing agreements with other gas companies as to joint capacity planning; 2) a forecast of the gas requirements of the company's customers; 3) actions proposed by the company to meet this demand, including expansion of existing facilities, proposed additional facilities and alternatives thereto; 4) the predicted effects of foregoing all these actions; and 5) predicted environmental impact of each facility or expansion proposed. MASS. SITING STATUTE, *supra* note 49, § 69I.

Both Massachusetts and New York give the applicant primary and unrestrained responsibility for generating alternatives. Both states allow intervenors at hearings to propose alternatives. But this is quite burdensome since detailed analysis of sites is expensive. Therefore, in many instances the applicant-generated alternatives will, by default, constitute the entire range of options.

California takes a completely different approach to alternative site proposal.[71] The ERC itself is primarily responsible for selecting, evaluating, and ranking possible sites. The ERC maintains a list of sites, subject to expansion through the suggestions of interested parties, including gas companies. All facilities certified by the ERC must be built on sites selected from the site pool. Presumably, the ERC will consider the rank of the chosen site when making a certification decision.

9. Continuing Enforcement

Since plans for safe design and operation are important considerations in determining the acceptability of a proposed LNG facility site, a siting regulatory agency must ensure that facility plans are implemented as approved. In California, the ERC may revoke or amend the siting certificate for any facility where the application contained materially false statements, where there has been significant non-compliance with the terms of a certificate, or where there has been a violation of any provision of the ERC's regulations. In addition, the ERC may request a civil action by the state attorney general against the facility owner, with penalties up to $1000 per day of violation.[72] New York's program is very similar to California's.[73] In addition, it provides for criminal penalties for knowing or willful violation. However, the criminal penalty, a misdemeanor, seems scant additional sanction beyond the $1000 per day civil penalty. Massachusetts has no provision for continued enforcement. This makes consideration by

71 Cal. Siting Bill, *supra* note 45, at § 26574.
72 *Id.* §§ 26610-13.
73 NY SITING STATUTE, *supra* note 47, § 23-1715.

the EFSC of an applicant's promised future performance in operating a proposed LNG facility open to abuse.

10. Cooperation with Local Fire Departments

The principal risk associated with an LNG facility is fire. Proper training and equipment for fighting these fires, when and if they occur, is vital to safe siting of an LNG facility.

Of the three states, New York has the best program. During the certification process, the DEC meets with the fire departments of localities that may be affected by a proposed facility and determines what is necessary to train and equip them to cope adequately with LNG accidents. A program and list of needed equipment is then included with any approved certificate. A certificate's continued validity is contingent upon the applicant's purchasing the necessary fire equipment and paying for needed additional training and personnel.[74] This program, though extremely effective in securing proper firefighting protection, may seem inequitable to the applicant. The benefits from the additional equipment and personnel paid for entirely by the LNG facility owner flow not only to him but also to the community where the facility is sited since the equipment is available for general firefighting use. However, since the community bears a risk from the facility, this benefit can be seen as a *quid pro quo* well deserved.

California provides only that effective firefighting standards will be promulgated as ERC regulations.[75] The statute does not specify who must pay for added fire protection. Massachusetts makes no provision for fire protection and, without powers of continued enforcement, it is doubtful that such a provision could be enforced.

11. Liability for Accidents and Insurance

No matter how carefully an LNG facility is designed, operated, and sited, there will always be an element of risk to the area surrounding it. Liability for accidents and insurance

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74 *Id.* § 23-1717.
75 Cal. Siting Bill, *supra* note 45, § 26572(c)(5).

with which to cover this liability must therefore be addressed.

The most pressing consideration regarding liability is the standard of care to which a facility owner will be held. Even after this standard of care is established, proving a negligent failure to meet this standard at a facility as complicated as an LNG plant is difficult. In addition, states must establish the degree to which compliance with its regulatory program can be used as evidence of due care. Finally, in order to be sure that a judgment will be honored, the state should require adequate liability insurance.

Both New York and California impose liability without regard to fault upon any LNG facility owner for any damage done outside the facility as a result of an accident originating within the facility. New York goes one step further, eliminating all distinctions between direct and consequential damages.[76] Massachusetts has no provision for liability for LNG accidents without regard to fault.

Only California requires a minimum amount of insurance. An LNG facility owner must carry insurance of $250,000 per person in the indigenous or working population within a six-mile radius of the facility.[77] Neither of the other two states requires any proof of financial responsibility.

12. Judicial Review

All three states provide some measure of judicial review of the regulatory agencies' decisions. None provides for de novo trial on the issues involved in site certification or forecast approval. Both California and Massachusetts provide for review of agency decisions with respect to state and federal constitutionality, statutory authorization, and abuse of discretion. Massachusetts, in addition, provides for review to determine whether a decision is supported by substantial evidence. New York allows that review provided by writs of certiorari, mandamus, and prohibition.

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76 NY SITING STATUTE, *supra* note 47, § 23-1717(8).
77 Cal. Siting Bill, *supra* note 45, § 26615.

III. Model Statute

Section 1. *Definitions*

(a) Except as otherwise required by context, for the purposes of this Act the following terms have the meanings indicated.

(1) "Applicant" means any person who submits an application for a certificate or long-range forecast pursuant to this Act.

(2) "Application" means any request for a certificate or long-range forecast filed with the Council pursuant to this Act.

(3) "Certificate" means a certificate of environmental, health, and safety impact as provided for in Section 4 of this Act.

(4) "Council" means the Siting Council established under the provisions of Section 2 of this Act.

(5) "Facility" means any unit, including associated buildings and structures, designed for or capable of liquefying, storing, or regassifying liquefied natural gas and located within the State.

(6) "Gas Company" means (A) a gas company as defined by the State Department of Public Utilities; (B) a corporation organized under the laws of the State empowered to manufacture or store gas for resale or distribution to a gas company; (C) a foreign corporation empowered under laws of incorporation of this state to manufacture or store gas for resale or distribution to a gas company; (D) a natural gas pipeline company, as defined by the State Department of Public Utilities; and (E) a municipal corporation empowered to operate a municipal gas plant.

(7) "Interested Party" means any person, agency, or group which has applied for and has been included on the interested parties list provided for in Section 2(g)(7) of this Act.

(8) "Long-Range Forecast" means a plan approved by the Council projecting gas supply and demand, and forecasting plans to meet these projections, as provided for in Section 2 of this Act.

(9) "Liquefied Natural Gas" means natural gas which has been rendered into the liquid phase by cooling to approximately negative (-) 260°F.

(10) "LNG" means liquefied natural gas.

(11) "Natural Gas" or "Gas" means a vaporous gas consisting primarily of methane mined from the ground.

(12) "Non-Conforming Facility" means a facility on which construction was started or completed before the date of enactment of this Act.

(13) "Person" means any person, firm, association, organization, partnership, corporation, or company. "Person" also includes any unit of local or state government and any unit of the federal government, to the extent permitted by federal law.

(14) "Site" means any location upon which a facility is, or is proposed to be, constructed.

(15) "Site Pool" means the compilation of alternative sites as provided for in Section 3(g) of this Act.

Section 2. ***Establishment of the Siting Council***

(a) There is hereby established the Siting Council which shall be responsible for enforcing the policies of this Act. The Siting Council shall perform the duties and exercise the powers conferred upon it by this Act in order to insure that LNG facilities built within this State will have the minimum impact on health, safety, and the environment which is consistent with the state's energy needs.

