

tion should be capable of a double or triple dose without any toxic reaction because of the possibility of this happening to the measuring of the dose by the mothers. Dr. Jarvis felt that the information provided by the G. D. Searle Company was wholly inadequate, and his feelings are expressed in the letter which he sent to Dr. Goddard, dated May 19, 1966, which is quoted below:

"The G. D. Searle Company apparently knows little or nothing about their product Lomotil (Diphenoxylate HCl with/Atropine). On February 25 I performed an autopsy on a three-year-old boy who (I believe) died as a direct result of Lomotil overdosage. Enclosed is a copy of a report from the Searle Company which appears to say that the postmortem serum samples submitted to them for assay had a Diphenoxylate level as high as their high standard. However, in personal conversation with Dr. McGovern of their Division of Clinical Research, I gather that they do not know what an overdose is, or how it reacts on the living organism.

"I find this state of affairs somewhat appalling, so I am referring the matter to you. If you wish, I will send a copy of the autopsy."

The sequence of events with respect to this case are as follows:

The patient was examined at a Minneapolis Naval Air Station, Outpatient Clinic on 10/20/65, 1/22/66, 1/29/66, and 1/30/66. (The father was a member of the Navy at this time.) The patient was seen for respiratory problems. (See exhibit #6, which is a copy of "Doctor's Progress Notes" from the Naval Air Station.) The "Doctor's Progress Notes" indicate that in the course of the visit to the facility, Penicillin and an expectorant were prescribed. Note that the entry dated 1/30/66 indicates an Rx of referral to a private M.D. for hospital admission.

On 1/30/66 at 4:05 p.m., the patient was admitted to Bethesda Lutheran Hospital, St. Paul, Minnesota; again, with a diagnosis of respiratory distress. (See exhibit #7 for the complete chart of this hospital admission.) The attending physician was Dr. S. Loken, St. Paul, Minnesota. Again the patient was given Penicillin and also Decadron, Chloromycetin, and on 2/3 and 4, Lomotil was given. (The progress and treatment record dated 2/3/66 indicates a "loose stool," and this was when the Lomotil was first prescribed. The patient was discharged on 2/6/66. On 6/15/66, I talked with Dr. Loken at his office. Dr. Loken stated that the patient was suffering from upper respiratory trouble with difficulty in breathing, and that he was rather acutely ill for what his temperature and other vital things would indicate. He stated that he was rather alarmed and called in Dr. Jack Hilgen, an ear, nose, and throat specialist. (See exhibit #7 for notes of Dr. Loken and Dr. Hilgen and others.) Dr. Loken stated that the patient was listless and had difficulty in breathing over and above what would be expected from his temperature.

On 6/14/66, I talked with the parents of the deceased, Mr. and Mrs. Richard Ehrich at their home at Route 1, Hugo, Minnesota. (The address of 445 Sherburne, St. Paul, Minnesota, on the hospital forms is not correct since the family has recently moved.) According to the mother, the patient was receiving Penicillin for his throat, and on approximately February 19, a prescription for Lomotil was obtained from Dr. Loken for diarrhea. According to the mother, the Lomotil was given at the rate of 1 teaspoon four times each day. On 2/24/66, the child could not be awakened and was again taken to Bethesda Lutheran Hospital, St. Paul, Minnesota. The provisional diagnosis, discharge summary, etc., may be seen on the chart for this second admission to Bethesda Hospital, which is exhibit #8. The child was admitted in a comatose state as indicated. Dr. Martha Strickland, pediatrician at Childrens Hospital at St. Paul, Minnesota, was brought in as a consultant. The child was transferred to Childrens Hospital on the same day.

The patient was admitted to Childrens Hospital on 2/24/66 at 6:45 p.m. and expired on 2/25/66 at 10:00 a.m. The sequence of events and the notes on this episode may be seen on the chart for this admission to Childrens Hospital, which is exhibit #9. Many of the entries are by Dr. Strickland and some by Dr. Bloom, who was a pediatric resident at that time. On 6/20/66 I talked with Dr. Strickland at Childrens Hospital, St. Paul, Minnesota. Dr. Strickland stated that she first saw the patient at Bethesda Hospital when he was brought in comatose on 2/24/66. The patient had pinpoint pupils and other indications which caused her to think first of an overdose of some opiate. The patient at his best downhill course did not appear to have the classic encephalitis symptoms. According to Dr. Strickland, the patient had very low blood pressure (impossible to get a blood pressure reading initially) and low renal function, neither condition being