



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

CLARENCE J. SUNDRAM
CHAIRMAN

March 1979

I. JOSEPH HARRIS
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COMMISSIONERS

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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 significant 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

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

(ii)

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.

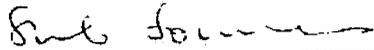
This investigation did not address the broader consideration of the use of tranquilizing and sedating drugs, their long term consequences, adverse reactions, and benefits or successes in behavior modification. It was not the purpose of this study to contribute to the general scientific debate on the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

(iii)

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


Sheldon C. Sommers, M.D.
Chairman, Mental Hygiene
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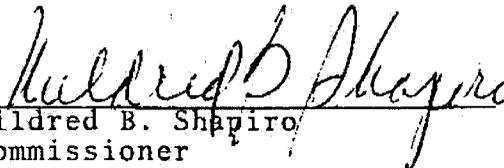
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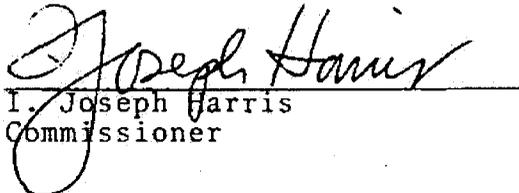
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SUMMARY OF FINDINGS AND CONCLUSIONS

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 Office³ 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, 25 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 tranquilizing 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

Medication
noted on
autopsy protocol

<u>Persons on Medication</u>	<u>Yes</u>	<u>No</u>
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

<u>Total cases</u>	<u>Not tested</u>	<u>Tested</u>	<u>Tests requested</u>		<u>Tissues submitted</u>		
			<u>General unknown</u>	<u>Alcohol barbiturates</u>	<u>Blood alone</u>	<u>Bile urine</u>	<u>Liver brain, etc.</u>
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.

* * *

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.

Now, I know that in clinical work things are much more complex than that, and I am asking whether you considered these additional features, and that is that there were deaths, even aspiration deaths, and I know, because I antedate the use of these tranquilizers, there have been aspiration deaths in the mental institutions for the psychotics, as well as for retardates, before the use of these drugs, whether you took into consideration the fact that many patients of this variety have pica, eating foods, swallowing them often without the niceties of custom, and that many of them...not only have an inability to feed themselves but they can't even move appropriately, that many psychotics have some symptoms that are well known, such as negativatism, they hold food in their mouths, frequently expanding into large volumes, before they swallow it, that it is not correct to say that the only difference between these deaths, giving an incidence, I think, of about thirty per cent, as compared to two per cent in the general population, as if you are comparing two equal groups, that for research purposes that is a very, very inaccurate comparison to make, because other very significant variables have been omitted.

Now, I am not trying to indicate that drugs are unimportant in this whole situation, and I think we are very much interested in the effect of drugs on the general physiological status of the individuals. We share your concern, and we certainly want to have as many safeguards as are possible for this purpose.

But I think if we do that without a consideration of all of the other very important areas we will not be seeing very clearly, and I don't know whether you share this.

A I think your points are very, very well taken. I think your points are well taken. In some of the studies -- and I wish you would read that, because some of the studies --

Q I know most of them, but it's unfortunate that it came through.

* * *

DR. ZUGIBE: But there is a reason for why these statistics show a larger percentage in these institutions as compared to the outside, accepted on the same basis. There is a reason for it, and the only common denominator we could find, as I mentioned in my statement, the only common denominator we could find is this, and when you go back to the literature--

DR. HERMAN: I just listed other common denominators. How could you find--

DR. ZUGIBE: What other--

DR. HERMAN: You said that that is the only common denominator, and I listed three or four others.

DR. ZUGIBE: But you listed other possible causes, but not common denominators.

* * *

DR. WEINBERG: How many of these wore dentures?

DR. ZUGIBE: I don't know.

DR. WEINBERG: I think that would be an important consideration. Were they ill-fitting dentures? (Tr. p. 82-84, 91)

II. Deaths From Causes Other Than Aspiration

Doctor Zugibe stated in his press release: "the factor of alteration of pain perception by tranquilizers and sedative drugs must be fully explored in institutional patients since our autopsies have revealed a significant number of cases where patients died from diseases such as bronchial pneumonia, peritonitis due to ulcer perforations, etc. These cases revealed no reported complaints of the usual symptoms associated with those diseases and were either found dead or discovered in a terminal state."

The subpoena served on Doctor Zugibe invited the submission of any death reports related to the cases in which tranquilizing and sedative drugs had contributed to deaths by pneumonia or peritonitis due to ulcer perforation, etc., as he had alleged. Since the Commission was unaware of the identities of the persons about whom these statements were made, the subpoena invited the submission of any cases he deemed relevant, but none were submitted.

WE FIND THAT DOCTOR ZUGIBE HAS FAILED TO SUBSTANTIATE HIS CHARGE THAT TRANQUILIZING AND SEDATIVE DRUGS MAY HAVE ALTERED PAIN PERCEPTION THUS RESULTING IN DEATHS FROM DISEASES SUCH AS BRONCHIAL PNEUMONIA, PERITONITIS DUE TO ULCER PERFORATIONS, ETC., WITHOUT COMPLAINTS OF THE USUAL SYMPTOMS ASSOCIATED WITH THOSE DISEASES. HE COULD NOT IDENTIFY A SINGLE CASE IN WHICH THIS OCCURRED IN FACT, NOR ANY CAUSE AND EFFECT RELATIONSHIP BETWEEN A SPECIFIC DRUG AND SUCH A DEATH.

At the hearing, the following exchange took place:

MR. SUNDRAM: We went through the figures in your autopsy reports for the nine years you were speaking about and did not find one in which there was a mention of perforation of ulcers.

DR. ZUGIBE: You didn't ask for those.

MR. SUNDRAM: Our subpoena said so.

DR. ZUGIBE: I don't think that the final court order did. I think you are --

MR. SUNDRAM: Let me read you the subpoena. The relevant part of it says that we asked for these records relating to the deaths and the causes thereof, both in the cases listed below and any additional ones which are deemed relevant by the Rockland County Medical Examiner pertaining to the death or the causes thereof for the following individuals, so we asked you for two things. One is the listing of the names listed, since you declined to ever identify the cases you are speaking about, and second is to leave you the option of supplying us with any other cases.

DR. ZUGIBE: May I see that statement, where it says that I may have given others, because I called the County Attorney about that.

MR. SUNDRAM: We will be most anxious to have you identify the cases where you feel there is a cause and effect relationship, because we have been waiting for that since July, and I assume you declined simply because you could not identify a cause and effect.

DR. ZUGIBE: I told you it's on a statistical basis and from what the literature said.

