

are taken, new drugs must be tested on man with the greatest caution. A central computing office for the evaluation of these reports is essential. Such an office must be impartial and must have no financial interest in the product.

Absolute safety is impossible. The final test of any drug used by man is how it affects man. Nevertheless, the medical profession must make a concentrated effort to give the public the greatest possible protection. Therefore, extremely careful records must be kept when drugs are first given to various groups of persons. Furthermore, these records must be filed in such a manner that possible untoward late complications can be correlated with the various drugs. Although this is especially important for drugs used during pregnancy it is by no means limited to such drugs. Other drugs may have late untoward effects on man; consequently, all new drugs require careful scrutiny. Therefore, it should be re-emphasized that drugs should be prescribed with the greatest of caution to women in the childbearing age.

The list of drugs in Table 1 that I have been able to verify is not a complete one since Dr. Fanconi (10) told me that he had seen a list in Switzerland containing more nearly 100 than 50 names. Nevertheless this list illustrates the many names under which a single drug may be marketed, and thereby shows the wisdom of the recent change in the laws requiring that official names be printed on the label in letters half the size of the trade name.

REFERENCES

1. Lenz, W. Kindliche Missbildungen nach Medikament-Einnahme während der Gravidität. *Deutsche med. Wchnschr.* 86:2555, 1961.
2. McBride, W. G. Thalidomide and congenital anomalies. *Lancet* 2:1358, 1961.
3. Lenz, W., and Knapp, K. Die Thalidomid-Embryopathie. *Deutsche med. Wchnschr.* 87:1232, 1962.
4. Lenz, W. Presented at Fourth World Congress of Cardiology, Mexico City, Mexico, October 7-13, 1962.
5. *Idem.* Personal communication.
6. Somers, G. F. Thalidomide and congenital abnormalities. *Lancet* 1:912, 1962.
7. Spencer, K. E. V. Thalidomide and congenital abnormalities. *Lancet* 2:100, 1962.
8. Somers, G. F. Personal communication.
9. Green, J. M., and Benson, B. C. Spectrophotometric determination of thalidomide in body fluids. *J. Pharm. & Pharmacol.* 13 (Supp.):117-121, 1961.
10. Fanconi, G. Personal communication.

[From the Washington Post, July 15, 1962]

"HEROINE" OF FDA KEEPS BAD DRUG OFF MARKET

(By Morton Mintz)

This is the story of how the skepticism and stubbornness of a Government physician prevented what could have been an appalling American tragedy, the birth of hundreds or indeed thousands of armless and legless children.

The story of Dr. Frances Oldham Kelsey, a Food and Drug Administration medical officer, is not one of inspired prophecies nor of dramatic research breakthroughs.

She saw her duty in sternly simple terms, and she carried it out, living the while with insinuations that she was a bureaucratic nitpicker, unreasonable—even, she said, stupid. That such attributes could have been ascribed to her is, by her own acknowledgement, not surprising, considering all of the circumstances.

What she did was refuse to be hurried into approving an application for marketing a new drug. She regarded its safety as unproved, despite considerable data arguing that it was ultra safe.

It was not until last April, 19 months after the application was filed with the FDA, that the terrible effects of the drug abroad were widely reported in this country. What remains to be told is how and why Dr. Kelsey blocked the introduction of the drug before those effects were suspected by anyone.

Dr. Kelsey invoked her high standards and her belief that the drug was "peculiar" against these facts: