STATE OF NEW YORK

An Investigation into Charges by
the Rockland County Medical Examiner . . .

ALLEGATIONS WITHOUT SUBSTANTIATION

by

COMMISSION ON QUALITY OF CARE
FOR THE MENTALLY DISABLED

March 1979

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PREFACE

A prime function of the State Commission on Quality of Care for the Mentally Disabled (Commission) established by Article 45 of the Mental Hygiene Law is "ensuring that the quality of care provided to the mentally disabled in the State is of a uniformly high standard." Any charge reflecting on the quality of care for the mentally disabled would be of concern to the Commission.

The investigation undertaken in this case was limited to the specific charges by the Chief Medical Examiner of Rockland County, to wit:

(1) "that a large percentage of the deaths we investigated from both Letchworth Developmental Center and Rockland Psychiatric Center were believed to be contributed to by tranquilizing and sedative drugs;" and

(2) "our autopsies have revealed a significiant number of cases where patients died from diseases such as pneumonia, peritonitis due to ulcer perforations, etc." without reported complaints of usual symptoms because of the alteration of pain perception by tranquilizing and sedative drugs.[1]

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1. Undated press release by Dr. Frederick T. Zugibe, Chief Medical Examiner, Rockland County (@ July 20, 1978).

Such charges emanating from a person in a position of public responsibility, such as a Chief Medical Examiner, are obviously not to be taken lightly, particularly if those charges relate to life and death matters.

This investigation did not address the broader consideration of the use of tranquilizing and sedating drugs, their long term consequences, adverse reactions, and benefits or successes in behavior modification. It was not the purpose of this study to contribute to the general scientific debate on the use of psychotropic drugs.

If the specific allegations of the Chief Medical Examiner of Rockland County are valid, remedial measures should be undertaken immediately to ensure the safety and quality of care of the mentally disabled clients or patients. If the charges are invalid, refutations should be made public to inform the residents and their families who may have been exposed unnecessarily to grief and anxieties.

The findings contained in this report were arrived at after an exhaustive investigation which included review of autopsy reports, case histories, toxicological studies, microscopic slides, examination of a key witness under oath, as well as interviews with numerous authorities in pathology and psychiatry.

The findings, conclusions and recommendations represent the unanimous opinions of the Commission and the Mental Hygiene Medical Review Board.

Clarence J. Sundram
Chairman

Sheldon C. Sommers, M.D.
Chairman, Mental Hygiene
Medical Review Board

Mildred B. Shapiro
Commissioner

I. Joseph Harris
Commissioner

Michael Baden, M.D.
Chief Medical Examiner
City of New York

Sidney Weinberg, M.D.
Chief Medical Examiner
Suffolk County

Ancel Blaustein, M.D., Pathologist

Elizabeth A. Goessel, M.D., Internist

Morris Herman, M.D., Forensic Psychiatrist

SUMMARY OF FINDINGS AND CONCLUSIONS

Dr. Frederick T. Zugibe, the Chief Medical Examiner of Rockland County, has charged that certain medication practices in the mental hygiene system may have contributed to the deaths of 33 patients of Rockland Psychiatric Center and 35 residents of Letchworth Village Developmental Center over a nine year period. Untold numbers of patients and residents of these two facilities, he alleged, may have died as a result of serious medical conditions such as pneumonia and peritonitis of which they did not complain because tranquilizing and sedative drugs altered their perception of the pain associated with these conditions.

Despite repeated oral and written requests for information which would substantiate his public statements, Dr. Zugibe failed to identify specific cases where such phenomena were observed, leaving both the Commission and the general public in the dark as to the nature and dimension of the alleged problems relating to the usage of tranquilizing and sedative drugs. Since his press releases and interviews failed to identify the scientific basis or actual laboratory findings that justified his statements, Dr. Zugibe was invited to appear before the Commission and Mental Hygiene Medical Review Board on November 27, 1978.

During his testimony, Dr. Zugibe, who is not a board certified pathologist, could not identify a single named individual whose death was caused or contributed to by tranquilizing or sedative drugs (Transcript pp. 11, 86-87, 97). Dr. Zugibe was similarly unable to identify an instance of such medications

completely masking pain or other usual symptoms of other serious illnesses such as pneumonia or peritonitis which led to a patient's death. Indeed, Dr. Zugibe repeatedly acknowledged under oath that he did not routinely examine hospital records of cases referred to his office from Rockland Psychiatric Center and Letchworth Village Developmental Center, on a case by case basis, to determine if any drugs at all were being used by the patient; what types of drugs were administered, if any; or, what the dosage levels were (Tr. p. 77). Toxicology was done in less than half of the cases.