MR. SUNDRAM: So you cannot establish a cause and effect relationship in any specific case, is that a fair statement?

DR. ZUGIBE: It's a fair statement, yes. I cannot for any specific case, I cannot, no.

MR. SUNDRAM: Do you agree that the subpoena says what I just read?

DR. ZUGIBE: Wait a minute. I haven't finished yet.

MR. SUNDRAM: If you would like, we will be happy to serve you another, more clarified subpoena than that one.

DR. ZUGIBE: Oh, I see, you didn't specifically mention those particular cases. You said "additional ones which are deemed relevant by the Rockland County Medical Examiner pertaining to the deaths and causes thereof for the following individuals."

MR. SUNDRAM: It's an open invitation. The invitation still stands.⁴ (Tr. pp. 93-95)

4. Since the hearing on November 27, 1978, Dr. Zugibe has failed to identify any case of ulcer perforation or pneumonia of the type he described in his press statements.

CONCLUSIONS

After extensive investigation (reviews of autopsy reports, case histories, toxicologic studies, microscopic slides), examination of the key witness under oath, and interviews with numerous authorities in pathology and psychiatry, including the Mental Hygiene Medical Review Board, it is this Commission's conclusion that:

A. Since Dr. Zugibe was unable to present even one case in which the patient's death caused by asphyxiation due to aspiration of gastric contents was related to the use of tranquilizing or sedative drugs, he is not in a position to substantiate his charge that such deaths are so related. His statements were not based on any scientific studies or observations of deaths at Rockland Psychiatric Center or Letchworth Village Developmental Center. Food-related aspiration in a typical mental hygiene facility afflict those who are on tranquilizers as well as those who are not, which indicates that aspiration phenomena are multifactored and can depend on causes unrelated completely to drug administration. Complete toxicological studies were not conducted on any of the 41 decedents whose records Dr. Zugibe furnished, to test for the presence and levels of tranquilizing and sedative drugs in the system. Such tests should have been done if Dr. Zugibe wished to establish a direct or indirect causal relationship between a drug and a death.

B. Dr. Zugibe failed to present evidence or documentation to sustain his charge that persons were dying of peritonitis due to

perforation of ulcers and other severe maladies because tranquilizers or sedative drugs had inured them to pain. Despite oral and written requests, subpoenas and a court order, he has not identified a single death attributable to these causes. Dr. Zugibe is unable to substantiate this charge as well. Moreover, had such cases been presented, a causal relationship would have had to have been established between any fatal condition and pain desensitization attributed to tranquilizing and sedative drugs. The mortality rate of the mentally disabled was excessive prior to the introduction of psychotropic drugs, and such persons, particularly the non-verbal, may experience difficulties in communicating perception of pain. It should also be noted that for a variety of clinical reasons,⁵ the psychiatric patient may not report pain. Furthermore, the lack of consistent procedures for the gathering of information on the medication history of patients, coupled with the total absence of complete toxicological analysis of blood and tissue specimens to determine the presence and quantitation of drugs, render the Rockland Medical Examiner inherently unable to draw a scientifically justified cause and effect relationship. Moreover, the Chief Medical Examiner's failure to distinguish between aspiration of gastric contents as a primary cause of death, or as an agonal or concomitant phenomenon of the dying process should be noted.

5. John A. Talbott, M.D. and Louis Linn, M.D., "Reactions of Schizophrenics to Life-threatening Disease", Psychiatric Quarterly, Fall, 1978.

C. The clear import of the statements made in both the reported newspaper interviews and Dr. Zugibe's press release appended hereto, that Doctor Zugibe's conclusions were based on empirical evidence, specifically the autopsies conducted on former patients at Rockland Psychiatric Center and Letchworth Village Developmental Center, was erroneous. Dr. Zugibe did not produce any data from cases at Rockland Psychiatric Center or Letchworth Village Developmental Center to sustain his statements and characterizations of treatment rendered there. His only proffer of authority on his allegations came during his appearance and testimony under oath before the Mental Hygiene Medical Review Board and Commission and consisted of his reports of personal conversations with other pathologists and a bibliography of scientific and medical journals. The Commission considers these inherently inadequate to substantiate the specific allegations that there is a strong causal relationship between aspiration deaths and other deaths and the use of tranquilizing and sedative drugs at Rockland Psychiatric Center and Letchworth Village Developmental Center.

RECOMMENDATIONS

A. There should be minimum standards for the performance of autopsy and toxicological procedures and for reporting the findings. These standards should be developed with the assistance of appropriate professional groups and should also include periodic professional review.

B. In cases where an autopsy is performed on a patient at a State facility by the Office of Coroner or Medical Examiner, medical and clinical records of the individual should be obtained, as indicated, to be considered by the coroner or medical examiner in the post mortem investigation and in the final report.