COMMENT: The Model Act envisions a separate and newly created regulatory body like that in Massachusetts. The competing considerations in the decision whether to create a new agency or expand the duties of an existing one have been discussed above.[78] While a few states may have existing agencies with both experience in energy facility regulation and an environmentally conscious outlook, the Model Act assumes that most states will not be in such a position.

Even those states which do have existing agencies with some energy facility regulatory experience and an environmentally conscious outlook can benefit from the Model Act by fashioning what will most likely be a new division or office in accord with the provisions of this Act.

(b) The Siting Council shall be composed of the following members: a permanent chairperson appointed by the governor of this State for a four-year term; the secretary of public finance of this State or his designee; the secretary of the public service commission of this State or his designee; the secretary of the energy department of this State or his designee; one representative each for

78 *See* text accompanying notes 46 to 51, *supra.*

the gas industry, for labor within the gas industry, and for consumer interests, to be appointed by the permanent chairperson to serve terms coterminous with his; and an authority on LNG safety from outside the gas industry, to be appointed by majority vote of the other seven members of the Council.

Upon resignation or termination of the term of any member of the Council, his successor shall be appointed in a like manner to serve the remainder of the unexpired term. No person shall serve more than two consecutive terms. Each Council member shall have an equal vote in deciding Council business. A majority vote of those Council members in attendance shall be necessary to approve Council business, provided those in attendance constitute a quorum.

COMMENT: The composition of the Council closely tracks that of Massachusetts' EFSC. The purpose of the chairperson is to lend continuity to the actions of the Council and to administer its day-to-day operations. The other Council members will not have Council work as their sole occupation.

(c) All of the appointed members of the Council except the permanent chairperson, shall receive $50 per diem for his or her services and shall be compensated by the State for all reasonable expenses incurred in performance of official duties. The permanent chairperson shall be compensated at a salary rate comparable to that received by the Secretaries of executive departments within this State.

COMMENT: By paying per diem, it is possible to allow more flexibility in the time demands upon the part-time Council members and to avoid the implication that Council duties are full time. It is hoped that by so doing, people with extensive private commitments but who could nonetheless contribute significantly to the Council may be encouraged to accept positions.

(d) The Council is empowered to represent this State in dealing with local governments of this State, with other states, or with the federal government in all matters of LNG facility siting and safety regulation.

(e) The Council is authorized to enter into contracts with and receive appropriations from any local, state, or federal government unit, with the purpose of carrying out the policies of this Act. The Council is specifically authorized to enter into agreement with the United States Department of Transportation for the purpose of enforcing that department's LNG facility safety programs.

COMMENT: These two sections are introduced principally to authorize Council participation in the OPSO enforcement program, with its concomitant funding. By explicitly stating this authority, it is hoped that such problems as those experienced by Massachusetts in getting the EFSC certified to enforce the OPSO regulations will be avoided.[79]

(f) The Council is authorized to sue and to be sued.

(g) The Council shall have the following specific duties and powers:

(1) to appoint and fund a staff necessary to carry out the provisions of this Act;

(2) to promulgate rules and regulations consistent with this Act, after notice and opportunity for comment;

(3) to charge fees for certificates and long-range forecasts sufficient to cover the variable costs of decisionmaking, implementation, and inspection by the Council necessary for these certificates and long-range forecasts;

(4) to levy a surcharge, subject to approval by the state legislature, on all natural gas sold in this state sufficient to cover those costs of the Council not covered by Section 2(g)(3);

(5) to accept applications for certificates and long-range forecasts;

(6) to hold public hearings and receive written comments upon applications received;

(7) to establish a list of interested parties including other agencies of the State and federal government, to which copies of all applications received by the Council will be sent by an applicant, and which are empowered to send written comments to the Council concerning any applications received in addition to attending and participating in public hearings and to submit alternative potential sites pursuant to Section 3(g);

(8) to issue or deny or modify certificates or long-range forecasts in response to applications received; and,

(9) to cause to be enforced the terms of any certificate issued and the rules and regulations promulgated by the Council by either revocation of certificates or by requesting civil action by the state's attorney general.

COMMENT: Subsections (3) and (4) are important because they isolate the funding of the Council from direct legislative control and place the financial burden upon the regulatees. The

79 *See* text accompanying notes 36 to 44, *supra.*

isolation is only partial, however, since the legislature reserves the right to approve the subsection (4) surcharge which covers overhead or operating expenses. Thus, the legislature retains some control over staff expenditures authorized under subsection (1).

The second purpose of subsections (3) and (4) is to force the price of gas sold within the state to reflect internalization of regulatory costs. Note that subsection (4) forces gas of non-LNG origins to bear some of the cost of the Council, even though its production requires no direct regulation. This allocation is simpler from an accounting standpoint and may not be inefficient to the extent that consumption of non-LNG gas necessitates LNG supplies.

Section 3. *Long-Range Forecasting*

(a) In order to provide the Council and Interested Parties with a long-range view of the total gas requirements in the State, the interrelationships of the gas companies in meeting these requirements, and the plans of the gas companies for construction or expanding facilities to meet these requirements, each gas company must have on file with the Council a current approved long-range forecast.

COMMENT: By requiring all gas companies within the state to predict their expansion and future service, including plans for LNG operations, it is possible for the Council to more appropriately coordinate present requests for new facilities with long-range policies and goals.

(b) Each long-range forecast shall include both five- and fifteen-year projections. Once an application has been approved, a long-range forecast shall be in effect, subject to application for modification, for five years. At the end of five years, the years representing the sixth through the tenth years of the original fifteen-year projection shall be accepted automatically at the request of the applicant as the new five-year projection. If an applicant chooses to request this automatic updating, the years representing the eleventh through fifteenth years of the original fifteen-year projection shall become the sixth through the tenth years of the revised fifteen-year projection. Application must then be made for new projections for the eleventh through fifteenth years. Neither the new five- nor fifteen-year projections shall be considered on file or approved by the Council until the new eleventh through fifteenth years are applied for and approved.

If the applicant chooses not to request the automatic update, he shall apply for a new long-range forecast. No portion of any existing long-range forecast that the applicant may have on file and approved shall be deemed in force, should he choose to forego the automatic update.

(c) No gas company shall operate any gas facility within the state unless it has a current, approved long-range forecast on file with the Council; *except,* every gas company shall be exempt from this section for the duration of the time after which the gas company applies for an automatic update or new long-range forecast and before which the automatic update or new long-range forecast is approved by the Council.

COMMENT: The long-range forecasts envisioned by the Model Statute will consist of a refined five-year projection and a more nebulous fifteen-year one. To induce gas companies to reify the fifteen-year projection as much as possible, these sections allow for convenient adoption of part of the fifteen-year projection as a new five-year projection at the end of five years.

(d) Each application for a long-range forecast shall include the following information:

(1) a tabulation of the estimated supply of and demand for gas for each year during the five- and fifteen-year projection periods;

(2) a list of existing facilities and supply sources available to the applicant together with an estimate of the future capacity and reliability thereof;

(3) a breakdown of the demand estimates in subsection (1) by sectors of the economy, including residential, commercial, and industrial;

(4) a description of projected population growth and industrial expansion within the area served by the applicant;

(5) a list of proposed and potential future supply sources and facilities, with a general description of cost, location, capacity, and commitment thereto by the applicant;

(6) any joint ventures or contractual arrangements with other gas companies to meet future demand; and,

(7) an affidavit attesting that a copy of the application as described in Section 3(d) has been sent to each Interested Party within 30 days of its filing with the Council. The estimated supply and demand in subsections (1) and (2) and the projected population growth in subsection (4) shall all be derived from standard assumptions, data, and models as provided by the Council.