Dr. Zugibe admitted that no quantitative analyses were done to determine drug dosage levels in the tissues in cases which were autopsied by his office (Tr. p. 77). Dr. Zugibe could not demonstrate a cause and effect relationship or any other scientifically valid correlation between the death of any patient and the administration of tranquilizing and sedative drugs (Tr. pp. 11, 86-87, 89, 94); he could not produce actual findings in cases reviewed by his office which indicated that such a relationship did exist; and, in summary, Dr. Zugibe has failed to supply this Commission and the Mental Hygiene Medical Review Board with any evidence in support of his highly publicized charges. His only offer in substantiation of his charges was a compilation of generalizations and excerpts from scientific journals on the possible effects of certain specific drugs coupled with vague allusions to conversations he has had with other pathologists. These sources of information do not substantiate his sweeping statements, particularly since,

by his own admission, he was not aware of whether the drugs cited in the journals were used by the persons autopsied. However, more importantly, these actions indicate that Dr. Zugibe's opinions and statements to the press were in no way based upon any scientific study conducted by his office, nor, significantly, were they based upon studies of individual death cases from Rockland Psychiatric Center or Letchworth Village Developmental Center.

The Commission and Board conclude that Dr. Zugibe has failed to substantiate his charges and that his public statements have caused unnecessary anguish to patients and their families. His statements have reflected unfairly on public employees by the erroneous and misleading impressions they have left on the public mind.

There are unquestionably many policies and practices in a human enterprise as large and complex as the State mental hygiene system that warrant criticism and correction. Criticism and condemnation must serve as catalysts for constructive and corrective action. If critical comments, particularly from persons in public office, are not firmly rooted in a bedrock of fact, they are merely destructive. They destroy hope. They destroy morale. They destroy incentive. Unjustified criticism undermines efforts to maintain motivation in the staff and thus adversely affects the quality of care provided.

Attempts to eradicate the misleading and damaging impressions of the medical practices at Rockland Psychiatric Center and Letchworth Village Developmental Center will inevitably not be

completely effective. Responsible refutations or clarifications of dramatic and sweeping charges are rarely communicated as widely or as prominently as the original charges.

The weight given to statements emanating from those in positions of high public trust carries its own burden of responsibility. Public officials must exercise particular caution in their public statements. They must weigh the effects of their speech upon the community at large and be ever vigilant that an allegation is not represented as a fact. Dr. Zugibe has failed to follow these precepts. We believe an examination into his conduct in office by the appointing authority, the county legislature, is warranted.

This report, while refuting specific allegations, is not intended to assure the general public that the use of psychotropic drugs is without problems or risks. The relationship of possible benefit to risk of dispensing powerful drugs must be constantly evaluated both in general and for each individual. Research in that area should continue so that benefits to the patients and clients will be maximized as risks are minimized. Public and private agencies which are entrusted with the care of a mentally disabled and dependent population have an obligation to provide safe and high-quality care in the treatment of illnesses as well as in the promotion of maximum independent functioning, to the degree possible in the least restrictive environment consistent with the needs of the patients. The judicious use of medication, and necessary medical and emergency care, are aspects of that charge.

INTRODUCTION

On July 16, 1978 and July 17, 1978 the Rockland Journal News and the New York Times, as well as other publications,[2] reported that the Rockland County Medical Examiner, Dr. Frederick T. Zugibe, in interviews, had alleged that tranquilizing and sedative drugs had contributed to the deaths of a significant number of mental patients at Rockland Psychiatric Center and Letchworth Village Developmental Center.

The newspaper interviews followed a study by the Comptroller's Office[3] which criticized the drug dispensing policies at several psychiatric institutions and Letchworth Village Developmental Center, although the Comptroller's report noted that Rockland Psychiatric Center had a much smaller percentage of "deficiency occurrences" than the other two psychiatric centers reviewed.