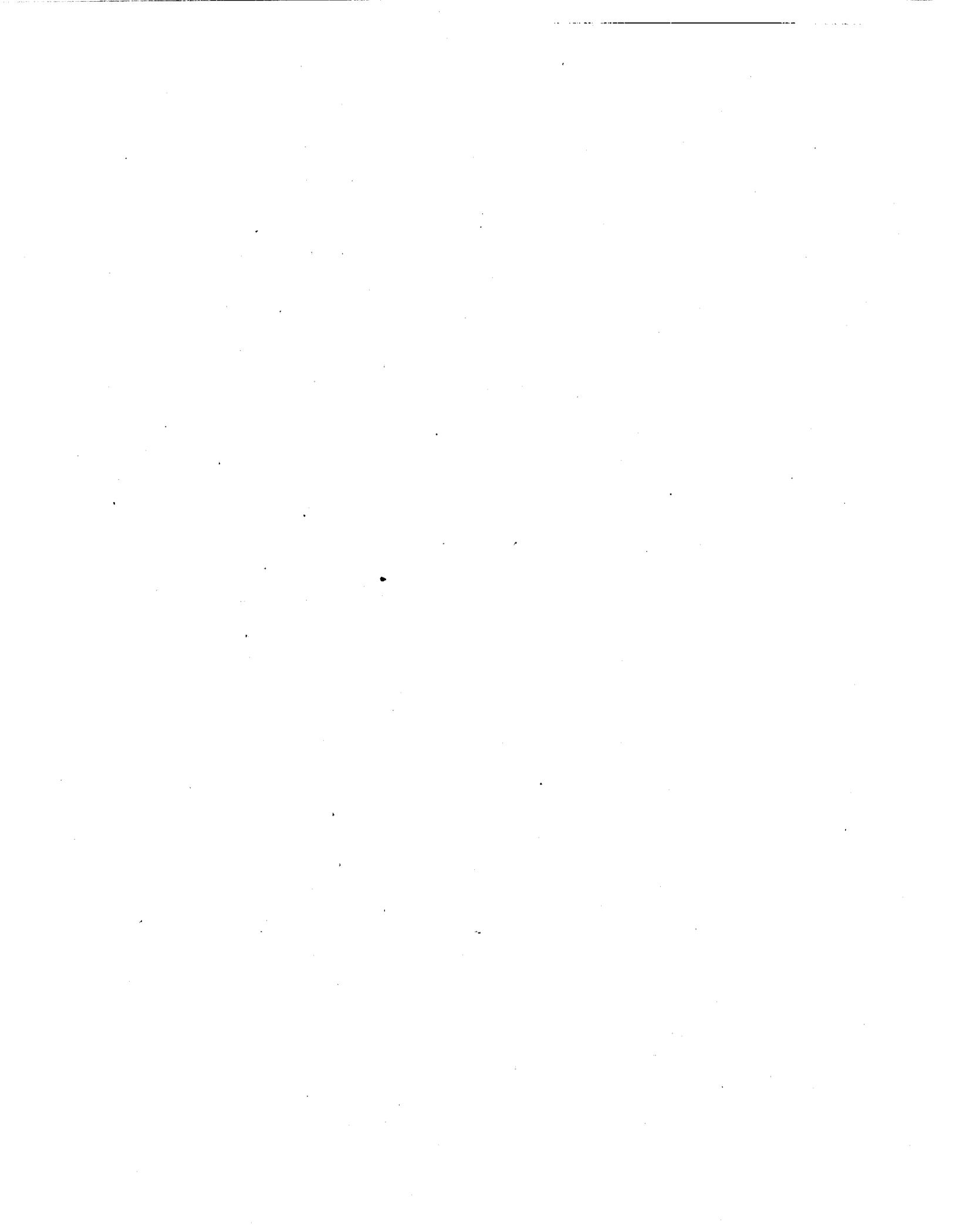
C. There should be greater mutuality in sharing information between State mental hygiene facilities and county coroners or medical examiners. The relevant medical and clinical history of a case undertaken by a coroner or medical examiner should routinely and expeditiously be communicated by the facility. Conversely, the findings of the post mortem study should be shared forthwith with the facility to allow ameliorative measures to be taken where appropriate.

Such reports in cases of mental hygiene patient deaths should also be sent to the Commission on Quality of Care for the Mentally Disabled because of the statutory responsibility of its Mental Hygiene Medical Review Board to review all deaths which occur in State mental hygiene facilities (N.Y. Mental Hygiene Law §45.17(a)).

D. On matters of the seriousness of life and death, which potentially cause severe distress and anxiety to patients, their families and to those charged with their care and treatment, public officials should clearly separate and distinguish scientific fact, allegation and personal opinion.

Additionally, in instances where press reports inaccurately disseminate such potentially injurious and distressful information, a public official has the responsibility to attempt to clarify and minimize any potential misimpressions.

E. The Rockland County legislative body is respectfully advised that this Commission's report, as well as the transcript of the hearing conducted (copies of which are being forwarded to the chairman of the legislature), should be carefully studied to enable the appointing authority to determine whether the Medical Examiner's Office is being operated in a manner consistent with the public interest.



APPENDICES



It is of paramount importance that the facts concerning the recent articles in the press be placed in proper perspective. It is also essential to note that the original news article did not appear as a result of a press release, but as a consequence of an informal telephone conversation, which occurred almost a week earlier, where, in response to queries made by a reporter regarding the Levitt report, I indicated that it was the opinion of the Medical Examiner's office that a large percentage of the deaths that we investigated from both the Letchworth Developmental Center and the Rockland Psychiatric Center were believed to be contributed to by tranquilizing and sedative drugs. Moreover, this is a problem that exists not only at the Letchworth and Rockland State facilities, but is perhaps endemic to all mental institutions.

In checking our files we found that during the same time period, 110 cases were accepted for autopsy from the Rockland Psychiatric Center and 93 cases from Letchworth Village Developmental Center. Out of the 110 cases, 33 cases or about 30% were aspiration deaths and out of the 93 cases, 35 cases or about 38% were aspiration deaths. This is in striking contrast to Medical Examiner cases outside these institutions which are accepted for autopsy, using the same criteria, where aspiration deaths accounts for only two out of one hundred cases or about 2%. Aspiration deaths are due to sucking into the airways, of vomitus, food, or foreign bodies causing suffocation. The cause of aspiration in the institutional cases could not be attributed to brain damage because the Rockland State facility had a similar percentage of aspiration cases and none of those cases showed evidence of brain damage. The only common denominator in the institution cases that was apparent was the use of tranquilizing and sedative drugs. These agents are known to alter the

normal swallowing and vomiting mechanism. If these drugs were not the causative agents responsible for the aspiration into the airways, then what is? This must be emphasized that this must not be confused with medication overdose.

Moreover, 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 perforations, 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.

These findings are only presented at this time in answer to the disparaging remarks questioning this office's integrity and responsibility. It is important to note that there should be no medical need to report these findings since the effects of tranquilizers and sedative drugs as indicated above are well known to medical professionals, particularly psychiatrists.

It is apparent that there are approximately twenty times more deaths from aspirations in autopsy cases from the institutions than from autopsy cases from non-institutional unattended deaths and when the only common denominator among the institutional aspiration cases is the fact that tranquilizers and sedatives are used. The conclusion that these drugs contributed to the deaths in these cases appears obvious. The two Rockland County facilities apparently are not deviating from the current accepted standard of care and the question, therefore, arises as to whether the current practice of treating institutional residents by the widespread administration of tranquilizers and sedatives should be re-evaluated and more trained personnel implemented. It is this query that

this office suggests be pursued by competent and constructive research and
Investigation.



James A. Prevost, M.D., Commissioner
Office of Mental Health

For further information contact:
Bob Spoor, Director of Communications
(518) 474-6540

Thomas A. Coughlin, III, Commissioner
Office of Mental Retardation & Developmental
Disabilities

FOR IMMEDIATE RELEASE
Monday, July 17, 1978

JOINT STATEMENT OF JAMES A. PREVOST, M.D.
COMMISSIONER OF MENTAL HEALTH, AND THOMAS A. COUGHLIN, III,
COMMISSIONER OF MENTAL RETARDATION AND DEVELOPMENTAL
DISABILITIES, REGARDING ALLEGATIONS OF DRUG-CONNECTED
DEATHS IN ROCKLAND COUNTY FACILITIES

Totally irresponsible statements have been made by the Rockland County medical examiner charging that heavy doses of tranquilizers have been a contributing factor in numerous deaths at Rockland Psychiatric Center and the Letchworth Village Developmental Center.