COMMENT: This section is intended to provide a framework within which gas companies can and must to the best of their knowledge answer the following three questions about the future: 1) How much gas will be required in the next five and fifteen years? 2) From where will the supply come to meet this demand? and 3) What facilities will be necessary to handle this supply? By providing a standardized framework, set of assumptions, data, and models, the resulting forecasts from different gas companies should be comparable.

(e) Within ninety days of the date of filing of an application, the Council shall hold a public hearing on the application in each municipality within which the applicant provides gas service or where the applicant has existing or proposed facilities. Notice of the hearing shall be published in a daily newspaper serving each municipality and shall be sent to Interested Parties. At the hearing, opportunity shall be given for any person to object to or support the application, and to propose additional alternative sites to supplement those proposed by the applicant pursuant to Section 3(d)(5). A record shall be made of each hearing. The Council shall also receive any written comments which are made by Interested Parties.

COMMENT: The Model Statute provides people living in affected areas with a hearing on the proposed long-range forecasts. Interested Parties are given in addition the opportunity to comment in writing on the proposed forecasts which they receive automatically, pursuant to Section 2(g)(7). It is felt that the mode of input available to each group is peculiarly appropriate to it.

Public hearings are a good device by which to receive input from members of the community who are unlikely to be carefully organized and to gauge their depth of feeling. The Interested Parties are likely to be better organized. Their inputs can be effectively received through the written comment procedure. While they are allowed to participate in the public hearings, it is envisioned that they will primarily use the written comment procedure.

(f) Within ninety days of the last public hearing held on an application pursuant to Section 3(e), the Council shall adopt a long-

range forecast for the applicant, accepting the application or modifying it. This decision shall be on the record of the hearings and of the written comments received by the Council from Interested Parties.

COMMENT: Section (f) envisions a written decision which addresses the relevant arguments pro and con which have been made in the hearings and in written comments. The main purpose of a decision on the record is to provide an adequate basis for judicial review of the decision, should such review be sought.

(g) The Council shall compile into a site pool the proposed and potential facilities and sites as represented in all the long-range forecasts it has approved. This site pool shall be subject to expansion by written request from any Interested Party. The Council may rank these sites according to its preferences therefor, taking into account the environmental, health, and safety impacts of the sites.

COMMENT: Since all proposed sites are recorded in the site pool, the Council can compare sites chosen by any one gas company for a Section 4 certificate with the sites proposed by all other companies. The pool is further expanded by interested parties' requests.

By ranking sites, the Council can provide a valuable service to future certificate applicants who will want to know in advance the Council's relative preference for various sites upon which they may wish to propose a facility.

(h) Modification of approved long-range forecasts proposed by an applicant are subject to the notice, comment, and hearing provisions of Sections 3(e) and (f).

(i) The Council is authorized to require gas companies which have valid long-range forecasts on file to recalculate the relevant projections when, after notice and comment, the Council changes its standard assumptions, data, and models.

COMMENT: This section represents a compromise between the virtues of providing the gas companies security in their forecasts and the virtues of changing forecasts to reflect changing expectations of the future. A gas company's forecast shall not be subject to fresh scrutiny after it has been approved, except when the Council's standard assumptions,

data, and models are changed. These standards are rules and regulations within the meaning of Section 2(g)(2). They may be changed only after notice and comment, and are subject to judicial review. By limiting changes in forecasts to those required by changes in the general standards, the gas companies are afforded substantial protection against discriminatory challenge of their forecasts.

Section 4. *Site Certification*

(a) Prior to the commencement of construction of any facility, the person or persons proposing the facility must obtain a Certificate of Environmental, Health, and Safety Impact from the Council.

COMMENT: The Model Statute takes the New York and California position requiring a permit for any LNG facility within the state.

(b) An applicant for a Certificate must have a valid, approved long-range forecast on file with the Council as a condition precedent to consideration by the Council of his application.

COMMENT: While only gas companies must file a long-range forecast pursuant to Section 3(a), this section extends the Section 3 requirements to any other person who may seek to build a LNG facility.

(c) An application for a Certificate shall include the following:

(1) a description of the geographic location of the proposed site and facility;

(2) a description of proposed transportation facilities which must be used for transporting LNG or natural gas to and from the proposed site and facility;

(3) a description of the design of all structures proposed for the facility;

(4) the predicted environmental, health, and safety impacts of the facility at the proposed site;

(5) a copy of the applicant's approved five-year long-range forecast, indicating the need for the proposed facility to meet demand and supply balances as predicted in the forecast;

(6) proof of insurance, or self-insurance under State self-insurance requirements, sufficient to meet the obligations of Section 6(e);

(7) population size, density, and demographic characteristics for all areas within five miles of the proposed facility;

(8) predicted growth and changes in the population, consistent with the applicant's five-year long-range forecast;

(9) accident contingency plans for the proposed facility, and proposals for equipping and training the fire departments of the municipality in which the proposed facility is situated such that the fire departments can adequately respond to the requirements of the accident contingency plan;

(10) alternative sites listed in the site pool at which the applicant would be willing to locate his proposed facility should the Council decide to reject the primary proposed site; and,

(11) an affidavit attesting that a copy of the application has been sent to each municipality in which the proposed facility is to be located, including those in which the alternative sites under Subsection (10) are located, and to each Interested Party, within 30 days of initially filing the application.

COMMENT: While the Model Act is only concerned with the siting of stationary LNG facilities, the risks posed by transportation of LNG to and from the facility could render an otherwise acceptable site unacceptable and so transportation routes must be proposed in Subsection (2).

Subsection (4) will require extensive modeling and the specification of a design accident scenario around which the impacts are developed. The Council may desire to standardize the design accident in order to permit comparison of different risks. Since the Council's prime emphasis is on safety, the environmental impact statement required here need not be as detailed as federal Environmental Impact Reports. Subsection (7) requires an analysis of both population size and density because neither factor alone gives an accurate description of the local population.

(d) Upon receipt of an application, the Council shall hold a hearing in the locality where it is proposed that the facility be built and shall include as formal participants representatives of those municipalities listed as alternative sites under Section 4(c)(10), as well as representatives of the municipality containing the primary site and representatives of those municipalities' fire departments.

(e) Within ninety days of the public hearing under Section 4(d), the Council shall decide upon the application. This decision shall either grant a Certificate to the applicant for his primary site, grant a Certificate for one of his alternative sites, or deny the application.

A grant of a Certificate shall be accompanied by any conditions which the Council deems necessary to implement the policies of this Act. Council decisions shall be on the record of the hearing and any written comments it has received from Interested Parties, and shall further expressly address the following in its decision:

(1) the need for the facility to meet energy needs of the locality and state;

(2) the risk imposed by the facility and by its alternatives as listed in Section 4(c)(10) upon the various aspects of the population described in Subsections 4(b) and 4(c)(7), (8);

(3) the compatibility of the facility with the policy of minimizing the environmental, health, and safety impacts of supplying state energy demands; and,

(4) the risk imposed upon the entire state's population by transporting LNG or natural gas to or from the proposed facility and alternatives thereto as listed in Section 4(c)(10).