Articles published by the New York press received nationwide attention. On July 20, 1978, Doctor Zugibe issued a clarifying statement (Appendix I), claiming that of the 110 cases accepted for autopsy from the Rockland County Psychiatric Center, 33 cases or about 30 percent were aspiration deaths. Of the 93 cases accepted

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2. Rockland Journal News, July 16, 1978; New York Times, July 17, 1978; New York Post, July 17, 1978; and Albany Times Union, July 17, 1978, among others.

3. Administration of Psychotherapeutic Drugs at Creedmoor, Rockland and Utica, Marcy Psychiatric Centers and Letchworth Village Developmental Center, New York State Department of Mental Hygiene, Audit Report AL-St-22-73, and NY-St-6-78, Office of the State Comptroller, Division of Audits and Accounts. Reports filed June 16, 1978.

for autopsy from Letchworth Village Developmental Center, 55 cases or about 38 percent were diagnosed by him as aspiration deaths. Doctor Zugibe noted that in the non-institutional population where deaths are accepted for autopsy, aspiration accounts for only about 2 percent of all autopsies.

In his statement, aspiration deaths were defined as due to "sucking into airways, of vomitus, food, or foreign bodies causing suffocation." According to Doctor Zugibe, "the only common denominator among the institutional aspiration cases is the fact that tranquilizing and sedative drugs are used. The conclusion that these drugs contributed to the deaths in these cases appears obvious (emphasis supplied)." He asked: "If these drugs were not the causative agents responsible for the aspiration into the airways, then what is? This must not be confused with medication overdose" (emphasis supplied).

The press release noted that "the factor of alteration of pain perception by tranquilizers and sedative drugs must be fully explored in institutionalized patients since our autopsies have revealed a significant number of cases where patients died from diseases such as pneumonia, peritonitis due to ulcer perforation, etc. These cases revealed no reported complaints of the usual symptoms associated with these diseases and were either found dead or discovered in a terminal state" (emphasis supplied).

CHRONOLOGY OF INVESTIGATION

July 17, 1978: In a joint statement, James A. Prevost, Commissioner of Mental Health, and Thomas A. Coughlin III, Commissioner of Mental Retardation and Developmental Disabilities, requested the Commission to investigate Dr. Zugibe's allegations, noting that no cases of suspicious drug-related deaths had been called to the attention of the facility directors or other appropriate agencies (Appendix II).

July 17, 1978: Counsel to the Commission wrote to Doctor Zugibe requesting certified copies of reports on death cases to which the Chief Medical Examiner had alluded. Counsel noted that pursuant to section 45.09 of the Mental Hygiene Law, the Commission is legally entitled to receive such records and that all information, records, or data which are confidential by law would be kept confidential by the Commission.

July 25-26, 1978: The Commission requested all reports which the Office of Mental Health and Office of Mental Retardation and Developmental Disabilities had in their possession relating to the deaths referred to by Dr. Zugibe.

August 3, 1978: Commission made same request of Medical Examiner's Office. Dr. Zugibe agreed in phone conversation with Counsel to turn over the death records of patients without a subpoena.

August 7, 1978: Letter from Commission Counsel to Dr. Zugibe to confirm Dr. Zugibe's agreement to turn over death records without a subpoena and to attend meeting on September 11, 1978 of the Mental Hygiene Medical Review Board.

August 8, 1978: Director of Letchworth Village Developmental Center reported that since 1969, 23 persons died due to food aspiration, 17 of whom were on tranquilizers, all of low dosages, and none on dosages exceeding the guidelines of the Department's psychotherapeutic drug manual.

August 10, 1978: Commissioner Coughlin submitted materials requested by the Commission.

August 23, 1978: Commissioner Prevost submitted the materials requested by the Commission indicating that of the 1,737 deaths at Rockland Psychiatric Center between January 1, 1970 and May 31, 1978, 21 resulted from aspiration of gastric contents and 9 from aspiration pneumonia.

August 25, 1978: Further efforts were made by Commission Counsel to obtain documentation as agreed to by Rockland County's Medical Examiner without necessity of subpoena, as well as to secure agreement for Dr. Zugibe's appearance at a Mental Hygiene Medical Review Board meeting.

August 30, 1978: Dr. Zugibe's office called to decline invitation to Mental Hygiene Medical Review Board meeting stating he would be vacationing.

September 19, 1978: Because Dr. Zugibe had failed to turn over records as agreed upon, the Commission issued the first subpoena duces tecum to Chief Medical Examiner for 46 autopsy reports as identified by the two facilities and demanding records of any other deaths relevant to the Commission investigation.

September 26, 1978: A subpoena duces tecum was issued to the Chief Medical Examiner of Rockland County requesting all documentary evidence in his custody pertaining to the deaths of a list of 46 individuals -- the total number of persons who had reportedly died at Rockland Psychiatric Center and Letchworth Village Developmental Center of aspiration of gastric contents since 1971. The subpoena requested autopsy and toxicological reports, death certificates, pathological findings, etc. The Commission also obtained a court order issuing a judicial subpoena requesting original autopsy slides in 12 of the 46 cases which were listed.

September 28, 1978: State Supreme Court Justice Theodore A. Kelly signed court order requiring Dr. Zugibe to produce relevant records by October 4, 1978 at the Commission's New York City Office.

October 2, 1978: Dr. Zugibe issued a press release noting that neither his office nor the County Attorney's office had opposed the subpoena, and that for the purpose of assisting the Mental Hygiene Medical Review Board, he had submitted an 11-page review of psychiatric and medical literature which included a bibliography of 125 references (Appendix III). This literature review, according to Dr. Zugibe, fully supported his previous statements that a large percentage of

deaths investigated from Letchworth Village Developmental Center and Rockland Psychiatric Center "may have been contributed to by psychiatric and/or sedative drugs."

October 4, 1978: Pursuant to judicial subpoena of September 26, 1978, Dr. Zugibe produced 139 microscopic slides pertaining to 5 individuals and 42 autopsy reports to this Commission.

November 13, 1978: Invitation extended to Dr. Frederick Zugibe by Chairman Sundram to attend a special session of the Mental Hygiene Medical Review Board to be held on November 27, 1978 at the Office of the Governor in New York City. This invitation was accepted.

November 17, 1978: A supplemental judicial subpoena was signed by Morton B. Silverman, Justice of the Supreme Court, at the request of the Commission and the Mental Hygiene Medical Review Board. The subpoena requests additional original autopsy slides for 34 cases and, as with the previous subpoenas, also requested "any additional ones which are known to the Rockland County Medical Examiner as a result of studies by his office of deaths occurring at the Rockland Psychiatric Center and Letchworth Village Developmental Center pertaining to his public statements on a relationship between the administration of certain medications and the aspiration deaths of certain patients and the failure to treat such physical conditions requiring treatment" (Appendix IV).

November 17, 1978: The additional slides produced were only in those cases specifically requested by the Commission and were provided by the Rockland County Medical Examiner's Office for evaluation by the Mental Hygiene Medical Review Board.

November 17, 1978: Cases were assigned to expert pathologists serving on the Mental Hygiene Medical Review Board for their personal review of the autopsy reports and examination of slides where available. The routine practices of the two facilities in disseminating information regarding deaths to the Medical Examiner's Office were inquired into by staff investigators.

November 27, 1978: Dr. Frederick T. Zugibe appeared at the special meeting of the Commission and the Mental Hygiene Medical Review Board along with Dr. Burton Allyn, Assistant Medical Examiner, and James Costello, Medical Investigator, in the Medical Examiner's Office. Dr. Jesse Bidanset, a consulting toxicologist for the Rockland County Medical Examiner's Office, arrived for the latter portion of the meeting. Dr. Zugibe, after being duly sworn, was given the opportunity to submit an opening statement and then to respond to questions from the Commissioners and members of the Medical Review Board. Excerpts from the proceedings are included in the section on "Findings."

FINDINGS

I. Aspiration Deaths

A. DR. ZUGIBE HAS FAILED TO IDENTIFY A SINGLE NAMED INDIVIDUAL WHOSE DEATH WAS CAUSED BY OR CONTRIBUTED TO BY TRANQUILIZING OR SEDATIVE DRUGS. (1) IN MANY OF THE CASES REVIEWED, HIS FINDING OF DEATH DUE TO ASPIRATION OF GASTRIC CONTENTS COULD NOT BE CONFIRMED. (2) WHERE EVIDENCE OF ASPIRATION WAS PRESENT, IT WAS UNCLEAR FROM HIS METHODOLOGY WHETHER ASPIRATION WAS THE PRIMARY CAUSE OF DEATH OR MERELY A CONCOMITANT PHENOMENON ACCOMPANYING DEATH FROM OTHER CAUSES. (3) EVEN IN CASES WHERE ASPIRATION WAS A PRIMARY CAUSE OF DEATH, HIS FAILURE TO ROUTINELY INQUIRE INTO THE MEDICATION HISTORY OF THE DECEASED AND TO PERFORM COMPLETE TOXICOLOGICAL ANALYSIS TO DETERMINE THE PRESENCE AND QUANTITATION OF DRUGS, MAKE IT IMPOSSIBLE TO ESTABLISH A CAUSE AND EFFECT RELATIONSHIP BETWEEN THE DEATH AND THE ADMINISTRATION OF TRANQUILIZING AND SEDATIVE DRUGS.