Although a county medical examiner is not legally bound to make autopsy reports available to state agencies as a matter of course, he is nonetheless bound by county law to inform appropriate authorities of any suspicions of improper practices which might have contributed to death.

Dr. Zugibe has not brought any suspicions regarding drugs as a contributing factor in patients' deaths to the attention of the facility directors or other appropriate agencies.

The Offices of Mental Health and Mental Retardation and Developmental Disabilities have requested the State Commission on the Quality of Care to convene an extraordinary session of the Mental Hygiene Medical Review Board to investigate allegations made by Dr. Frederick Zugibe, the Rockland County Medical Examiner.

As we have done in the past, our two agencies will seek through the court to obtain reports on the autopsies conducted by Dr. Zugibe's office on patients and residents of the two facilities.

These autopsy reports, together with pertinent records from the facilities, will be made available to the Mental Hygiene Medical Review Board for investigation.

In a preliminary review of deaths at the two facilities, accomplished by the two Offices, it was found that during the past 18 months eight cases of death involving Rockland Psychiatric Center patients were referred to the Rockland medical examiner's office. The review disclosed that excessive use of medication was not a contributing factor in any of the cases.

A similar review of 13 cases referred to the medical examiner from Letchworth Village since June 1977 showed only two of the deaths were related to asphyxiation due to aspiration of food or other substances. In one case, no tranquilizers were being used by the patient prior to his death while in the second only a very low dosage was prescribed.

Such unsubstantiated and thoughtless allegations by Dr. Zugibe cause great anxiety to patients, families, and other relatives concerning the quality of care in state facilities, particularly at a time when they are under stress in dealing with problems of loved ones.

Further, his charges constitute an unwarranted attack on the integrity of the thousands of facilities employees who labor to care for those less fortunate individuals suffering from mental illness or mental retardation.

In recent years, the Offices of Mental Health and Mental Retardation and Developmental Disabilities have been increasingly concerned with the quality of medical practices in State facilities and particularly with the administration of medications to patients and clients.

Since 1976, continuing education programs in medications have been required for medical staff of psychiatric and developmental centers. The first session was conducted for medical staff at Rockland Psychiatric Center by a prestigious panel of experts.

A formulary on the use of psychoterapeutic drugs was pioneered by the Department of Mental Hygiene and published in 1977. It has gained national attention having been requested for duplication in several other states. All facilities are now required to abide by these guidelines.

Recently, memoranda were issued requiring review of medication administered to patients over a three-month period and calling for the informed consent of patients for its continuance. Another called on medical staff to strictly comply with the formulary issued by the Department.

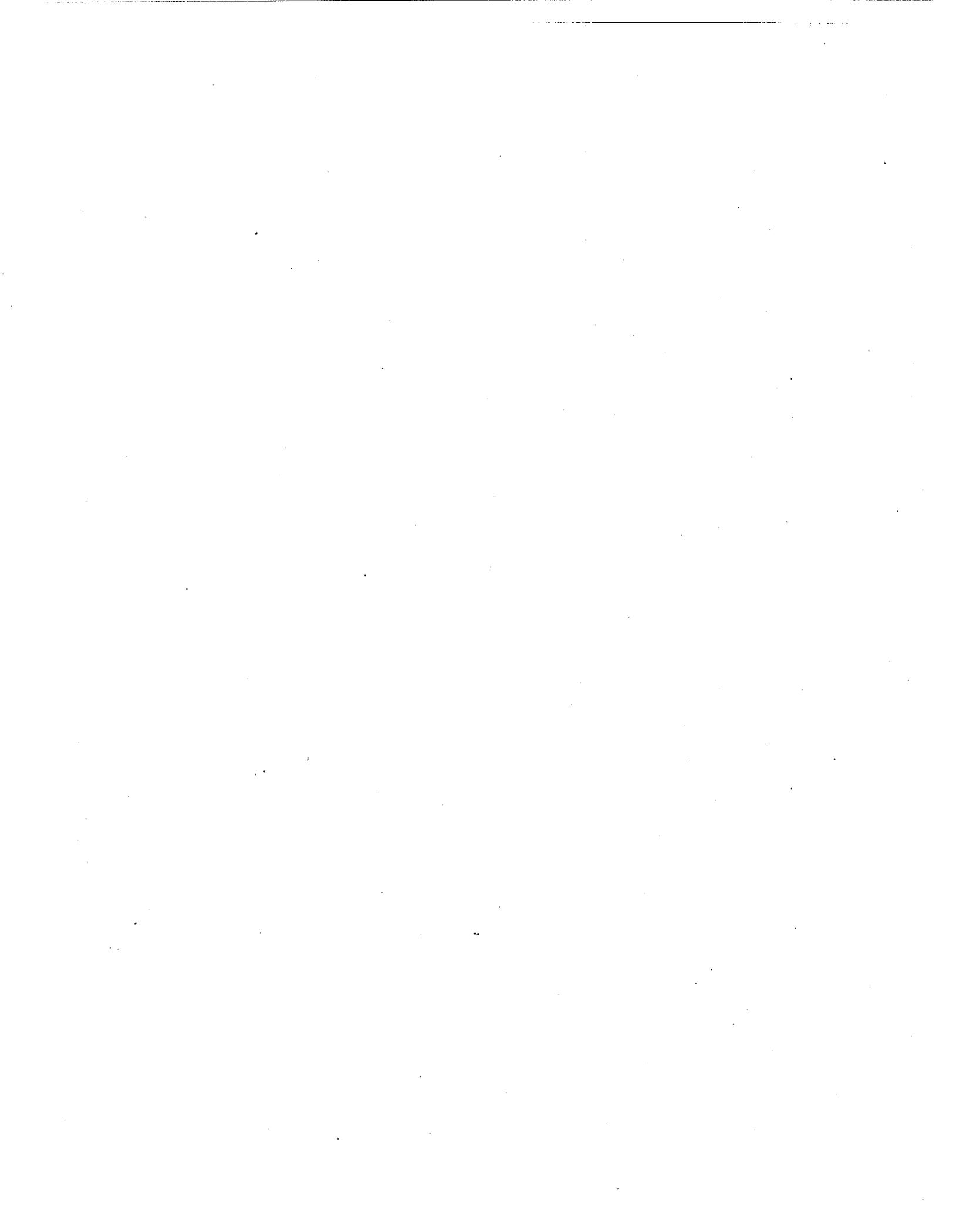
Rockland Psychiatric Center is also the site of one of the most advanced computerized drug monitoring systems in the world which has become a model for other states and other countries. In this system -- which has also been piloted in several New York City area state developmental centers -- all psychotropic drug orders are immediately computerized and any exception to the usual drug combinations or dosages are "flagged". The clinical burden for any physician is great and this system is welcomed by all physicians using it. This system will be fully implemented in all state facilities for the mentally ill and mentally retarded by April 1979.

In an effort to provide a mechanism to investigate the causes and circumstances surrounding deaths in state facilities, the Department of Mental Hygiene also pressed for the establishment of the Mental Hygiene Medical Review Panel as an independent investigatory body. The panel was created by Governor Carey through executive order in 1976.

Both Offices have worked closely with the panel and have provided guidelines to their medical staff for submission of cases.

I should also be noted that in recent years, because of improved medical practices, there has been a three-fold decline in the number of deaths in state facilities. This has occurred in spite of the fact that approximately 60 percent of the inpatient population of psychiatric centers is 65 or older and many residents of the developmental centers are not only profoundly retarded but suffer severe physical handicaps as well.

The State Offices of Mental Health and Mental Retardation and Developmental Disabilities will continue their efforts to improve care of the mentally disabled and will listen to any responsible criticism of services offered in conjunction with that effort.



OFFICE OF THE MEDICAL EXAMINER
 COUNTY OF ROCKLAND

FREDERICK T. ZUGIBE PH.D., M.D.
 CHIEF MEDICAL EXAMINER



ROCKLAND CO. HEALTH COMPLEX
 POMONA, NEW YORK 10970
 214-354-8420

October 2, 1978

I have this date complied with the Judicial subpoena issued by the Honorable Theodore Kelly. This subpoena was not opposed by the Medical Examiner's Office or the County Attorney's Office. The reports requested by the Mental Hygiene Medical Review Board includes cases in which the autopsies were performed by either myself, other pathologists from the Medical Examiner's Office, and by pathologists from the two Rockland County institutions involved. The scope of the cases requested was, unfortunately, limited to some of the aspiration deaths and did not include any of the other possible drug related deaths.

For the purpose of assisting the Mental Hygiene Medical Review Board, I have submitted an eleven page exhaustive review of the psychiatric and medical literature which includes a bibliography of 125 respected and authoritative references from psychiatric and medical journals. A list of recommendations, which may help to reduce the number of tragic complications and adverse reactions, has been incorporated at the end of the review. The psychiatric and medical literature warns of, and repeatedly reveals, a glaringly ostensible association between psychiatric drugs and deaths due to aspiration of food and vomitus, deaths due to toxic effects on the heart, deaths due to pneumonia and other drug related deaths. This review fully supports all of my previous statements regarding the opinion of the Medical Examiner's Office, that a large percentage of the deaths investigated from both the Letchworth Village Developmental Center

and Rockland Psychiatric Center, may have been contributed to by psychiatric and/or sedative drugs. Moreover, it fully substantiates my statement that there should be no medical need to report these findings to the facility directors of other agencies since the effects of these drugs have been scientifically established and are well known to medical professionals, particularly psychiatrists. The relationship of aspiration with psychiatric drugs is well known in Forensic Pathology. For example, Dr. W. Spitz, Chief Medical Examiner of Detroit, relates in one of the most prestigious reference books of medico-legal investigations of death, "Food aspiration following suppression of the gag reflex by tranquilizing drugs is a common phenomenon in mental institutions." Moreover, the voluminous catalogue of other articles in my review serves to support my contention.

In conclusion, I wish to emphasize that by profession, I am a researcher, scientist and physician. Moreover, it is the responsibility of the Medical Examiner as an independent "watch dog" of several aspects of the public welfare to report his findings as to causation so that needless deaths may be prevented. I am leaving for Europe as a member of the scientific panel of experts honored to study the authenticity of the Shroud of Turin, the cloth believed to be the burial shroud of Christ. While I am away, I sincerely hope those who are entrusted with this investigation do not pervert the undeniable scientific truth.

Frederick T. Zugibe, Ph.D., M.D.
Chief Medical Examiner

OFFICE OF THE MEDICAL EXAMINER
COUNTY OF ROCKLAND

FREDERICK T. ZUGIBE, PH.D., M.D.
CHIEF MEDICAL EXAMINER



ROCKLAND CO. HEALTH COMPLEX
POMONA, NEW YORK 10970
914-354-5420

TO: Commission on the Quality of Care for the Mentally Disabled,
Mental Hygiene Medical Review Board

FROM: Chief Medical Examiner
Rockland County, New York

TOPIC: Psychiatric and/or Sedative Drug Related Deaths

The association of sudden deaths and other forms of adverse reactions with psychiatric and/or sedative drugs, particularly in young psychiatric patients, is of great concern to both the clinician and the patient's family. As I previously indicated, during the same time period, 110 cases were accepted for autopsy from the Rockland Psychiatric Center and 93 cases from Letchworth Village Developmental Center. We found that over 30% of these deaths were ascribed to pulmonary aspiration as compared to about 2% in medical examiner cases accepted for autopsy outside these institutions. I also had indicated that the only common denominator that was apparent in the institution cases was the use of the psychiatric and/or sedative drugs. Moreover, there were a number of patients who died from diseases, such as: bronchopneumonia, lobar pneumonia, peritonitis due to viscus perforation, etc. where there were no reported complaints of the usual symptoms and they were either found dead or discovered in a terminal state. Moore and Book (80) have indicated that extrapolation of their data and the various reports in the medical literature regarding psychotropic and/or sedative related deaths suggest that many unrecognized or unreported deaths have occurred in psychiatric hospitals. The joint statement of Dr. Prevost, Commissioner of Mental Hygiene and Mr. Coughlin, III, Commissioner of Mental Retardation, on July 17, 1978, said, "Dr. Zugibe has not brought any suspicions regarding drugs as a contributing factor in patient's deaths to the attention of the facility directors or other appropriate agencies." Ergo the press picked this statement up and requested the reason why they were not reported. My answer to this in my press release was "It is important to note there should be no medical need to report these findings since the effects of tranquilizers and sedative drugs as indicated above are well known to medical professionals, particularly psychiatrists." In order that there be no misunderstanding that this is a glaringly ostensible fact, I am submitting the following critical review to refresh the memories of all those professionals who appeared astonished by my statements and to lighten the load of the Mental Hygiene Medical Review Board in this investigation and in their future investigations dealing with psychiatric drug deaths. It should also be recalled, at this time, that every time a death occurs in these institutions, a death certificate is issued directly to them since these facilities are unique in that they serve as their own registrars where they maintain their own death certificates and issue their own burial permits. The vast

literature from the prestigious psychiatric and medical journals have been critically reviewed and the significant bibliography afforded at the end of this review (1-123)

ASPIRATION DEATHS

SUPPRESSION of gag Reflex
↓ DEGLUTITIVE - RESPIRATORY Reflex
GLOTTAL SPASM.

The high percentage of aspiration deaths at both institutions related in my statement and attributed to the use of psychiatric and/or sedative drugs is well documented in the literature. W. Sultz, (123), Chief Medical Examiner of Detroit, relates in one of the most prestigious reference books of medico-legal investigations of death as follows: "Food aspiration following suppression of the gag reflex by tranquilizing drugs is a common phenomenon in mental institutions." Miller and Chinoy (76) in their scientific exhibit at the American Psychiatric Association's 123rd annual meeting on the effects of tranquilizers on the gag reflex, revealed that asphyxial deaths had a 10 fold increase in hospitalized patients receiving tranquilizers. They reported an absence of the gag reflex in 40.3% of psychiatric patients as compared to a control population and further showed that 15% of the patients receiving tranquilizers had no prior illness. There were 2.73 deaths per thousand in 1936-1945, versus 25.7 per thousand from 1956-1965. Pharmaceutical company package instructions reveals information as to adverse effects of their products. For example, the Thorazine package instructions relate, "because Thorazine can suppress the cough reflex, aspiration of vomitus is possible." Many of the sudden phenothiazine deaths due to asphyxia have been attributed to the result of a diminished deglutitive-respiratory reflex (80). Letsma and Koening (64) indicated the real entity of sudden death caused by phenothiazines and divided these deaths into those with aspiration and rapid asphyxia and those with sudden cessation of cardiovascular competence on an arrhythmogenic or hypotensive basis or both. Plachta (87) reported seven cases of psychiatric patients on phenothiazines who died of aspiration and reviewed the literature in this regard suggesting several mechanisms, which will be referred to later. The literature survey at the Association for Research in Nervous and Mental Disease revealed that of 19 deaths, 4 were attributed to aspiration (94). Farber (30A) attributed his report of aspiration to failure of the cough reflex and Jeune (56) specifically warned of the dangers of deglutitive reflex suppression by chlorpromazine in infants. Hollister (50) attributed his case to glottal spasm for aspiration.

RELATIONSHIP OF SEIZURES TO ASPIRATION

It is important to remember at this point as indicated by Wardell (114) that mentally deficient patients do not choke on food any more frequently than do normal individuals. Moreover, in non-medicated epileptic patients, a convulsive seizure associated with regurgitation of gastric contents rarely is fatal because the cough reflex remains functional (80). It cannot be too strongly stressed that when evaluating the etiological basis for aspiration deaths, that one not be misled because of the presence of seizure-like activity. It would be untenable to attribute the etiologic basis of the aspiration to a "seizure" since both the literature and pharmaceutical manufacturers report that these drugs may either cause seizures or lower the seizure threshold (24,41,50,53,59,65,66,67,75,91,97,109,114). Klerman (59) reports that chlorpromazine lowers the seizure threshold. Giacobomo and Lassenius (41) reported epileptic fits in three of their patients under chlorpromazine who had no history of previous seizures. Merills (75) reported a case of convulsions produced immediately after an injection of chlorpromazine. Lomas, et al (67) Schlichter, et al (97) and Liddell and Retterstol (65) also reported cases of epileptic seizures taking psychotropic drug therapy. Zlotlow and Paganini (120) concluded that

chlorpromazine may be epileptogenic in some brain damaged patients. Wardell (114) related that aspiration in a patient as a complication of a grand mal seizure is not a rare phenomenon and it is his opinion that the patient did not have a seizure but a failure of the cough reflex as well as the air-passageway defenses so that the response to the aspiration of food into the lungs was ineffective. Hollister (50,51) reported "the most logical possibility is that these drugs (reserpine or rauwolfia alkaloids, chlorpromazine or other phenothiazine derivatives) may induce seizures." He also adds that "the moral seems to be: the risk of rising tranquilizing drugs in brain damaged patients are those with known seizures. This increased risk should be measured against the potential benefits from the drug." Toone and Fenton (111) reported that in brain damaged patients on phenothiazine, the seizures occurred at a substantially lower drug dosage than those showing no evidence of brain damage. Seizures as a side effect of antipsychotic drugs which include representative antipsychotic drugs from the phenothiazine, butyrophenone, thioxanthene, dibenzoxazepine and dihydrindolone groups were reported by Honigfeld and Howard (53) and the incidence graded from frequent to rare. Frequent was interpreted as expected in 10-20% of patients treated and rare, 1-5%. Pharmaceutical package instructions also list seizures as an adverse effect.

MECHANISM OF ASPIRATION BY PSYCHIATRIC AND/OR SEDATIVE DRUGS

The mechanism of action of how these drugs cause aspiration has been investigated. The most notable of the reported mechanisms have been that proposed by Plachta (87) who indicates that the physiopathogenesis involves a tranquilizing effect on the central nervous system which affects the gastric reflex mechanism which prevents gastroesophageal reflux and cricopharyngeal reflux and subsequent interference with the normal ciliary mechanism in the respiratory tract area. The normal gag and deglutitive reflexes are also depressed as previously indicated.

Another mechanism that deserves further elucidation in the etiology of aspiration is whether the drug first causes cardiotoxicity resulting in tachyarrhythmias conducive to aspiration since cardiotoxic effects of the drugs have been implicated in a large number of reports where they have caused sudden deaths. This topic will now be discussed in detail.

Cardiotoxic Effects of Psychiatric Drugs

The most significant findings of recent years is the increasing evidence that serious cardiac complications, including death can occur after treatment with the psychotropic drugs including the phenothiazines and antidepressants in therapeutic doses. Lithium has also been implicated. The first association of cardiac complications of psychiatric drugs is credited to Kristiansen (62) who reported the association of death with imipramine. Kelly, et al (58) is credited with the first report of cardiotoxic fatalities associated with phenothiazine therapy. In this paper, he reported two fatalities and striking T wave changes with heart block and ventricular tachycardia in 28 patients on thioridazine (Mellaril). Subsequently, many papers confirming these cardiotoxic complications appeared (1,2,10,11,15,16,18,19,22,23,25,26,27,28,35,36,40,42,45,52,53,54,55,57,62,64,68,69,70,71,72,78,79,84,88,89,96,98,99,100,101A,104,105,107,113). A hospital based study by Molr, et al (78) had confirmed the cardiotoxic effect of tricyclic antidepressants. Moreover, in a recent study Fowler, et al (36) demonstrated in 8 patients, that major and fatal ventricular arrhythmias can occur in young patients without heart disease that are on therapeutic doses of

psychotropic drugs. Thoridazine (Mellaril) was responsible for 5 cases of ventricular tachycardia, amitriptyline (Elavil) and nortriptyline (Aventyl) each caused left bundle branch block in one patient and supraventricular tachycardia developed in one patient on chlorpromazine (Thorazine).

MECHANISMS OF CARDIOTOXICITY BY PSYCHIATRIC DRUGS

Electrocardiographic changes associated with phenothiazine, particularly thoridazine include inversion, flattening, bifid configuration and widening of the T wave, prolongation of QT, ST depression, PR prolongation, ventricular tachycardia, supraventricular tachycardia, ventricular fibrillation, heart block, bundle branch block, atrial tachycardia and extrasystoles. Alexander (11) was of the opinion that cardiac toxicity from phenothiazine and tricyclic antidepressants is not reversible and may cause damage to the heart that is serious and permanent. The demonstration of acid mucopolysaccharides in the arterioles and degenerating myocardial muscle reported by Richardson, et al (93) was suggested as the basis for the EKG changes in patients on phenothiazines. Phenothiazines appear to exert their effects similar to that of cardiac drugs such as: quinidine and procainamide. There is an effect on depolarization and repolarization, decreased membrane responsiveness, interference with the sodium pump and inhibition of the sodium and potassium dependent adenosine triphosphatase membrane system (3,4,12,46,55,85). The fact that the EKG changes were more marked when taken in an erect position (116) may be of more importance when examined in the light of the known hypotensive effects of phenothiazines (95) which may be fatal by either causing ischemic changes to the heart or by inducing a fatal arrhythmia in a patient showing abnormal drug induced EKG changes. There is no question that all of the effects discussed would be much more serious in individuals with cardiac disease and in elderly people, but there is an increasing number of cases in young individuals with no evidence of heart disease who are on therapeutic levels of psychiatric drugs. The cardiovascular effects of the tricyclic antidepressant includes ventricular tachycardia, AV conduction defects, supraventricular tachycardia, ventricular tachycardia, asystole and T and ST changes, prolongation of the HV interval on HIS bundle electrograms and alteration of terminal phases of the QRS-T complex. The mechanism of action of the EKG changes with these tricyclic antidepressants has been attributed to anticholinergic blockade and alterations in the potassium ion membrane balance (19,85). The hypotensive effect of tricyclics is also important (81). Caution must be exercised also in the pediatric use of tricyclic antidepressants which is used quite commonly in enuresis and in the treatment of hyperactive children (35,43) since fatalities have been reported in children.

PNEUMONIA AND PERITONITIS

The next topic that is in need of further clarification includes those patients that we indicated were either found dead or discovered in a terminal stage of disease and where autopsy revealed the cause of death to be due to pneumonia, peritonitis due to a ruptured viscus, etc., since there were no reports of complaints of the usual symptoms associated with these diseases. Three deaths were reported where autopsy revealed bronchopneumonia and in the same papers, four additional cases of extensive bronchopneumonia were investigated where the patients did not die. These patients did not show the usual premonitory signs and symptoms and in this regard, the author relates "these patients did not react to their illness in the manner we would have expected and the only new factor

which we are aware in the clinical picture was the tranquilizing agent. We raise the question of whether these agents may produce masking of both subjective complaints of intercurrent infectious illness and the characteristic somatic responses such as a temperature elevation. Further, the question can be raised whether these agents may have a specific effect on the respiratory process conducive to the development of pneumonia and possibly diminishing the usual defensive alarm reaction to blocking the airway," (114). There appears little doubt that the pneumonias in many cases is the result of minor drug induced aspirations in which the patient survives only to slowly develop pneumonia. Zlotow and Paganini (120) refers to a "masked fit". Kline, et al (60) and Kline (61) caution that patients on reserpine and combined reserpine-chlorpromazine appear to develop infections more easily. Reinert and Hermann (91) could not fully explain the pulmonary findings in 5 deaths at autopsy which showed a striking similarity in the behavior of the patient as well as an indication of autonomic instability and suggested that particularly during sleep, depression of autonomic regulation by the drugs may be related to the deaths. Cases of bronchopneumonia have been reported following usage of major tranquilizers such as haloperidol (Haldol). The pathogenetic mechanism is reported as follows: "lethargy and decrease sensation to thirst due to central inhibition may lead to dehydration, hemoconcentration and reduced pulmonary ventilation."

Our cases involving peritonitis from ruptured visci and pneumonia cases, where there was an absence of complaint of the usual symptoms associated with the condition can also be explained on the basis of alteration of pain perception, since this concept is used in normal hospitalized patients for pain control, not only by their synergistic effect with analgesic drugs but because they retard the process of pain interpretation. Even an animal in pain makes some type of perceptible signal such as whining, but if tranquilizers are administered this response may be suppressed.

OTHER ADVERSE EFFECTS OF PSYCHIATRIC DRUGS

There is an extensive catalog of other adverse effects reported but I will limit my review to some of the pertinent items in this regard. A study comparing the pretranquilizer period from 1952-1955, with the tranquilizer period 1956-1959 found that 90% of the patient who committed suicide had been on tranquilizers (54), and speculated that in some patients the "lucid interval" resulting from the drug therapy may be inductive to suicide. This study was supported by the report of Belsser & Blanchette (121).

The extrapyramidal effects including the dystonias, akathisia and Parkinsonism are the most common adverse effects encountered. A literature review will not be discussed at this time except to relate that cases of dystonias involving the tongue and throat muscle have been reported and may be an additional basis for aspiration. Tardive dyskinesia which is reversible is a dreaded complication of the psychotropic drugs. Swett (109) found adverse reactions in 31.9% (150 psychiatric patients) to chlorpromazine during monitoring and .6% (3 patients) were considered life threatening. Autonomic effects which include blurred vision, constipation, diarrhea, dizziness, dry mouth, retrograde ejaculation, faintness, nasal congestion, nausea, orthostatic hypotension, etc. are well known. Moreover, the endocrine effects include galactorrhea, gynecomastia and menstrual changes. Other feared reactions include agranulocytosis which may be fatal and hepatitis. Photosensitivity and lens and corneal opacities are also

relatively common. The tricyclic antidepressants include those relating to the central nervous system such as: tremors, dysarthria, ataxia, visual hallucinations, etc. and those affecting the autonomic nervous system such as: cardiac palpitations, tachycardia, sweating, urinary retention and hypotension. Lithium has been shown to produce fatalities and the effects vary from fine tremors to gastrointestinal disturbances such as: diarrhea and vomiting, muscle twitching, coarse tremors, drowsiness, hyperactive reflexes, neurological signs, impaired consciousness, confusion, stupor, difficulty speaking and seizures to coma and death (53). A marked contraindication to the use of lithium is kidney or cardiovascular disease and medical conditions which require low salt dietary regimens (19A, 53, 101).

RECOMMENDATIONS

The following recommendations are herein being reported in an attempt to reduce the number of tragic complications and adverse reactions that appear to be increasing.

① The problem of aspiration must be studied vigorously and methods of prevention instituted. Since clinical studies indicate that excessive and large amounts of food triggers reflux of food initiating the aspiration mechanism by its action on the muscularis controlling the gastric mucosa rosette, there is need to place patients receiving psychotropic and/or sedative therapy on frequent small feedings to abort reflux. Plachta (87) recommends the application of pressure recording techniques and manometric methods which are used in the evaluation of esophageal sphincter incompetence to be used to evaluate predisposition to esophagogastric incompetence during tranquilizer therapy.

② A re-evaluation of psychiatric drug treatment, primarily in brain damaged and epileptic patients in view of the effect of these drugs in lowering the seizure threshold and by their direct effects of inducing seizures is of paramount importance. The increased risk of using the drug must be measured against the potential benefits. Moreover, the use of the psychotropic drugs in mentally retarded patients should be restricted to specific cases such as those with self destructive tendencies.

③ Moreover, the implementation of more trained ancillary personnel and the training of existing personnel is a sine qua non since the ancillary personnel are in daily direct contact with the patients and supervise their activities. This training should include, early detection and reporting adverse drug reactions, techniques in first aid such as the Heimlich procedure, how to supervise eating activities, etc. The use of thorough medical histories, frequent complete physical examinations, both at initial contact and periodically by physicians. Monitoring procedures by ancillary personnel such as: periodic lab tests, checking daily for early signs of adverse reactions, temperatures, recording changes in behavior, blood pressure, etc. may detect those individuals with various diseases such as pneumonia, peritonitis, hepatitis, agranulocytosis, and tardive dyskinesia and other adverse reactions. This may be particularly effective where the patient does not manifest the usual disease related complaints. Remedial treatment can then be initiated immediately.

There is also a need to individualize drug therapy today in considering the complete evaluation and study of that patient in relation to his physical and mental condition, mental drug interactions, variations in drug metabolism,

presence or absence of brain damage, seizure activity, etc. Moreover, the use of polypharmacy or combination therapy has been shown to be an additional risk to aspiration and cardiac toxicity and its use should be weighed against the potential benefits. Every patient on chronic drug therapy with phenothiazines, tricyclic antidepressants and lithium must have a cardiological evaluation, including electrocardiogram and chest x-ray at the onset of therapy and at intervals not to exceed 6 months. An electrocardiogram and crash cart should be placed in or near psychiatric patient quarters. It is significant to note that deSautels, et al (25) reports that bigeminal arrhythmias due to atrial premature beats appear before the development of ventricular tachycardia. Pre-medication blood levels of sodium, potassium and magnesium should be taken and followed periodically. The consideration of possible discontinuance or lowering of the dosage of the medication must be entertained if EKG or other changes become manifested. It must be understood that after phenothiazine therapy, the drug is highly bound to plasma protein and since they are principally excreted via the biliary system, attempts at hemodialysis and peritoneal dialysis have been unsuccessful. Also in the presence of cardiac toxicity, one must control the cardiovascular complications until excretion of the drug is effected by the body (36). If ventricular tachycardia or other tachyarrhythmias develop, lidocaine is recommended as the drug of choice since it increased the conduction velocity of the myocardium. If lidocaine is ineffective, a temporary transvenous bipolar pacemaker should be inserted. Quinidine or procainamide should not be used as they may aggravate the problem since they have a similar action to the phenothiazines. In general, treatment of cardiotoxicity caused by the tricyclic antidepressants are similar to that of phenothiazine, except that physostigmine (17,30,36,37,106) should be tried before inserting a pacemaker. Hypotension and other cardiovascular complications usually respond when the ventricular arrhythmia is corrected. If this is ineffective, pressor agents and fluid replacements with Swan-Ganz catheter control is necessary. In general, for the other adverse effects, careful monitoring by medical and ancillary personnel is important. In agranulocytosis, which may cause death, one may find the following preliminary signs; sore throat, severe fatigue, fever, etc. If this is reported immediately and a medical examination and blood test are done, a fatality may be averted. This factor should be stressed to personnel regardless of the number of false negatives that may occur. Patients on lithium must be watched extra cautiously for neurological symptoms so that they may be reported immediately to avoid a crisis. Surveillance of patients for early signs of scleral icterus, anorexia and malaise may indicate hepatic involvement. Dystonias involving the neck muscles must be treated with antiparkinson agents or antihistamines to avert fatalities. Since tardive dyskinesia is irreversible and resistant to treatment, it is necessary that close surveillance for early signs be initiated. The presence of fine vermicular movements of the tongue have been reported to herald tardive dyskinesia and appears reversible at this stage.

CONCLUSION

Alexander (1) in an editorial relates that "the total needs of institutionalized patients are readily overlooked and it would not be surprising that manifestations of drug toxicity might go unrecognized". This is what we want to prevent. Since the adverse effects of psychiatric and/or sedative drugs occurs in the therapeutic range then the current practice of treating institutionalized residents with psychiatric drugs, etc. must be re-evaluated. In this regard, critical recommendations for monitoring must be initiated, more trained personnel implemented and current personnel given additional training as indicated above.

Therefore, it behooves the State Mental Health Department to re-evaluate their current programs with the above recommendations in mind.

I believe that a quotation from Dr. Michael Baden, Chief Medical Examiner of New York City sums up the duty of the Medical Examiner, "Because it is in the medical examiner that society has invested the exclusive opportunity of investigating unnatural deaths, he has had to assume responsibility for translating these deaths into terms that can be used for prevention"....."To the extent that death occurs because postmortem data are not applied to the premortem condition, to that extent do medical examiners fail their medical obligation; to the extent that unnatural causes of death remain unrecognized as problems deserving of attention by the medical community, to that extent do medical examiners fail their scientific obligations; to the extent that persons die because medical examiners remain uninvolved in those community areas that only they are permitted to investigate, to that extent do they fail their public trust. The self-interests of forensic pathology itself demand involvement in the areas of community pathology". (122)

Sincerely yours,

Frederick T. Zugibe, Ph.D., M.D.
Chief Medical Examiner

FTZ/ms

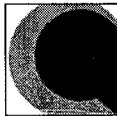
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The New York State Commission on Quality of Care and Advocacy for Persons with Disabilities is an independent, New York State government agency charged with improving the quality of life for New Yorkers with disabilities, protecting their rights, and advocating for change.



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