COMMENT: For comment on the hearing and comment provisions, see comment to Sections 3(e) and (f).

It is anticipated that the Council will supplement these general decisional criteria with detailed rules and regulations.[80]

(f) A Certificate for a facility within this State shall be in lieu of all other permits, certificates, or other similar documents required by state, local and, to the extent permissible by federal law, federal agencies.

COMMENT: This is the so-called "one-stop" provision and is the clearest indication of the Model Statute's policy of consolidating regulation in one agency. The inclusion of federal agencies among those circumvented authorizes Council action to the limits of the preemption doctrine.[81]

(g) A Certificate shall not be required for any non-conforming facility operating within the State at the time this Act is enacted. Non-conforming facilities not holding a Certificate are not exempted from state, local, or any federal agency requirements as are Certificate holders under Section 4(f). Nothing in this Section shall be construed to exempt a non-conforming facility from Section 6(e).

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80 *See* text accompanying notes 17 to 22 *supra* for a discussion of the four most important factors that should be considered.

81 *See* text accompanying notes 29 to 35 *supra.*

COMMENT: A trade-off must be made in regulating extant non-conforming facilities. This trade-off is between frustrating existing expectations of the owners of the non-conforming facilities and the fulfillment of the state's siting policies. In the Model Statute, this balance is struck by requiring non-conforming facilities to meet all the other agencies' requirements from which a certified facility is exempt. This leaves open the possibility of the Council enforcing OPSO's, but not its own, regulations with respect to non-conforming facilities.

Section 5. *Continuing Enforcement*

(a) It is hereby recognized that the policies of this Act can be effectively implemented only by permitting the Council to monitor continually Certificate holders to promote faithful adherence to the conditions and terms of the Certificate. The Council is therefore given authority under this Section to enforce continually those terms and conditions it sets out in Certificates.

(b) A Certificate can be revoked or modified by the Council for the following reasons:

(1) failure of the Certificate holder to obey the conditions and terms of the permit;

(2) materially false statements made by the Certificate holder in his application;

(3) disobeying the Council's rules and regulations as these apply to the Certificate holder; or

(4) failure by a Certificate holder to cause the fire department of the municipality within which his facility is located to be trained and equipped in accordance with his plan required by Section 4(c)(9), or failure to cooperate with this fire department in implementing the Certificate's accident contingency plan.

COMMENT: Since the Council has within its authority the consolidated siting powers, it is imperative that it be given jurisdiction over continuing enforcement.

Section 5(b)(4) puts a large burden on the Certificate holder if the fire department is uncooperative. Given the importance of proper fire protection this seems appropriate in order to force compliance with the Certificate.

(c) In addition to the sanctions of Section 5(b), any holder of a Certificate who has been found, after a public hearing, to be in violation

of any of the conditions or terms of his Certificate may be assessed a civil penalty of up to one thousand dollars ($1000) per day. Notice of public hearing shall be given to all those who received notice of the holder's application for his Certificate.

COMMENT: These sanctions are likely to be inconsequential under normal conditions; the revenue from an LNG facility would greatly exceed $1000 per day and thus the sanctions of Section 5(b) would overshadow the impact of the fine. However, the threat of fine may bring about adherence to Certificate requirements for facilities that are no longer in use or that are being shut down.

(d) The Council may petition the attorney general of this State to enjoin a violation as described in Section 5(b) and to collect any civil penalties assessed pursuant to Section 5(c).

Section 6. *Judicial Remedies*

(a) Review in the state court of first appeal may be had of Council decisions made under Sections 2(g)(2), 3(f), 3(h), 4(e), 5(b), and 5(c).

(b) Judicial review of Council decisions shall extend only to determination of:

(1) whether this Act or actions of the Council under this Act violate terms of this State's or the United States Constitution;

(2) whether the Council acted without statutory authority in making the decision under review;

(3) whether the Council's decision was arbitrary, capricious, or an abuse of the discretion with which the Council is invested by this Act; and

(4) whether the Council's decision was supported by substantial evidence. Section 6(b)(4) shall not apply to review of Council decisions made under Section 2(g)(2).

COMMENT: A review for substantial evidence is not extended to rulemaking under Section 2(g)(2) because it would be too burdensome to require a record of rulemaking proceedings. No Council decision will be subject to trial de novo.

(c) Subject to the provisions of Sections 6(a) and (b) for judicial review, no court in this State shall have jurisdiction to hear or determine any case concerning any matter which was or could have been determined in a proceeding before the Council or to enjoin the operation or construction of a facility which is subject to this Act, except to compel compliance with a decision of the Council.

COMMENT: The Siting Council has the right of prior determination of any issue within its authority. Once the Council has acted, judicial review is the only remedy. This Section is intended to limit delay by opposing parties of actions approved or approvable by the Council.

(d) Any citizen of this state may bring suit to compel compliance with a decision of the Council.

COMMENT: The conferral of standing to all citizens of the state to compel compliance serves as a safeguard against dereliction of continuous enforcement duties by the Council.

(e) Any person operating a facility in this State shall be liable for damages to persons or property outside the facility and within this State resulting from the operation of the facility, without regard for negligence or direct causation. Each person operating a facility within this State shall carry insurance or proof of self-insurance sufficient to provide at least $250,000 of coverage for every person living or working within a five mile radius of the facility.

COMMENT: Strict liability without regard for causality is necessary to keep suits against LNG facilities from becoming hopeless factual morasses. This policy further recognizes that LNG facilities are dangerous, even when designed, operated, and sited with great care. It is unfair to impose this risk upon those situated nearby.

BOOK REVIEW

AMERICAN MULTINATIONALS AND AMERICAN INTERESTS. By *C. Fred Bergsten, Thomas Horst, and Theodore H. Moran.* Washington, D.C.: The Brookings Institution, 1978. Pp. xiii, 535. $18.95, cloth; $8.95, paper.

*Review by Thomas A. Balmer**

Economists have long understood that production and general welfare are maximized by the efficient allocation of resources throughout a society. While there is debate as to the meaning of "efficiency" and "welfare," most economists have turned to the market forces of supply and demand as leading to the "proper" distribution of labor, capital, and land.[1] Similarly, Fred Bergsten, Thomas Horst, and Theodore Moran turn primarily to market analysis in their assessment of American multinational corporations. In *American Multinationals and American Interests*, the authors critique American companies in foreign countries in terms of market efficiency and productivity. Focusing generally on American concerns, the authors examine world economics and international foreign policies as a means of analyzing the impact of United States policies on both America's economy and economies abroad. With the proponents of multinationals, they agree that multinationals can promote global welfare through an open U.S. policy; with the critics they agree that what's good for multinationals is not necessarily good for the world. And with the nationalists, they accept the idea that the United States must develop a policy that promotes the interests of domestic American groups.

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1 *See generally* C. LINDBLOM, POLITICS AND MARKETS: THE WORLD'S POLITICAL-ECONOMIC SYSTEMS (1977).

2 C. BERGSTEN, T. HORST, AND T. MORAN, AMERICAN MULTINATIONALS AND AMERICAN INTERESTS (1978) [hereinafter cited as *American Multinationals*]. Bergsten is now Assistant Secretary of the Treasury for International Monetary Affairs, Horst is Assistant Director for International Taxation in the Treasury Department, and Moran is on the State Department's Policy Planning Staff.