The Commission's methodology in attempting to verify the allegation that a large number of patients at Rockland Psychiatric Center and Letchworth Village Developmental Center died of aspiration of gastric contents as a result of tranqulizing and sedative drugs altering their swallowing and vomiting mechanisms was described in the affidavit of Dr. Sheldon C. Sommers, Chairman of

the Mental Hygiene Medical Review Board, in support of the motion for a judicial subpoena requiring the production of autopsy slides (Appendix V):

> "By examining autopsy slides of tissue or organs in the upper or lower respiratory tract, it is possible, using standard, medically recognized procedures, to determine whether gastrointestinal contents or other materials from the stomach, esophagus or gastrointestinal tract were aspirated into the upper or lower respiratory tract.
>
> "...upon the determination of whether a death was due to aspiration, and with analysis of the specific psychotherapeutic drugs which were administered to a patient, as determined by reviewing the medical and clinical records, the Mental Hygiene Medical Review Board will attempt to determine the relationship, if any, between the aspirational nature of the death and the administration of psychotherapeutic drugs in each of the listed cases."

The so-called "aspiration deaths" fall into two classes. First, those where the person choked on a piece of food (a bolus), and second, those where the stomach contents were aspirated into the respiratory system (Tr. pp. 59-60).

The Mental Hygiene Medical Review Board reviewed the autopsy reports in the 42 cases for which they were available and the autopsy slides in 31 cases in which slides were available. The Board concluded that on review of 42 autopsied cases from the Rockland County Medical Examiner, in 27 cases, the Rockland

County Medical Examiner's Office reported finding grossly recognizable boluses in or obstructing the tracheobronchial tree. The Board stated:

> "In 15 other cases no bolus is described. Two of these, based on history or slide review, did have significant aspirations of gastric or esophageal contents. On two cases slides were not available. The other 11 are not independently confirmed. Thus in one-third of cases, without a clinical record of associated eating, and without slide confirmation, the diagnosis of death due to aspiration rests on otherwise unconfirmed gross findings."

1. In many of the cases reviewed, Dr. Zugibe's findings of death due to aspiration of gastric contents could not be confirmed.

We accept the finding of aspiration death in the 27 cases in which the Medical Examiner reports that boluses were observed, as well as in the two cases where the Board confirmed significant aspiration of gastric or esophageal contents upon slide review. We cannot confirm or refute the finding of aspiration of gastric contents in the remaining 13 cases. The Commission and Board did not have sufficient information in these cases to make an informed evaluation or conclusion.

Regarding the Board's inability to confirm aspiration death in the remaining cases, in his testimony before the Commission and Board, Doctor Zugibe indicated that microscopic slides are virtually useless in confirming aspiration deaths (Tr. pp. 30, 31, 52).

DOCTOR ZUGIBE: * * *

Microscopic examination, I agree, is certainly of paramount importance if you are dealing with aspiration pneumonia. In cases of aspiration pneumonia, but where the death is sudden, it's going to contribute nothing, because we have found through our experiences that the greatest majority of all cases of aspiration will show nothing microscopically, because either the formalin, when we cut our sections there, we cut them at the autopsy table, the formalin or other processing dissolves out most of the aspirate.

In fact, it can even act as a two-edged sword in this way. You see gastric aspirate all the way down to the fine radicles, you do a microscopic, there is none present, and a good lawyer may be able to utilize that to try to question integrity, heresay. If you say it was aspiration, we don't see it on the microscopic section, maybe there wasn't anything. It's the gross that is important.

I think that any good pathologist worth their salt should be able to diagnose or have their diagnosis in over 90-some per cent of the cases from the gross pathology before they even look at the slides. (Transcript p. 31. See also pp. 30, 52)

When challenged by members of the Medical Review Board, who strongly criticized the quality of the microscopic slides, on his assertion that microscopic examination in aspiration cases is useless, Doctor Zugibe suggested that the Board's inability to confirm the aspiration of gastric contents, which was allegedly noted in the gross autopsy, might be due to his office's technique in preparing the slides (Tr. pp. 55, 58).

