

But he said there was a serious danger that Mann and his staff would judge the drug industry, which requires large amounts of research to develop just a few new products, by the same standards as regular industries.

"He's taking industrial criteria to try to define the state of the art of medical treatment," Cray said.

The FTC study is just beginning, and no final report is expected for some time. But whatever the conclusions, the PMA will be ready with any necessary defenses.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, FOOD AND DRUG ADMINISTRATION—[21 CFR PARTS 1, 2, 4, 8, 121, 130, 135, 146, 191]

PUBLIC INFORMATION—NOTICE OF PROPOSED RULEMAKING

The effect of Public Law 89-487, the Public Information section of the Administrative Procedure Act, more commonly known as the "Freedom of Information Act," has been to increase requests made of the Food and Drug Administration for release of documents contained in Food and Drug Administration files. In response, it has been the policy of the Department of Health, Education, and Welfare to provide disclosure consonant with statutory obligations of confidentiality and administrative necessities recognized by the act. Because of the vast amount of information in FDA files and the fact that FDA has never before attempted to set out in detail the rules applicable to public disclosure of this information, the Commissioner of Food and Drugs has concluded that it is in the public interest to reexamine the agency's practices on public disclosure of information and to adopt detailed regulations specifying the extent to which public disclosure is and is not permitted.

The Freedom of Information Act adopts a general rule that, except where specifically exempted, all documents in Government files shall be made available to the public. The Commissioner fully endorses this approach. Public disclosure should be the rule rather than the exception. Accordingly, all information in FDA files will be available for public disclosure unless they fall within one of the explicit exemptions contained in that act or other applicable statutes.

The Freedom of Information Act itself contains in 5 U.S.C. 552(b) nine exemptions from public disclosure in the following areas:

1. *National defense or foreign policy.*—This exemption has raised no difficulties with FDA.

2. *Internal procedure.*—FDA has recently reappraised the status of all of its internal operating manuals with the intent of separating all confidential material in order to make the remaining material publicly available. This review is now complete, and the manuals will shortly be made available through the office of the Assistant Commissioner for Public Affairs.

3. *Information specifically exempted from disclosure by statute.*—This exemption incorporates by reference the general and specific confidentiality provisions contained in other statutes. The Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act (1967) mentions 18 U.S.C. 1905, which is quoted below, as one of the specific confidentiality statutes not intended to be changed. Similarly, the specific confidentiality provisions in the various statutes administered by FDA, which are also quoted below, are incorporated by reference under this provision.

4. *Trade secrets and commercial or financial information obtained from any person and privileged or confidential.*—The Senate Report explained this exemption as follows:

This exception is necessary to protect the confidentiality of information which is obtained by the Government through questionnaires or other inquiries, but which would customarily not be released to the public by the person from whom it was obtained.

The House Report similarly stated that:

It exempts such material if it would not customarily be made public by the person from whom it was obtained by the Government. The exemption would include business sales statistics, inventories, customer lists, scientific or manufacturing processes or developments * * *.