To encourage efficient capital flow and protect American jobs, they recommend increased surveillance of foreign direct investments and foreign expansion of firms based in the United States. They also advocate innovative remedies for antitrust violations as a means of fostering a policy that promotes efficiency and productivity — goals which the authors frequently define in terms of American, rather than global, interests.

As a background to their findings, the authors summarize major schools of thought regarding multinationals and their place in the world order.[3] They update existing empirical studies and present new statistics on the foreign taxes of American-based foreign affiliates. In addition, they provide a wealth of new empirical evidence on the exceedingly complex relationship between U.S. trade, foreign direct investment, the balance of payments, and the competitive relation between U.S. multinationals and domestic firms.[4]

Nonetheless, this vast amount of new data is not enough to make the book the truly important and groundbreaking work it might have been. Instead, the book suffers from rather serious omissions and an unduly narrow analysis of "American" and multinational interests. While the authors commendably present new insights and factual observations, they fail more generally to construe the problems of multinational corporations on an integrated global scale.

In separating their analysis of economic policy from foreign policy considerations, Bergsten, Horst, and Moran are able to look more clearly at the sometimes confusing policy issues affecting multinationals. They avoid to some extent the heavy

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3 *Id.* at 46-67, 314-35. These earlier analyses include R. BARNET & R. MULLER, GLOBAL REACH: THE POWER OF THE MULTINATIONAL CORPORATIONS (1974) (asserting that multinational power is growing at the expense of home and host countries and criticizing that trend); R. VERNON, SOVEREIGNTY AT BAY: THE MULTINATIONAL SPREAD OF U.S. ENTERPRISES (1971) (approving the spread of multinationals at the expense of home and host country power); H. MAGDOFF, THE AGE OF IMPERIALISM: THE ECONOMICS OF U.S. FOREIGN POLICY (1969) (seeing multinational activities as an extension of the imperialist policies of a political-business elite); R. GILPIN, U.S. POWER AND THE MULTINATIONAL CORPORATION (1975) (viewing government and multinational activities as directed towards the same nationalist goals).

4 *American Multinationals, supra* note 2, at 230-47.

political emphasis of the anti-multinationals and the narrow economic approach of the pro-multinationals.

Given these factors, the authors can suggest that differences among American multinationals demand special political and economic perspectives. Indeed, the fact that multinationals vary greatly among themselves leads the authors to call for a substantial yet qualified need for control of capital outflow and tax treatment of the foreign activities of American corporations.

In the long run, however, these suggestions present only traditional and limited solutions to making American multinationals more competitive and more responsive to noneconomic interests.

Numerous nuances of multinational development are frequently ignored, leaving critical gaps in the authors' analysis of mechanisms designed to facilitate efficient and equitable workings within multinationals. They correctly point to the powerful incentives the market system provides for the efficient allocation of resources, but they neglect the corporation's drive to maximize its global profits.

While perceiving the problem, the authors thus fail to articulate in a convincing way the means by which the multinationals can be led to act rationally in a global rather than merely a corporate sense. At some point, presumably, the ends are the same — corporations and individual countries may realize that their long-term interests are best served by global allocation according to comparative advantage — but the authors present no particular criteria for determining where that point is.

Part of this problem stems from the authors' admittedly narrow perspective. As the title suggests, the authors view the issues in terms of American political and economic benefits, giving particular attention to the diplomatic aspects of American policy. Although Bergsten, Horst, and Moran generally believe that multinationals can contribute to national and international welfare, they argue against affirmative support for foreign investment in light of "American interests":

> American policy must be based on a calculation of whether

> the activities of U.S. multinationals will contribute to American national interests or to the interests of other countries where they operate at U.S. expense, when trade-offs between home and host countries are unavoidable and important welfare or security interests of the United States are at stake.[5]

Bergsten, Horst, and Moran are persuasive in their assertions that certain U.S. interests are not always synonymous with multinational interests. That comparison, however, raises the difficult question of just what American interests are. The authors never define the "national interest" in general terms, although they assume that such a thing exists. From their policy recommendations, it appears that the U.S. should be interested in maximizing global welfare,[6] but should also retaliate against foreign countries which impede that goal by imposing import quotas or subsidizing foreign investment.[7]

The fact that the contours of national interest are rather ill-defined obscures another important question: what is the relation of American interests to global interests? It is certainly legitimate for the authors to argue that an adequate supply of raw materials is important to the United States. For a developing country which produces some needed raw materials, however, it may be more advantageous to limit exploitation, to hold back supply as prices increase, or to conserve what may be its only salable resource. By focusing on American interests the authors have thus been able to examine only this country's relations with multinationals. And this approach has meant that critical problems of the world economy — international distribution of resources, economic autonomy of developing countries, global access to raw materials — are not discussed.

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5 *Id.* at 313.

6 *See, e.g., id.* at 451: "Future U.S. policy should be explicitly neutral toward foreign direct investment, neither encouraging nor discouraging it. Foreign direct investment should be guided to the maximum extent by market forces; the goal should be the maximization of global welfare."

7 *E.g., id.* at 459: "Our basically liberal trade policy does admit some apparent exceptions. When foreign countries provide export subsidies or foreign exporters dump their goods on the American market, the United States will retaliate." *See also id.* at 452-53.

Thus, in the long run, the major deficiency of *American Multinationals* is not its treatment of the issues but its complete omission of many critical issues. Multinational corporations raise important questions which are simply not discussed in this book. Fundamental, for example, is the ultimate issue of power in a society. Bergsten, Horst, and Moran are concerned with harnessing multinationals to serve global and American economic welfare.[8] Yet their analysis necessarily ignores important noneconomic values such as public participation, democratic control of social and economic policy, and ethics. For example, none of the authors' prescriptions would control the activities of multinationals which provide clandestine and illegal support for Rhodesia.[9] The moral basis for declining to support apartheid apparently has little if any place in a policy designed to further "economic welfare."

Bergsten, Horst, and Moran's antitrust recommendations and the limitation of those recommendations to steps that will increase economic welfare also illustrate a larger problem with which they fail to deal: To what extent can or should multinationals be controlled by the countries in which they operate in the interests of noneconomic social goals? As the authors show, American multinationals have an important and frequently uncontrollable effect on European economies,[10] and despite increases in the bargaining power of developing countries, the destinies of many are subject in large part to the economic interests of multinationals.[11] The essential question is who is to control a country's economy and politics, its recognized government or private corporations based abroad? While multinationals may certainly contribute to efficiency, that efficiency is not universally or at all times perceived as the greatest good.

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8 While these "traditional" goals are first seen as rather limited and faulty, *id.* at 17-18, the authors return to them as their own goals at the conclusion of the book, *id.* at 493.

9 *See* CENTER FOR SOCIAL ACTION OF THE UNITED CHURCH OF CHRIST, THE OIL CONSPIRACY: AN INVESTIGATION INTO HOW MULTINATIONAL OIL COMPANIES PROVIDE RHODESIA'S OIL NEEDS (1976).

10 *American Multinationals, supra* note 2, at 408-09.

11 *See generally* R. BARNET & R. MÜLLER, GLOBAL REACH, *supra* note 3.