DOCTOR SOMMERS:

Q I would like to comment that having been on on the Histopathologic Technique Committee of the College of Pathologists for some years, the slides that were provided to us were not of a quality that anyone could obtain their registry certificates for histopathologic technique.

DR. SOMMERS: Dr. Weinberg, may I ask how you felt about these slides that you examined?

DR. WEINBERG: Frankly, I thought those slides were horrendous, really. I can't believe you even tried to diagnose.

DR. ZUGIBE: How old were these slides? Were they ones we sent out?

DR. SOMMERS: The cases are right here.

DR. ZUGIBE: On all of them?

DR. WEINBERG: The best ones were the ones from Letchworth Village. Now, the ones that were, I guess, directly from your office --

DR. ZUGIBE: And we taught them how to do this staining.

DR. WEINBERG: And since you have written a book on histochemistry, I think certainly you would be dissatisfied with this caliber of work.

DR. ZUGIBE: I would say at the early days I was very dissatisfied, but in recent years I have been quite satisfied with them.

* * *

DR. FERRARO: In my review of the slides, I found them to be of inferior quality. Many of them were extremely small in size, overstained and so on. Age has nothing to do with it. I have slides forty years of age that are still, in fact they are better, because we had better stains in those days.

I disagree with you on the concept that you will wash out the fluid which is contained within the alveolar spaces by fixation, because formalin fixes that. If that were true, then we would never be able to see pulmonary edema or anything else on the slides that I reviewed. On only one was I able to determine that there was a moderate amount of fluid within the alveolar spaces. The others were perfectly clear. They had some minimal, other, minor changes.

DR. ZUGIBE: Then how do you account for the fact that if we visually see gastric aspirate down into the fine radicles that when we do fix them they are not there? Then it must be our techniques in preparing them.

But you cannot just down our gross observation of it.

DR. FERRARO: I am not always certain that I can identify gastric fluid as such that is being aspirated. (Transcript pp. 52-55. See also p. 58)

2. Even in the cases in which aspiration of gastric contents could be verified, it was unclear from Dr. Zugibe's methodology whether the aspiration was the primary cause of death or merely a concomitant phenomenon accompanying death from other causes (Tr. pp. 60-71, 87, 89).

DR. ZUGIBE: Yes. You see, another point of interest to me is this: What is this semi-liquid material that literally fills the entire tracheobronchial tree, that usually smells like vomit, if it isn't gastric aspirate? That doesn't show up on the microscopic examination. What is it? What can it be? Maybe I will have to do another study, but any time I see these--

* * *

Dr. Herman raised the question as to why the Medical Examiner did not consider the possibility of agonal aspiration.

EXAMINATION BY DR. HERMAN:

Q Why could that not be an agonal aspiration? The individual, in the process of dying, emits these fluids because of the spasm of dying.

A In other words, then, the gastric aspirate--

Q No, no, he is dying from something else.

A But what is the material coming?

Q Gastric aspirate.

A Gastric aspirate, though--

Q But not the cause of death.

* * *

A (Continuing) That is what I am going into. I am trying to go into this business of so-called agonal aspiration. Now, look at it from this point of view:

As far as gastric aspirate goes, it's extremely rare that we, in our experience, see it in the lungs. In every case that we did, particularly after we saw the 1970 study, every single case was deliberately opened in the way we do in these particular cases, everyone was deliberately opened to determine gastric, if the movement of the body -- some of them we took down cliffs, out of the woods for miles, upside down by the heels, -- maybe I am exaggerating a little bit -- turned for photography and everything else. Nothing was found.

MR. SUNDRAM: But that is different from what Dr. Herman asked.

DR. ZUGIBE: I realize that. By the same token, as far as heart attack cases, I am not even convinced that when an individual who showed aspirate, frequently with a heart attack, he's had a heart attack. We see a heart attack, an infarction at autopsy, and we also see what some people call agonal type of aspirate. If the aspirate was not the cause of death and not the heart attack, the heart attack is precipitated, in much the same way as many of the drugs caused cardiotoxicity.

