

Appendix B.—Conclusions and Recommendations of the Joint Commission on Prescription Drug Use, Jan. 23,1980

1. Postmarketing surveillance (PMS) can be used to develop information about prescription drugs that is unavailable from premarketing studies but necessary and, or useful for the clinical practice of medicine or ongoing regulation of drugs. Existing postmarketing surveillance programs should be coordinated with new programs to form a comprehensive system.

2. The purpose of postmarketing surveillance is to detect important drug effects earlier than would otherwise be possible. The surveillance, per se, or its results will not and cannot be used to change the biological properties or effects of drugs, but they can be used to minimize the harmful consequences and maximize the optimal use of drugs.

3. Certain risks posed by a PMS system must be recognized, accepted, and addressed, although they are judged by the Commission to be far outweighed by potential benefits.

4. Highest priority in a PMS system should be given to surveillance of new chemical entity prescription drugs, delayed or slowly developing drug effects, commonly used drugs, populations in which drug effects are not well documented, certain important medical events (e. g., births, deaths, etc.) and their relationship to drug use, and patterns of prescription drug use. Other, but secondary, priorities should include the study of: certain important non-prescription drugs, the drug-taking practices of patients, the frequency of given drug effects, dose-response relationships, the characteristics of patients who experience certain effects as compared to those who do not, the relative risks and benefits of individual drugs, changes in frequencies of drug effects over the course of time, and the comparative efficacy and safety of different drugs within the same class.

5. PMS must operate, to the maximum extent possible, in a setting of actual medical practice. In the majority of instances, PMS should be concerned primarily with drugs marketed without special restrictions beyond those already enforced for drugs of certain classes. Data collection for PMS should not interfere with the normal delivery of health care.

6. A PMS system will require both an alerting (hypothesis-generating) mechanism and a confirming or rejecting (hypothesis-testing) mechanism. Hypotheses must be recognized as *suggestions* about cause-effect relationships and not as established fact.

7. An hypothesis-generating mechanism should

ideally have access to all animal and clinical data about a drug.

8. A great deal of selectivity will be required for judicious decisions about which of the available hypotheses to test.

9. PMS must insure that great attention is paid to research design and to the sequence of studies. Particular attention should be paid to the validity of the methodology and to the sample size required. Possible types of study are prospective or retrospective, experimental or non-experimental, controlled or uncontrolled, cohort or case-control, studies of drugs or of events, and studies of prophylactic, therapeutic, or diagnostic drugs.

10. Development of new methodology for study of drug effects must be a high priority for the PMS system.

11. The drug effects requiring study will be expected toxicity, unexpected toxicity, intended efficacy and unintended efficacy.

12. Currently available methodology can be used to study expected or unexpected toxicity and unintended efficacy, successfully detecting events that occur with a frequency of at least one event per 1000 exposures. Less frequent events (e.g., one in 10,000 uses) can be detected less reliably.

13. The Commission strongly recommends against PMS that ignores the determination of intended efficacy and of long-term drug effects.

14. An intensive system of surveying the medical literature should be established and particular attention given to a systematic review of data comparing drug responses in various countries.

15. A PMS system should develop methods of seeking and receiving brief reports from large numbers of health professionals.

16. Prospective, non-experimental cohorts that are long-term and lifelong, if possible, should be established for PMS studies.

17. Liaison between the various components of a PMS system will be necessary. This would require development of a standardized terminology for describing PMS and for use in PMS.

18. Reports must be prepared, published and distributed to all parties involved in or affected by PMS. Multiple types of reports will be necessary, tailored to the differing needs and interests of the recipients.

19. For a prescription drug surveillance system to

be effective, it must have the confidence of the public at large, including health care providers and patients. This confidence must extend not only to the validity of the information generated, but also to the manner in which the information will be used.

20. In order to maintain trade secret protection for manufacturers without prejudicing the PMS system's public and academic accountability, only the FDA should have the power to require the disclosure of such secrets. Because of this restriction, the FDA must assume responsibility for reviewing this trade secret data for any hints of drug effects in man that it may contain.

21. In order to protect patient confidentiality, individually identifiable information should be kept strictly confidential by any PMS system unless patients specifically authorize release, with only the following exceptions:

- a. Such information could be released to organizations engaged in similar research if an express finding with supporting written statements is prepared documenting that such disclosure is necessary and identifying the individual receiving the information. Such organizations must have comparable guarantees of confidentiality as the organization releasing the data. Redislosure by the receiving organization would be prohibited without written approval of the original organization.
- b. Disclosure could be made to a properly identified recipient pursuant to a bona fide medical emergency.
- c. Both patient and provider must have access to their own identifiable data and the ability to make corrections or amendments.

22. Given the fact that the law is developing on the issue of provider liability for disclosing patient identifiable medical records, the Commission recommends that the organizations concerned with PMS review the issue of liability as they begin to undertake PMS functions.

23. In order to assure adequate security for data gathered, a PMS organization should:

- a. Maintain only that information which is relevant and necessary to accomplish the purpose.
- b. Maintain all records used in making any decisions

about an individual with such accuracy, relevance, timeliness, and completeness as is reasonably necessary to assure fairness to the individual in the determination.

- c. Establish administrative, technical, and physical safeguards to insure the security and confidentiality of records.

24. The value for PMS of a limited shield law is recognized. Such a law would specify that identifiable information of the patient or provider submitted voluntarily to a PMS organization could not be admissible as evidence in a medical or product liability action, and might remove a deterrent to voluntary reporting. Even without such a law however, the PMS functions of the CDS [Center for Drug Surveillance] should commence and the results should be used to define whether evidence needs to be gathered to support the need for and formation of shield law in order to have an optimal PMS system.

25. A national Center for Drug Surveillance (CDS) is necessary in the United States.

26. The objectives and functions of the CDS should be to educate scientists, prescribers and the public, to perform and encourage research into drug effects and to promote cooperation among all existing PMS programs.

27. In using its resources, the CDS must be strictly accountable for fairness, scientific accuracy, and honesty.

28. The activities of the Center for Drug Surveillance (CDS) should not unnecessarily duplicate the functions of other organizations engaged in PMS activities, whether public or private.

29. The CDS should be a private, non-profit, non-regulatory organization with a full-time staff and a physical facility located in an environment that can support and be supported by academic endeavors.

30. After five years, there should be an external review of the effectiveness of the CDS. If the projected benefits from the CDS are not realized, the CDS should be abandoned.

31. Support for the CDS should be in addition to, not instead of, added support for other worthwhile PMS activities,