There are excellent reasons for the United States or any other country to seek to limit, for example, the absolute size of corporations.[12] Large multinationals have frequently shown themselves to be beyond the control of all but the most powerful national governments. This inability to exercise political control over such important economic entities poses basic questions about the nature of political sovereignty. The efficiency argument which Bergsten, Horst, and Moran adopt justifies intervention to foster competition, but because it implicitly assumes the present structure and size of multinationals, it fails to deal with the problem of political control over these entities.

Another important area inadequately treated in *American Multinationals* is host country adjustment to multinational activities. Large corporations may be more callous to community needs than local small businesses while their impersonal operations contribute to employee alienation. They may also exercise power in ways that conflict with such host country policies and indeed threaten the very idea of national sovereignty. The authors assume, however, that multinationals are desirable because of their ability to allocate resources efficiently. Changes in allocation, such as closing down an engine assembly plant in Ohio and shifting production to West Germany, nonetheless may contribute to overall welfare while causing serious dislocation to the employees and the local economy near the Ohio plant. If such "efficient" changes are to be allowed, there must be some means of helping the employees to retrain for other jobs or to relocate. While the authors clearly recognize this problem and point to remedies such as the Trade Act of 1974,[13] one would appreciate empirical evidence regarding the efficacy of present policies. Moreover, much current policy is directed toward creating trade barriers to protect the threatened industry.[14]

12 *See, e.g.*, E. SCHUMACHER, SMALL IS BEAUTIFUL: ECONOMICS AS IF PEOPLE MATTERED (1973); L. BRANDEIS, THE CURSE OF BIGNESS (1930); Flynn, *The Social, Political and Economic Consequences of Corporate Size*, 2 J. CONTEMP. L. 163 (1976).

13 *See American Multinationals, supra* note 2, at 29-30, 282-83, 459, 468-69. For interesting background on the politics of adjustment assistance, *see* G. SCHULTZ & K. DAM, ECONOMIC POLICY BEYOND THE HEADLINES 139-45 (1977).

14 G. SCHULTZ & K. DAM, *supra* note 13, at 140-44 n.54.

Such assistance scarcely encourages the real adjustments that need to be made. When the United States is unable to make even domestic adjustments such as reducing the economy's dependence on defense spending or automobiles, through structural shifts of labor and capital to other uses, the present means of accommodating reallocation of worldwide resources seems unequal to the task.

A related issue lies in the adjustment cost to host countries, particularly those in the early stages of development. The impact of multinationals on frequently weak host economies is far greater than that felt in the United States, and the hosts' ability to cope with adjustment problems may be minimal. The coming and going of a large multinational corporation can wreak havoc on a developing country's economy and society. Modernization, often precipitated by multinationals, is almost always a destabilizing force.[15] Yet while Bergsten, Horst, and Moran are not oblivious to the effect of multinationals on developing societies,[16] they give only passing treatment to the very real political and social costs multinationals impose. One economic aspect they do point out is that multinationals may preempt the best local investment opportunities, forcing local capital to seek more advantageous investments abroad; multinationals may also foster unequal distribution of income by bidding up wages of a small local elite.[17] Again, however, the important political and social aspects of these possible economic effects are not examined.

Bergsten, Horst, and Moran also fail to confront the problem of international pollution, in part because the issue does not have a vocal constituency in the United States. Pollution laws do affect multinational behavior by inducing them, for example, to avoid American environmental laws and the cost they impose through locating polluting facilities in other

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15 Olson, *Rapid Growth As a Destablizing Force*, in POLITICAL DEVELOPMENT AND SOCIAL CHANGE 558 (J. Finkle & R. Gable eds., 2d ed. 1971). *See generally* THE MULTINATIONAL CORPORATION AND SOCIAL CHANGE (D. Apter & L. Goodman eds. 1976).

16 *American Multinationals*, *supra* note 2, at 364-67.

17 *Id.* at 361, 363.

countries.[18] These actions are harmful to host countries, too poor to refuse multinational investment even in light of long-term damage to the environment. They also introduce distortions into the international market for investment and trade because they are based on factors other than comparative economic advantage. To end this distortion, pollution laws would have to be harmonized on an international basis. Disputes between nations over pollution levels, both national and international, are bound to increase in the future, and the multinationals will play an important, if behind-the-scenes, role. But *American Multinationals* provides no guidance for that role.

Perhaps the most disturbing aspect of these omissions is that they are not merely inadvertent slips but are the result of the "conceptual framework" adopted by the authors, a framework which includes a great many economic and some noneconomic considerations, but which also excludes a number of other important factors. To illustrate this problem, let us consider one other significant omission: lack of extended discussion of limited supplies of natural resources. While Bergsten, Horst, and Moran note that the prospect of raw material shortages has increased bargaining power of certain host countries, the great bulk of their discussion centers on how the United States can ensure a steady supply from the producers,[19] rather than on the more serious problem of the exhaustion of natural resources altogether and the multinationals' role in that process. American policy, the authors urge, should be directed toward increasing production and competition in scarce raw materials. Scarcely a thought is given to conservation, alternatives to resources presently used, or more basic restructuring of industry to reduce dependence on finite resources. The authors' emphasis is understandable because their conceptual framework focuses on the short and medium term rather than on the next century. Dwindling resources, however, do pose questions — indeed, the ultimate question — of the survival of our

18 *See* Baldwin, "The Untouchables," BUS. WEEK, April 10, 1978, at 54. R. BARNET & R. MÜLLER, *supra* note 3, at 345.

19 *American Multinationals, supra* note 2, at 121-64.

society, and a national governmental policy toward multinationals which does not take account of their important impact on such resources is seriously deficient.

In the end, these deficiencies stem fundamentally from the authors' faith in the global market system and their limitation of noneconomic considerations to matters they deem to be "American interests." While their recognition of market forces is the basis for much of the excellent discussion of international trade and investment, their implicit faith in the market (with adjustments such as strict antitrust laws) causes them to neglect the issues just discussed. Limiting corporate size to make democratic control possible, dealing with international pollution, easing the trauma of economic adjustment, confronting the dilemma of finite resources — these are critical issues which have been brought to the fore by the activities of multinationals. They are also issues which demand something more than a free market approach to the phenomenon of the multinational corporation. If the market satisfactorily dealt with these problems, they would not be the pressing concerns they are today. Bergsten, Horst, and Moran's failure to come to grips with shortcomings of the global market system thus leads them to overlook these severe problems, not now — if ever — resolved by the market.

In *American Multinationals* Bergsten, Horst, and Moran have brought together the major theories regarding multinationals and much of the empirical evidence on the impact of those corporations. Their pluralistic synthesis is a careful distillation of positions asserted by other writers, and new data of their own. The book's flaws are its omissions. These omissions ultimately parallel the lacunae in the present debate over multinationals and in much of contemporary political and economic thinking — the failure to think more than several decades into the future, the failure to consider issues other than those pushed by vocal pressure groups, and the failure to see how or why economic inequality affects the democratic ideal of political equality.

RECENT PUBLICATIONS

SHAPING THE DEFENSE CIVILIAN WORK FORCE. By *Martin Binkin with Herschel Kanter & Rolf H. Clark.* Washington, D.C.: The Brookings Institution, 1978. Pp. 83, appendices. $2.95, paper.

The Senate Committee on Armed Services first published this study in September 1977. In the intervening months, Binkin and Kanter have updated and revised the information to provide a readable critique of the civilian military force.