DR. SOMMERS: Well, Dr. Herman reminds me of when I was not a pathologist and was taught to stay by the bedside of the dying, persons dying of cancer and miscellaneous diseases. The last gasp was a vomit, and they certainly didn't die of that.

Now, Betty [Dr. Elizabeth A. Goessel], is that your experience?

DR. GOESSEL: Right.

DR. SOMMERS: If you stay with the dying, many of them vomit as they die.

DR. ZUGIBE: We see that on occasion. It's seen on occasion. There is no question about that, that you have that, but I think it's because of the fact, if you have to go into what the causation in that particular person is, in other words, these kids from Letchworth and Rockland State are evaluated, what was the cause of death that caused the agonal aspiration?

MS. SHAPIRO: That is the question.

DR. ZUGIBE: That is what I say in my question. If the aspiration is not the cause of death, then what is?

MS. SHAPIRO: That is your job.

DR. ZUGIBE: Pardon?

MS. SHAPIRO: That is your job.

DR. ZUGIBE: Sorry. If that is the only common denominator in my statement, right from the very, very beginning, I say that the tranquilizing drugs, in my July 1st statement --

* * *

DR. HERMAN:

Q Didn't you affirm what I said by indicating that seizures are a very prominent effect in connection with the treatment of these patients, therefore the seizures are so prone to occur with these drugs and therefore it is not reasonable that a considerable number of them have died as a result of seizures? I am not commenting on the question whether the drug is responsible or not responsible, but as to whether the death is due to seizure or aspiration, and that the seizure is the cause of death in many of these instances, and that the aspiration is only concomitant, but not the basic cause of death. Is that not reasonable?

A I believe it is possible in some cases, yes. But I believe that the seizure actually caused the aspiration.

Q Yes, I say it's a concomitant, but the cause of death actually was the seizure. (Transcript pp. 64-68, 71. See also pp. 87, 89)

3. We find that Dr. Zugibe did not routinely inquire into the medication history of the deceased and that he did not perform complete toxicological analysis to determine the presence and concentration of drugs.

MS. SHAPIRO: But you are sure that all of the ones you speak about did, in fact, have some kind of medication?

A No. In fact what I gave you was, I went back through my records to find out how many aspiration deaths I had at Rockland State and Letchworth, as compared to the outside, and I showed you the comparison, so maybe some of those aspiration deaths may have a specific, you know, cause, for the aspiration other than drugs, possibly. (Emphasis supplied)

Every single case of lung cancer, I am sure, is not due to cigarette smoking. I don't know, I have no way of knowing.

DR. SOMMERS: But to quote again from the statement that you said you would agree with, and which is in this article, "The conclusion that these drugs contributed to the deaths in these cases appears to be obvious."

You agreed earlier in the session that that was your opinion.

MS. SHAPIRO: The assumption is they were all on medication.

DR. ZUGIBE: Pardon me?

MS. SHAPIRO: The assumption is there had to be drugs there for them to have had that reaction.

DR. ZUGIBE: I don't know what this statement means to you. My interpretation of that statement means this, that it is my opinion, to state it specifically, it is my opinion that from a statistical point of view in these institutions is that the drugs may have contributed to their deaths by causing the aspiration and so forth, and that is what my statement was in the press and so forth.

* * *

DR. ZUGIBE: ...at no time did I ever indicate anything about overdose, because to say overdose of drugs I have no data of overdose of drugs.

I did not do quantitative analyses on these drugs to find overdoses of drugs and so forth.

* * *

DR. SOMMERS:

Q Did you, case by case, examine the hospital records and determine what drugs and what doses of drugs were used?

A No. I even made my statement regardless of dose. You see, the point that I was trying to bring up is the need for, if you are going to utilize something like these drugs, which can be very, very dangerous, then proper safeguards have to be used.

MR. SUNDRAM: Do you identify whether the patients were receiving any kind of psychotropic drugs?

DR. ZUGIBE: Yes.

MR. SUNDRAM: How did you do that?

DR. ZUGIBE: Dr. Allyn, how do we do that? When we are doing an investigation and they report a death, we get a history from them and they tell us.

MR. SUNDRAM: Do you get their medical records and what drugs they are on?

DR. ZUGIBE: And they fill out a form. In fact, relative to most of these cases, if they told us the individual was on Elavil 100 milligrams tid, or something like that, this was completely satisfactory.

