

GAO

Report to the Chairman, Subcommittee on
Health and Environment, Committee on
Energy and Commerce, House of
Representatives

July 1988

MEDICAL DEVICES

FDA's Forecasts of Problem Reports and FTEs Under H.R. 4640



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**Program Evaluation and
Methodology Division**

B-231242

July 11, 1988

The Honorable Henry A. Waxman
Chairman, Subcommittee on Health
and Environment
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

This report responds to your request that we evaluate the methodological soundness of the approach the Food and Drug Administration (FDA) used to forecast the increase in the number of medical device problems that would be reported by hospitals and the number of agency staff that would be necessary to analyze the reports of those problems under the Medical Devices Improvement Act of 1988 (H.R. 4640).¹

Background

Since the implementation of the medical devices reporting regulation in December 1984, FDA has received approximately 18,000 medical-device problem reports per year. The current staff allocation for processing and analyzing these reports is 73 full-time equivalent (FTE) staff persons. From the provisions of H.R. 4640, as approved by the Subcommittee on May 17, 1988, FDA projected that it would receive as many as 90,000 additional problem reports per year and that it would need 281 additional FTEs to process and analyze them. The data FDA used to make this forecast were derived from one of two hospitals that participated in an experimental project (Hospital Experience Reporting System, or HERS) that required hospitals to report medical device-related problems to FDA. The HERS project on which the FDA analysis was based took place at Beth Israel Hospital in Boston, Massachusetts, between September 1, 1980, and August 31, 1983.

**Scope and
Methodology**

We used several data sources and collection techniques to produce our findings. A major data source was the latest available American Hospital Association (AHA) annual survey of hospitals, Hospital Statistics, 1987 edition. We also obtained agency documents such as Beth Israel's HERS project summary report and FDA's HERS statistical analyses and

¹We have several related studies under way in the area of medical devices. In the near future, we intend to provide your committee with the results of our related studies that deal with the 510k device-approval process and the implementation of the medical devices reporting regulation.

current staff allocation reports. We reviewed and analyzed these documents to evaluate FDA's methodology and the validity of its forecast.

We interviewed FDA's chief analyst and other agency staff who contributed to the development of the FDA forecast. In addition, we interviewed officials from AHA and the director of Beth Israel's HERS project to verify the results and ensure the completeness of our evidence. The analysis and findings in this report are based on commonly used research procedures and statistical principles. We discussed the issues in our report with FDA officials and have included their comments where appropriate. However, in accordance with your wishes, we did not obtain FDA's written comments on a draft of this report.

Analysis and Findings

Sample design, which is fundamental to empirical research, has two aspects: a selection process, or the rules and operations by which some member of a population is included in a sample and determines the sample's representativeness, and an estimation process for computing estimates of the population values from the sample statistics. In the case we are discussing here, any estimate or forecast of the number of medical-device problem reports and, consequently, of the number of FTEs necessary to process and analyze them, is only as good as assumptions about the representativeness of the hospitals in the sample.

We found that FDA used a sample of one hospital to provide the data base for the forecast. The sample hospital, Beth Israel, is relatively unique and not representative of U.S. hospitals for the following reasons. First, there are 6,841 hospitals in the United States. Beth Israel is a large hospital with 432 beds. According to AHA's statistics, 88 percent of the hospitals in the United States have fewer than 400 beds. The average number of beds is 189.² Second, it is a "tertiary treatment" facility—a teaching hospital and a referral hospital that treats the more-seriously ill patients, performs more complicated medical procedures than most hospitals, and therefore uses a greater number of technologically complex medical devices.

Third, because of the experimental nature of the HERS project, we also found that extraordinary efforts were made at Beth Israel to raise reporting awareness and reporting levels. These efforts, according to

²Beth Israel's HERS project reported an average of 0.0818 medical device problems per hospital bed per year. FDA multiplied 1,318,000, or the total number of beds in registered hospitals, by the 0.0818 problems per hospital bed per year to forecast the total of 108,000 medical device problems reported per year.

Beth Israel's report, resulted in a tenfold increase in device-related problem reports to FDA. In summary, FDA's forecast of the number of additional reports that would be required under H.R. 4640 is flawed because of the uniqueness and the nonrepresentativeness of the data base.

FDA's analysis shows that if the current number of device-related problem reports were to increase, the number of FTEs required to process and analyze those reports would increase proportionally. Specifically, FDA projected that it would need 1.6 times the current number of FTEs to process 2 times the current number of reports and 4.8 times the current FTEs to process and analyze 6 times the current number of reports.

In an earlier study about medical-device problem reporting, we reported that before the implementation of the medical devices reporting regulation in 1984, FDA was receiving approximately 2,000 reports annually through its problem reporting program.³ Since the implementation of the regulation in 1984, FDA has received approximately 18,000 reports annually, which is a ninefold increase. However, a preliminary analysis of the data from our current study of the implementation of the regulation shows that after the second year of the program, the number of problem reports declined annually. FDA received an average of 18,000 problem reports between 1985 and 1986 and 16,654 in 1987; FDA's projected 1988 figure is approximately 15,000. Our analysis indicates approximately a 15-percent decline in the total number of reports sent to FDA between 1985 and 1988. This finding suggests that consideration must be given to the possibility that reports resulting from the enactment of H.R. 4640 would tend to decrease after an early initial peak.

There is the potential for greater efficiency in processing and analyzing reports. It is expected that as report analysts become more experienced in processing and analyzing reports and as FDA's internal procedures are improved, the number of FTEs required to process and analyze the additional reports would decrease.

If these two factors—the decline that can be expected in the number of problem reports and the increase likely in report processing efficiency—are excluded from any forecast of problem reports and staff needs associated with H.R. 4640, then FDA's long-term resource requirements for the activity would appear to be overestimated.

³See U.S. General Accounting Office, *Medical Devices: Early Warning of Problems Severely Hampered by Underreporting*, GAO/PEMD-87-1 (Washington, D.C.: December 19, 1986).

Conclusion

The enactment of H.R. 4640 is expected to increase the number of medical-device problem reports that FDA would be required to handle and would increase the demand for FTEs to analyze those reports. However, the data base that FDA used to forecast the number of reports and additional FTEs tends to exaggerate the size of those increases because of the characteristics of the particular hospital selected for analysis. We found little statistical or substantive support for the forecast FDA derived. FDA's forecast of the effect of H.R. 4640 on its resources was based on a single, relatively unique hospital that is not representative of the population of all U.S. hospitals. That this is a sample of one hospital makes it impossible to determine the validity and variability of FDA's forecast. Further, staff at that hospital were sensitized to the need to report problems, because of the nature of the demonstration that they participated in, and therefore significantly increased their report submissions.

These two points suggest that FDA's forecast is biased and not representative of what would be generated from data obtained from U.S. hospitals in general. The nature of the data base FDA used to derive its forecast would tend to generate forecasts at the higher end of the range of the possible number of problem reports and FTEs that would be associated with the enactment of H.R. 4640.

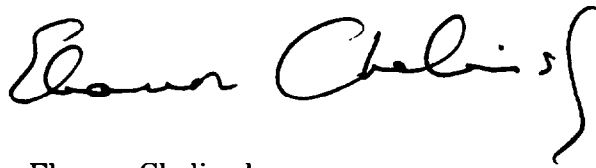
We also believe that the number of reports that FDA would receive would peak shortly after the legislation's requirements were implemented and would decline significantly as the program matured. The number of FTEs required to process and analyze the additional reports should also peak shortly after program implementation and then drop over time.

Because of time limitations, we did not develop independent estimates of the number of problem reports that would result from H.R. 4640 or additional FTEs that would be required to implement it.

As agreed with your office, we plan no further distribution of this report until 30 days after the issue date, unless you publicly announce the contents earlier. We will then send copies to persons who are interested and make copies available to others who request them.

If you have any questions concerning this report or any other aspect of our work on medical-device problem reporting, please call me (275-1854) or Mr. Kwai Chan, Group Director (275-6161).

Sincerely yours,

A handwritten signature in cursive script that reads "Eleanor Chelimsky". The signature is written in black ink and is positioned to the left of the printed name and title.

Eleanor Chelimsky
Director

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