

(The material referred to follows:)

TABLE 6.—PHARMACEUTICAL PRODUCTS INTRODUCED NATIONALLY

|           | Number<br>of firms | New<br>single<br>chemicals | Duplicate<br>single<br>products | Com-<br>pounded<br>products | (a) Total<br>new<br>products | (b) New<br>dosage<br>forms | Cumulative<br>total<br>(a and b) |
|-----------|--------------------|----------------------------|---------------------------------|-----------------------------|------------------------------|----------------------------|----------------------------------|
| 1966..... | 52                 | 13                         | 16                              | 53                          | 82                           | 26                         | 5,618                            |
| 1965..... | 65                 | 23                         | 23                              | 73                          | 119                          | 22                         | 5,510                            |
| 1964..... | 82                 | 17                         | 34                              | 111                         | 162                          | 41                         | 5,369                            |
| 1963..... | 89                 | 18                         | 43                              | 152                         | 213                          | 52                         | 5,166                            |
| 1962..... | 108                | 28                         | 47                              | 180                         | 255                          | 84                         | 4,901                            |
| 1961..... | 111                | 41                         | 33                              | 191                         | 265                          | 106                        | 4,562                            |
| 1960..... | 109                | 45                         | 64                              | 202                         | 311                          | 98                         | 4,191                            |
| 1959..... | 106                | 63                         | 49                              | 203                         | 315                          | 104                        | 3,782                            |
| 1958..... | 126                | 44                         | 73                              | 253                         | 370                          | 109                        | 3,353                            |
| 1957..... | 127                | 51                         | 88                              | 261                         | 400                          | 96                         | 2,884                            |
| 1956..... | 126                | 42                         | 79                              | 280                         | 401                          | 66                         | 2,388                            |
| 1955..... | 124                | 31                         | 90                              | 282                         | 403                          | 96                         | 1,921                            |

Note: New single chemicals indicates products that are new single chemical entities not previously known and developed by one manufacturer.

Duplicate single products include products such as dexamethasone or griseofulvin put out by various manufacturers. Compounded products comprise any product having more than one active ingredient.

New dosage form: if a product has originally been marketed in tablets and is now offered in ampules, suppositories, etc., the latter are considered new dosage forms.

Source: Paul de Haen, New York City.

Senator NELSON. Now, you also stated in this same paragraph that we have heard about or seen cases of ineffective drugs, harmful drugs, drugs marketed without adequate warnings, and dangerous drugs coming to the market as part of the "new drug flow" for which the industry claims credit.

Do you have specific examples of such harmful drugs, those without adequate warnings, and so forth?

Dr. SCHIFRIN. Yes, sir; I think the most harmful example of a new drug coming to the market was MER 29, which was withdrawn from the market because of its harmful effect on people taking it. Also in these hearings, the question of inadequate advertising has come up. I believe the Chlormycetin case is probably the most important one there. A highly promoted drug came to the market, a potent drug, with dangerous side effects, and the information as to the side effects was fully understood only after the problems of use of the drug had been so serious that it was withdrawn from the market for a year for a very careful study.

So I cite that as the most outstanding example of a drug, a dangerous drug, with inadequate information.

There are quite a number of other examples. The Merrell Co. was cited for false claims with MER-29. This is an article from the New Haven Register of December 20, 1963, that I happen to have here. That is just one of several examples I could name.

Senator NELSON. If you would submit that last article from it, we will print it in the record.

(The material referred to follows:)

[From the New Haven Register, Dec. 20, 1963]

#### DRUG FIRM INDICTED ON FALSE CLAIMS

WASHINGTON (AP).—The William S. Merrell Co. was indicted by a Federal Grand Jury today on charges of making false statements to the government about the anti-cholesterol drug, MER/29, and tests made to determine its safety.