If Dr. Allyn investigates a case, he would be talking to them on the telephone to send them in for autopsy. They would give him a little rundown on the background of this individual, this individual was found dead in bed, or the individual had such and such, and Dr. Allyn would maybe ask them what medications are they on, and he would put it in his report, and that's all.

MR. SUNDRAM: Dr. Allyn, who did you speak to?

DR. ALLYN: May I go off the records, sir, since I have not been sworn in?

MR. SUNDRAM: We can take care of that, if you would like.

DR. ALLYN: I am an Assistant Medical Examiner, and when we have a death that is accepted as a Medical Examiner's case, we, in all cases, speak to the physician in charge of the party that died. I will be on the phone with them and with the charge nurse of the institution or of the ward where he came from and obtain as close a history as I possibly can over the phone. This would include all drugs that the deceased had received during the past ninety-six hours, as well as the

length of time, where he had been in the institution, where he was found, whether he was worked on, resuscitated, CPR and what have you.

This would go into an Assistant Medical Examiner's report which would go into the Office of the Chief Medical Examiner. (Tr. pp. 87-88, 77-80)

As Table A indicates, although 41 of the deceased patients were receiving medication of some kind, only seven autopsy reports note the presence of any kind of medication.

TABLE A

Persons on Medication	Medication noted on autopsy protocol: Yes	No
41	7	34

Moreover, of the 41 cases in which patients were receiving medication, in no case was a complete toxicological analysis done. In 17 cases, a limited testing of blood samples for alcohol and barbiturates was done (Table B).

TABLE B

			Tests requested		Tissues submitted		
Total cases	Not tested	Tested	General unknown	Alcohol barbiturates	Blood alone	Bile urine	Liver brain, etc.
41	24	17	0	17	17	0	0

4. We find that Dr. Zugibe, by his own admission, failed to establish a cause and effect relationship between the death of any person and the administration of tranquilizing or sedative drugs to that person.

MR. SUNDRAM: Is it clear from everything that you have said, is it fair for us to conclude that there is not an identifiable person, that any particular person at Letchworth or Rockland State whom you are willing to identify and state that this person died because of these drugs? What you are really stating is that based on the literature, some of these people may have died as a result of the administration of the drugs.

DR. ZUGIBE: As I stated in my paper, I think the relationship is statistical.

MR. SUNDRAM: But there is no individual case?

DR. ZUGIBE: Similar to that of lung cancer and cigarette smoking. If you do an autopsy on an individual with lung cancer, we have no test to say that that individual dies as a result of those four packs he was smoking for twenty years.

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DR. ZUGIBE: How can I definitively take that particular statement and say because he is on drugs that he definitively died as a consequence of those drugs? Otherwise it would have been on my death certificate.

DR. SOMMERS: I would like to comment about your repeated assertion concerning the relationship between smoking and lung cancer. It is widely accepted that statistics cannot prove a cause and effect relationship, but can only suggest, by logic. Experiments will demonstrate a cause and effect relationship, and this has never been achieved for cigarettes in any model for forty-five years, and I have been in the field a long time, so I think it's a poor analogy, because here you have toxicology and you have toxicologists and, unlike cigarette smoke or nicotine, radioimmunoassay is not available. I think you can have a blood or tissue level of most or all of the drugs that are being administered, so it seems to me, if you look for the evidence and the type of drug and the dose schedule and the amount in the tissues, you could reach a scientific conclusion that they were insufficient to contribute to death, or that they were sufficient to contribute to death.

To me, to make an assertion short of a study like that is irresponsible. (Transcript pp. 86-87, 89-90. See also pp. 11, 29, 80.)

5. Under questioning by the Commission and Board, Dr. Zugibe retreated from his earlier press statements to state that the causal relationship between aspiration deaths and psychotropic drugs exists merely on a statistical basis because drugs were the only common denominator (Tr. pp. 8, 11, 24, 29, 80, 86-87, 88). We find that there is a fundamental flaw in this reasoning as it depends upon a comparison of noncomparables--i.e., a general population of a county with a population of mentally disabled persons who have been found to require institutionalization.

EXAMINATION BY DR. HERMAN:

Q I would like to ask a question.

A Yes.

Q As I understood what you have said in the press release, and also now, you are making a strong issue about the effect of drugs in connection with deaths, particularly the aspiration deaths, and as I recall what was said, it was that the only significant factor in the aspiration deaths is the drug usage.