Letters

The Use of Drugs

Charlotte Muller (5 May 1972, p. 488), in her socioeconomic foray into the field of drug therapy, assumes that an "overmedicated society" exists. But does it? It appears that there is a dichotomous use of drugs in the United States. On the one hand, an undetermined number of people use medications excessively, either constantly or occasionally. At the same time, another undetermined but certainly greater number of people who should be on medications ignore them because they don't get medical attention, can't afford it, refuse it, fail to get prescriptions filled, endure pain needlessly in accordance with the Puritan ethic, or are being educated to equate drug use with personal failings. On balance, then, we are probably an undermedicated society. The recent study for the National Institutes of Health by Balter and Levine (*1*) indicates that doctors, by and large, are conservative in their prescribing. This study clearly contradicts the labeling of our society as "overmedicated."

Muller appears to take seriously a chain of proposals that have luckily gotten nowhere. In cataloging "reforms," such as "stronger controls," she seems to be unaware that stringent control over drug advertising and labeling is increasingly exercised by the Food and Drug Administration (FDA). Advertising claims must be based upon FDA-approved labeling—a point critics invariably overlook. Similarly, Muller could have noted that free distribution of drug samples is already under careful restrictions and, for that matter, is a declining practice. Or that a single authoritarian compendium system has never elicited any real support from physicians, as it would largely duplicate what already exists—a voluminous and diverse literature. Her suggestion of a "neutral" detailing force to inform physicians about old and new drugs supposes (i) that physicians believe what the government tells them and (ii) that we are ready to inaugurate an era of "official" medicine—a stultifying threat, as the history of medicine demonstrates.

Muller also mentions an official formulary that would purport to list safe, efficacious, and reasonably priced drugs. Such a formulary would inevitably lower standards (the cheapest drugs would be the only reimbursable ones, for practical purposes), inhibit a doctor from prescribing outside the formulary, even if he felt it desirable, and cripple the incentive to develop improved medications, as their entry into a formulary could be speculative and subject to inordinate delay. Beyond that, a formulary would provide a convenient substitute for the needed work of utilization review. A formulary per se is not an indicator of drug excellence or of the quality of medical practice.

Muller reflects on the idea that drug firms must "prove" that a product is not only safe and efficacious (a formidable challenge) but is "superior" to others on the market. This, she opines, would reduce the flow of medications into practice. Indeed, it would. Just about to the vanishing point. In the world of medical reality, very few drugs can possibly attain during premarketing trials the status of "superior." Widespread use determines any medication's place and even then only in general terms. Progress in drug therapy results from a few breakthroughs—such as sulfanilamide, the first sulfa—followed by the development of a long series of related compounds, few of which show clear signs of superiority. Time and again incremental improvements, such as diuretics and antihypertensives, prove to be valuable.

Muller gives little attention to the present gains drug therapy affords society in lives saved, illnesses aborted or relieved, hospital stays shortened or prevented entirely, time saved on the job, and so on—all of incalculable human and economic benefit.

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References

1. M. Balter and J. Levine, "Character and extent of psychotherapeutic drug usage in the United States" (presented at the Fifth World Congress on Psychiatry, Mexico City, 1971).

The conscientious physician, if he looks even just casually, finds an appalling amount of sickness. If we state this categorically, however, we are accused of being "disease oriented."

Muller directs herself to the problem of mismedication, rather than overmedication. In fact, there is a very good argument for the fact that our society is undermedicated. Muller suggests one reason why. Practicing physicians are still mired down by a system which focuses all responsibility for decision-making and for services on the doctor and does not permit financial support for the services of paramedical workers. Because of lack of help, it is entirely likely that physicians constantly tend to "look the other way" when disease stares them in the face. A recent issue of the *American Journal of Medicine* (*1*) is given over to a discussion of hypertension. A correct précis of the entire issue would be, "high blood pressure, even when in the normal range, carries increased risk, but the experts are cautious in selecting who should be treated while deploring our failure to treat the majority meeting even that cautious selection." Sickle cell anemia is another example of a neglected disease that probably should be treated regularly with folic acid and prophylactic antibiotics.

By showing that much current medication is a hoax, Muller points to ways of restricting it, but by so doing may be throwing out the baby with the bath water. What we need is a better understanding of our pluralistic medical care system so that medication can be better directed.

In the process of taking the proper corrective measures we shall soon see what every honest doctor knows. There is currently not enough medicine available to help all of the sick people in our society if we earnestly set about trying to help them.

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1. *Amer. J. Med.* **52**, No. 5 (1972).

As pointed out by Charlotte Muller, one part of the solution to the complex problem of overmedication is closer federal regulation of the drug industry. Readers should be interested in the Omnibus Drug Bill, introduced by Senator Gaylord Nelson (D–Wis.) to accomplish this goal. The titles of this

legislation can be summarized as follows:

1) A National Drug Testing and Evaluation Center is to be established which will be responsible for the testing of all drugs, both prescription and over-the-counter, that are now or will be marketed in the United States. The Food and Drug Administration (FDA) must give approval prior to testing drugs on human beings, and the results and conclusions of all tests will be made public. In order for a new drug to be approved, it must be demonstrated that the new drug is safer or more effective than a drug already on the market. As it has been the manufacturer's responsibility in the past to bear the expense of a drug's testing, he will continue to bear the expense. However, there will be channels open for appeal if the manufacturer is dissatisfied with the testing procedure.

2) Provision is made for the publication of a compendium which will list all drugs available in the United States by both generic and brand names. Such a compendium would include, for each drug, the drug's purpose, side effects, dosages available, and cost, as well as other relevant information. As such a compendium could eliminate the need for inserts with full prescribing information now required, the cost of the compendium would be borne by the drug industry. Supplements will be issued from time to time to keep the compendium as up-to-date as possible, and it is also provided that all drug labeling and advertising must conform with the information found in the compendium.

3) A committee is to be established which will compile a formulary of drugs necessary for good medical practice, for purposes of direct procurement by the federal government and reimbursement for all government-financed programs, indicating the best drug available for each generic type, in order to assist the physician in his prescribing of medication.

4) All drugs produced and packaged in the United States are to be inspected and approved so as to protect the public health. Furthermore, every drug would be labeled in such a way as to identify its source and generic type, to facilitate the tracking down of defective drug batches. In addition, all drugs will have instructions for safe use printed on their package.

5) The secretary of Health, Education, and Welfare (HEW) is to be given the authority to require batch-by-batch certification of all drugs—when needed—which will include provisions prescribing standards and identity of strength, quality and purity, tests and methods to determine compliance with such standards, and other measures necessary for the public good.

6) The distribution of sample drugs is to be prohibited without the written request of the physician. Furthermore, the sale of sample drugs, either directly or indirectly, is prohibited.

7) Potentially dangerous drugs are to be labeled with the appropriate warning. Labeling of drugs will be required so that all active ingredients will be clearly labeled. No drug salesman shall make any oral presentation regarding any drug until he has placed before the physician or pharmacist an FDA-approved document about the drug. The secretary of HEW shall approve all advertising in advance that appears in either the electronic media, or in any publication or advertising circular, for any drug. The secretary will approve only advertising which does not mislead or misrepresent the product, either in text or layout.

The Omnibus Drug Bill has been referred to the Health Subcommittee of the Committee on Labor and Public Welfare. Interested parties should write to Senator Edward Kennedy (D–Mass.), chairman of the subcommittee, urging that hearings be scheduled.

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New Maser at Haystack

The Haystack Observatory, under the guidance of Sigfrid Yngvesson of the University of Massachusetts, is presently completing the development of a maser preamplifier, tunable from 21.5 to 23.7 Ghz, with instantaneous bandwidth better than 12 Mhz. The initial installation is expected to yield a system temperature on the order of 150° to 200°K. As development proceeds, wider bandwidths and lower system temperatures are anticipated.

Provided on-line tests of the system, scheduled for February 1973, proceed as expected, the new system should be available on the Haystack antenna beginning in April 1973 during periods when the radiometer equipment box (R-Box) is installed on the antenna. The R-Box alternates with a second equipment box, the so-called planetary radar box (PR-Box). The detailed box schedule depends primarily on observing requirements.

The Haystack Observatory is operated under agreement with the Massachusetts Institute of Technology by the Northeast Radio Observatory Corporation, with primary support of its research from the National Science Foundation and NASA. Inquiries and requests for observing time with the new system should be addressed to the director at the address below.

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Technological Advance

Scientists distressed by delays between submission of their manuscripts and publication may be interested in two historical precedents. Sigmund Freud decided to order a supply of cocaine from the pharmaceutical firm of Merck on or about 21 April 1884. By 18 June he had received the cocaine, tried it out on himself and two patients, and completed his first report. It was published in the July 1884 issue of the *Centralblatt für die gesammte Therapie* (*1*).

Wilhelm Conrad Roentgen caught his first glimpse of x-ray effects on 8 November 1895. He delivered the manuscript announcing his discovery to the secretary of the Physical-Medical Society of Würzburg on 28 December 1895, just in time for the December issue of the *Proceedings* of that society; he received reprints in time for mailing to other physicists on New Year's Day of 1896 (*2*).

Freud and Roentgen, alas, lacked the benefits of today's computerized phototypsetters, high-speed presses, and other technological advances. They also had to make do without a hierarchy of review and editorial procedures to facilitate publication of their manuscripts.

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1. E. M. Brecher and the editors of *Consumer Reports, Licit and Illicit Drugs: The Consumer Union Report on Narcotics, Stimulants, Depressants, Inhalants, Hallucinogens, and Marijuana (including Caffeine, Nicotine, and Alcohol)* (Little, Brown, Boston, 1972), pp. 272–273.
2. E. M. Brecher, *The Rays: A History of Radiology in the United States and Canada* (Williams & Wilkins, Baltimore, 1969), pp. 8–9.