In an examination long overdue, both recommend significant changes and budget cuts in the civilian defense force. They outline bureaucratic factors which have muffled technical assessment of the force and suggest that its size and composition have been too often dictated by institutional pressures rather than by needs of national security. According to the authors, alternative military manpower is critically necessary to offset exorbitant costs required to maintain the current all-volunteer force.

They suggest the Defense Department could save over $900 million in the next five years if legislation were passed to align civilian military salaries (far in excess of the comparable market wage) with those in the private sector.

As part of their readjustment plans, the authors also advocate more efficient base operations and closure of bases unnecessary for national defense. While they concede any such move would be politically difficult, they suggest economic assistance programs to mollify any economic displacement in communities affected by the closures. The authors also indicate that there are more than 300,000 military positions for which civilians could be substituted. By channelling more work to private contracts, the authors suggest, further budget cuts might also be achieved. Under present conditions however, criteria for government employment are undefined. The authors therefore recommend that the "Department of Defense and the Office of Management and Budget jointly develop more explicit rules governing the

restriction of certain industrial and commercial activities to in-house positions" (p. 76).

Through more productive use of resources, Binkin, Kanter, and Clark thus suggest that large increases in the defense payroll are unnecessary to maintain desired military standards. With their focus on civilians, they propose a 3-pronged approach: 1) redressing imbalances in federal civilian compensation; 2) pruning defense support establishment by conversion of military positions to civilian billets; and 3) increasing reliance on private enterprise.

Their analysis focuses on political and economic constraints and points to the severe problems of inertia likely to be met within the military establishment itself. Current legislation and regulations outlining the civilian retirement system present considerable obstacles to cost-effective military management. However the authors contend any such legislative constraints could be eliminated. According to Binkin, Kanter, and Clark: "appropriate legislation could give managers greater flexibility to deal with retirement, work schedule, and reduction in force problems. If enacted, some of President Carter's proposals to reform the federal civil service system would go a long way toward resolving these issues" (p. 81).

In an age of growing scrutiny of defense budgets, *Shaping the Defense Civilian Work Force* presents a novel alternative to drastic increases in the budget. Purporting to provide no pat solutions, it offers a welcome re-examination of civilian manpower deployment as a way of rendering the defense budget more lean and more efficient.

HUGO BLACK AND THE BILL OF RIGHTS. By *Virginia Van der Veer Hamilton*, ed. The University of Alabama Press: University, Alabama, 1978. Pp. 95, index. $8.00.

Trial judge, senator, Supreme Court justice — Hugo Black was a man for all seasons. And as a tribute to those achievements, the University of Alabama at Birmingham has printed lectures and reminiscences about Black delivered at the First Hugo Black Symposium in American History.

With an introduction by Chief Justice Burger, the book presents brief but pointed insights into Black's thoughts and theories of free speech, freedom of religion and the Fifth Amendment. In the first essay in the book, Leonard Levy offers a compelling critique of the Supreme Court's use of history to illustrate what he terms "the Notorious Fact: The Supreme Court has flunked history." According to Levy, the "justices stand censured for abusing historical evidence in a way that reflects adversely on their intellectual rectitude as well as on their historical competence." Advocates, says Levy, not justices, use the "law office history" found in Supreme Court decisions.

Donald Meiklejohn and Paul Freund present additional insights into Black's views and the leitmotifs of Black's jurisprudence. Meiklejohn offers a rather trenchant critique of the content-conduct analysis Black utilized in First Amendment cases. A putative absolutist, Black was much more a moderate, says Meiklejohn, by subordinating speech considerations in particular cases to the state's interest in the control of conduct.

In the third essay, Freund presents an analysis of recent exercise clause cases as a context for critiquing the Court's approach to concerns of religious thought. Max Lerner presents a personal paean to the former justice in a disappointing finale to the tribute and the book.

SETTING NATIONAL PRIORITIES: THE 1979 BUDGET. By *Joseph A. Pechman, ed.* Washington, D.C.: The Brookings Institution, 1978. Pp. 299, appendices. $12.95, cloth; $5.95, paper.

Each year the Brookings Institution presents a detailed critique and analysis of the federal budget and its underlying policy objectives. To that end, *Setting National Priorities*, the ninth in an annual series, addresses the basic budget proposals for 1979 and President Carter's major budget initiatives.

The first nine chapters outline policy issues and (with the aid of numerous charts and tables) investigate the underlying

aims of proposed budgets in education, employment and income security, taxation, urban policy, agriculture, and defense.

In the final and most interesting chapter, Joseph Pechman takes a detailed critical look at the Carter budget to analyze its assumptions and proposed revenue and outlay estimates for 1979. Not surprisingly, Pechman concludes that executive predictions are often unrealistic and far too optimistic. Objectives of reducing federal expenditures to 21 percent of the Gross National Product, setting a balanced budget, and reducing unemployment to below 5 percent by 1981, the author suggests, undercut rather than complement one another.

Social security, welfare payments, and other federal outlays already render reduction of federal expenditures unlikely. And as Pechman indicates, price increases and unemployment are likely to get worse before they get better. Without continuing budget deficits, Pechman argues the economy may not be able to expand at all. As he points out, "Few people believe that the policy of wage and price reductions will work [while] . . . [r]ecent history suggests that prices will probably continue to rise" by at least 6 percent a year rather than taper off to 5 percent in 1981 as Carter assumes. Furthermore, Pechman argues that most economists believe that "swift and sizable reversal of the deficit" would simply compound economic problems and lead to a recession rather than helping current economic woes. The Congressional Budget office estimated in January 1978 that a federal deficit of at least $40 billion would be needed in fiscal year 1979 to keep the economy growing at the rate projected by the administration (p. 273).

From a political perspective, Pechman also indicates that Carter's objectives look extremely difficult to attain. To reduce outlays to the level Carter has proposed would require not only retaining the status quo but actual cuts in current administration policies and programs dear to members of Congress. And with national health insurance and the federal energy plan in store, it is highly unlikely, says Pechman, that Congress will settle quietly for any curtailment of spending.

In light of these critiques, the book's budget recommendations and alternative proposals present an excellent overview of the morass of federal budgetary problems. By explaining both economic and policy issues, *Setting National Priorities* provides a welcome gloss of the federal budget and current administration objectives. Its chapters present a thoughtful perspective on budget proposals and policies, useful to both the layman and the expert.

BOOKS RECEIVED

THE BROTHERHOOD OF OIL: ENERGY POLICY AND THE PUBLIC INTEREST. By *Robert Engler.* Chicago, Ill.: University of Chicago Press, 1977. Pp. 250, notes and index. $12.50.

CHILDREN'S HEARINGS. By *F. M. Martin & Kathleen Murray*, eds. Edinburgh: Scottish Academic Press, 1976. Pp. 240. £5.00 UK cased.

CRIMINAL RUSSIA: CRIME IN THE SOVIET UNION. By *Valery Chalidze.* New York: Random House, 1977. Pp. 215, notes and index. $10.00.

CURING CHRONIC INFLATION. By *Arthur M. Okun & George L. Perry*, eds. Washington, D.C.: The Brookings Institution, 1978. Pp. 287, index. $11.95.

DEINSTITUTIONALIZATION: PROGRAM AND POLICY DEVELOPMENT. By *James L. Paul, Donald J. Stedman & G. Ronald Neufeld, eds.* Syracuse, N.Y.: Syracuse University Press, 1977. Pp. 292, index. $13.95.

