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DEPARTMENT OF AGRICULTURE

HOUSEKEEPERS' CHAT

Monday, December 13, 1937

(FOR BROADCAST USE ONLY)

Subject: "ELIXIR SULFANILAMIDE-MASSENGILL." Facts from the Federal Food and Drug Administration, U. S. Department of Agriculture.

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Early last month our Washington correspondent sent us a news letter concerning the deadly new drug, known as "Elixir Sulfanilamide" (E-LIX-ER SUL-FAN-IL-A-MID). This drug has caused the death of at least 73 persons.

According to our correspondent, enough of the "elixir" to kill five or ten thousand more persons was on the market before local, State and Federal authorities began their intensive campaign to seize all lots of it.

Today's Washington letter contains additional facts about the dangerous drug, tells how it got on the market, and how it was removed from the market. Quoting directly:

"To date, at least 73 persons have died as a direct result of taking 'Elixir Sulfanilamide.' Twenty other persons who took this drug have died, but authorities have not yet proved that the 'exlixir' was exclusively responsible. The 93 deaths occurred in 15 States, as far East as Virginia, as far West as California.

"Elixir Sulfanilamide was manufactured and sold by the S. E. Massengill Company of Bristol, Tennessee. The Company manufactured a total amount of 240 gallons, Fortunately, every gallon has been accounted for.

"The drug was never tested for its effect on human life, before it was put on the market. The elixir was tested for <u>flavor</u>, but not for its effect on human life. The <u>existing</u> Food and Drugs Act <u>does not require</u> that new drugs be tested, before they are placed on sale.

"Elixir Sulfanilamide was first distributed commercially a little over three months ago, beginning September 4. Commercial distribution continued to October 15. The first word that it was killing people reached the Food and Drug Administration on October 14. Two days later a Food and Drug investigator telegraphed from Tulsa, Oklahoma, that nine persons had died in Tulsa, after taking the elixir. Immediately, the Food and Drug Administration ordered seizure of all outstanding shipments.

"Now, as you have been reminded time and time again, the Food and Drugs Act <u>contains no provision protecting the consumer against the presence in</u> <u>proprietary remedies of certain dangerous drugs</u>. Under the circumstances, how could the Government agency that enforces the Act <u>legally</u> order the seizure of 'Elixir Sulfanilamide'?

"The answer to this is, seizures had to be based on a charge that the word 'elixir' implies an <u>alcoholic</u> solution, whereas the drug in question was a <u>diethylene glycol</u> (DYE-ETHEL-EEN GLY-COL) solution. If the product had been called a 'solution,' rather than an 'elixir', the Administration could <u>not</u> have brought a charge of violating the Food and Drugs Act.

"The deadly effect of the 'elixir' was caused by the diethylene glycol, which was used as a solvent in making a <u>liquid</u> preparation of the sulfanilamide. The victims of this liquid preparation were sick from one to three weeks. They suffered intense pain.

"Sulfanilamide itself is a valuable drug. It was <u>not</u> responsible for the disaster which has resulted in 73 deaths. Properly used, sulfanilamide may be brilliantly successful in treating various infections. It is usually administered in tablet or powder form.

"For some time before the S. E. Massengill Company put 'Elixir Sulfanilamide' on the market, the Company had been selling sulfanilamide in capsules and tablets. Last June, salesmen reported a demand for the drug in <u>liquid</u> form. The chief chemist of the Company decided upon a formula which produced 'Elixir Sulfanilamide.' However, no tests were made to determine the poisonous effects of either the separate ingredients or of the finished product. The so-called control laboratory checked the 'elixir' merely for appearance, flavor, and fragrance. No experimental animals were used, no clinical tests of any kind were made, to determine either the <u>effectiveness</u> of the drug, or its <u>poisonous</u> properties.

"On August 28, the formula for 'Elixir Sulfanilamide' developed by the chemist was sent to the Kansas City branch of the Company, where 40 gallons were made. In the plant at Bristol, Tennessee, 200 gallons were made. The stuff was rushed onto the market.

"The preparation was a semi-secret one. The presence of dicthylene glycol was not disclosed. There was no warning of danger. A few simple and inexpensive tests would have quickly shown the poisonous properties of the 'elixir'. These tests were not made.

"In addition to the regular shipments, a lot of <u>samples</u> were manufactured -- several hundred one-ounce samples for physicians, and 187 two-ounce samples for salesmen. Most of the elixir was administered on physician's prescriptions."

Now, still quoting today's report:

"It was through the persistent and untiring efforts of local, State, and Federal forces throughout the country that a complete round-up of the deadly 'elixir' was accomplished. Officials were spurred on by the knowledge that any lot not accounted for might add others to the list of tragic victims.

"One Texas State inspector, within twenty-four hours, drove 460 miles and called on 45 druggists and three doctors, in 17 towns. As a general rule, the physicians and druggists who had prescribed and dispensed the medicine were most cooperative."

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In conclusion, our correspondent states: "Although the 'elixir' incident has been spectacular, and has received much publicity, aside from the brief period in which the killings occurred it is but a repetition of what has frequently happened in the past in the marketing of such dangerous drugs as <u>dinitrophenol</u>, <u>cinchophen</u>, and other poisonous <u>substances</u>. And these substances will be discussed at length, in later reports."

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