ECONOMIC INTEGRATION IN CENTRAL AMERICA. By *William R. Cline & Enrique Delgado.* Washington, D.C.: The Brookings Institution, 1978. Pp. 711. $19.95.

ESSAYS ON THE CONSTITUTION OF THE UNITED STATES. By *M. Judd Harmon, ed.* Port Washington, N.Y.: Kennikat Press, 1978. Pp. 159, notes. $12.95.

EVERYDAY LAW MADE SIMPLE, NEW REVISED EDITION. By *Jack Last.* New York: Doubleday & Company, Inc., 1978. Pp. 153, Glossary, index. $2.95, paper.

THE GRAY LOBBY. By *Henry J. Pratt.* Chicago, Ill.: University of Chicago Press, 1977. Pp. 218, appendices, bibliography, index. $15.00.

THE (GUILTY) CONSCIENCE OF A CONSERVATIVE. By *Craig Schiller.* New Rochelle, N.Y.: Arlington House, 1978. Pp. 151, notes and index. $8.95.

HEALTH AND THE WAR ON POVERTY: A TEN-YEAR APPRAISAL. By *Karen Davis & Cathy Schoen.* Washington, D.C.: The Brookings Institution, 1978. Pp. 224, index. $11.95.

A HISTORY OF SOCIAL WELFARE AND SOCIAL WORK IN THE UNITED STATES. By *James Leiby.* New York: Columbia University Press, 1978. Pp. 358, references, index. $17.50.

THE IDEAL IN LAW. By *Eugene V. Rostow.* Chicago: The University of Chicago Press, 1978. Pp. 295, index. $20.00.

THE IMPLEMENTATION GAME: WHAT HAPPENS AFTER A BILL BECOMES A LAW. By *Eugene Bardach.* Cambridge, Ma.: The MIT Press, 1977. Pp. 316, index. $4.95, paper.

JAPAN'S FOOD PROSPECTS AND POLICIES. By *Fred H. Sanderson.* Washington, D.C.: The Brookings Institution, 1978. Pp. 99. $2.95, paper.

LAW AND IDENTITY: LAWYERS, NATIVE AMERICANS, AND LEGAL PRACTICE. By *Linda Medcalf.* Beverly Hills: Sage Library of Social Research, 1978. Pp. 145. $14.95, cloth; $6.95, paper.

A MANUAL FOR COMPUTER-ASSISTED LEGAL RESEARCH. By *James A. Sprowl.* Chicago, Ill.: American Bar Foundation, 1976. Pp. 113, index. $5.00.

MONITORING REVENUE SHARING. By *Richard Nathan, Allen D. Manuel & Susannah Calkins.* Washington, D.C.: The Brookings Institution, 1975. Pp. 313, appendices. $11.50.

MUST WE BUS? SEGREGATED SCHOOLS AND NATIONAL POLICY. By *Gary Orfield.* Washington, D.C.: The Brookings Institution, 1978. Pp. 455, index. $16.95.

NATIONAL HEALTH INSURANCE AND HEALTH RESOURCES: THE EUROPEAN EXPERIENCE. By *Jan Blanpain.* Cambridge, Ma.: Harvard University Press, 1978. Pp. 289, index. $18.50.

THE NEW JERSEY INCOME-MAINTENANCE EXPERIMENT. By *Harold Watts & Albert Rees, eds.* New York: Academic Press, 1977. Pp. 414, index. $28.50.

ONE L. By *Scott Turow.* New York: Penguin Books, 1978. Pp. 269. $2.95, paper.

PARABLE BEACH: A PRIMER IN COASTAL ZONE ECONOMICS. By *J.W. Devanney, III., G. Ashe & B. Parkhurst.* Cambridge, Ma.: MIT Press, 1976. Pp. 99. $7.95.

THE POLITICS OF CRIME AND CONFLICT: A COMPARATIVE HISTORY OF FOUR CITIES. By *Ted Robert Gurr, Peter N. Grabosky & Richard C. Hula.* Beverly Hills: Sage Publications, Inc., 1977. Pp. 792. $25.00.

THE PRESIDENTIAL CAMPAIGN (REVISED EDITION). By *Stephen Hess.* Washington, D.C.: The Brookings Institution, 1978. Pp. 117, bibliography. $2.95, paper.

PRISONERS AMONG US: THE PROBLEM OF PAROLE. By *David T. Stanley.* Washington, D.C.: The Brookings Institution, 1976. Pp. 191, bibliography and index. $3.95, paper.

PRISON REFORM AND STATE ELITES. By *Richard A. Berk & Peter Rossi.* Cambridge, Ma.: Ballinger Publishing Co., 1977. Pp. 202, notes. $15.00.

PUBLIC REGULATION OF SITE SELECTION FOR NUCLEAR POWER PLANTS. By *Ernest D. Klema & Robert L. West.* Washington, D.C.: Resources for the Future, 1977. Pp. 119, index. $5.75.

REVOLUTION IN THE THIRD WORLD: MYTHS AND PROSPECTS. By *Gerard Chaliand.* New York: The Viking Press, 1976. Pp. 195. $11.95.

SCHOOL POLITICS CHICAGO STYLE. By *Paul E. Peterson.* Chicago, Ill.: University of Chicago Press, 1976. Pp. 256, notes and index. $15.00.

SETTING NATIONAL PRIORITIES: THE 1979 BUDGET. By *Joseph A. Pechman,* ed. Washington, D.C.: The Brookings Institution, 1978. Pp. 299. Appendix. $5.95, paper.

SHAPING THE DEFENSE CIVILIAN WORK FORCE: ECONOMICS, POLITICS, AND NATIONAL SECURITY. By *Martin Binkin.* Washington, D.C.: The Brookings Institution, 1978. Pp. 113. $2.95, paper.

SOCIAL SECURITY: TODAY AND TOMORROW. By *Robert M. Ball.* New York: Columbia University Press, 1978. Pp. 513, index. $14.95.

SOVIET AIR POWER IN TRANSITION. By *Robert P. Berman.* Washington, D.C.: The Brookings Institution, 1978. Pp. 82. $2.95, paper.

SPECIAL INTERESTS AND POLICYMAKING: AGRICULTURAL POLICIES AND POLITICS IN BRITAIN AND THE UNITED STATES OF AMERICA, 1956-70. By *Graham K. Wilson.* London: John Wiley and Sons, 1977. Pp. 178, appendix and index. $17.95.

THE SUBURBAN ENVIRONMENT: SWEDEN AND THE UNITED STATES. By *David Popenoe.* Chicago, Ill.: University of Chicago Press, 1977. Pp. 245, notes and index. $19.00.

UNACCEPTABLE RISK: THE NUCLEAR POWER CONTROVERSY. By *McKinley C. Olson.* New York: Bantam Books, 1976. Pp. 253, references, index. $2.25, paper.

WALL STREET SWINDLER. By *Michael Hillerman*. New York: Doubleday & Company, Inc., 1977. Pp. 365. $10.00.

WELFARE IN RURAL AREAS: THE NORTH CAROLINA-IOWA INCOME MAINTENANCE EXPERIMENT. By *John L. Palmer & Joseph A. Pechman*. Washington, D.C.: The Brookings Institution, 1978. Pp. 267, Index. $11.95.

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