Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13336

7 - PROCEDURES

01/30/99
09:06

[redacted]

AUTO RESULT REPOR
PAGE

NAME: [redacted]
H# :
ACCT:

LOC:
DR:

AGE: 47Y SEX: F
CODE: [redacted]

[redacted] COLL: 01/30/99 08:41 REC: 01/30/99 08:54 PHYS: [redacted]

CBC WITH DIFF

WHITE BLOOD COUNT		7.5	[3.6-10.6]	10^3/uL
RBC		4.66	[4.00-5.30]	10^6/uL
HEMOGLOBIN	--	14.8	[12.1-15.2]	g/dL

Stat

CFSAN Project #13336
02/17-19/1999
MMA MMA

ATTACHMENT #4.14

HEMATOCRIT	42.6	[35.1-45.7]	%
MCV	91.4	[80.0-96.9]	fL
MCH	31.8	[26.7-33.2]	pg
MCHC	34.8	[32.4-34.9]	g/dL
RDW	13.0	[11.0-16.0]	%
PLATELET COUNT	269	[150-400]	10^3/uL
MPV	8.9	[6.6-10.1]	fL
DIFFERENTIAL TYPE	Automated diff		
NEUTROPHIL %	63.4	[40-71]	%
LYMPHOCYTE %	25.5	[20.0-49.0]	%
MONOCYTE %	5.1	[3.3-13.0]	%
EOSINOPHIL %	5.4	[0.5-6.7]	%
BASOPHIL %	0.6	[0.3-3.8]	%
NEUTROPHIL ABS. COUNT	4.8	[1.8-6.8]	10^3/uL
LYMPHOCYTE ABS. COUNT	1.90	[1.2-3.4]	10^3/uL
MONOCYTE ABS. COUNT	0.40	[0.2-0.8]	10^3/uL
EOSINOPHIL ABS. COUNT	0.40	[0.0-0.5]	10^3/uL
BASOPHIL ABS. COUNT	0.00	[0-0.3]	10^3/uL

CFSAN Project #13336
02/17-19/1999
MMA mma

ATTACHMENT # 4,15

[redacted] 02/03/99 02/13/99 [redacted] 47Y F

CBC & DIFFERENTIAL COUNT

DATE	TIME	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLTS	MPV	BAND	SEG	LYMPH	MONO	EOS	BASO	NRBC
		10^3/UL	10^6/UL	G/DL	%	FL	PG	G/DL	%	10^3/UL	FL	%	%	%	%	%	%	/100WBC
04FEB	07:20	7.8	4.52	14.0	40.9	90.4	30.9	34.1	13.0	263	9.2							

*** End of Lab Data for this Date Range ***

CFSAN Project #13336
02/17-19/1999
MMA MMA

ATTACHMENT # 5.10

[redacted] [redacted] I 02/03/99 02/13/99 [redacted] 47Y F

MAJOR CHEMISTRY PANEL

DATE TIME	NA	K	CL	CO2	GLUC	BUN	CREA	CA	TPRT	ALB	PHOS	CHOL
	MMOL/L	MMOL/L	MMOL/L	MMOL/L	MG/DL	MG/DL	MG/DL	MG/DL	GM/DL	GM/DL	MG/DL	MG/DL
04FEB 07:20	139	4.3	106	27	86	12	.7	9.0	6.7	**3.3 L**		168

DATE TIME	TRIG	URAC	TBIL	CBIL	UBIL	ALKP	AST	ALT	LDH	GGTP	MG	AMY
	MG/DL	MG/DL	MG/DL	MG/DL	MG/DL	U/L	U/L	U/L	U/L	U/L	MG/DL	U/L
04FEB 07:20	**207 H**		.5			71	16					

*** End of Lab Data for this Date Range ***

CFSAN Project #13336
02/17-19/1999
MMA MMA

ATTACHMENT #5.11

[redacted] 02/03/99 02/13/99 X 47Y F

Date: 02-17-99.15:12 Page: 1

[redacted] I 02/03/99 02/13/99 [redacted] 47Y F

LIPID PROFILE

DATE TIME	CHOL MG/DL	TRIGLYC MG/DL	HDL MG/DL	LDL MG/DL	VLDL MG/DL
04FEB 07:20			**35L**	92	**41H**
04FEB 07:20	168	**207H**			

*** End of Lab Data for this Date Range ***

CFSAN Project #13336
02/17-19/1999
MMA MmA

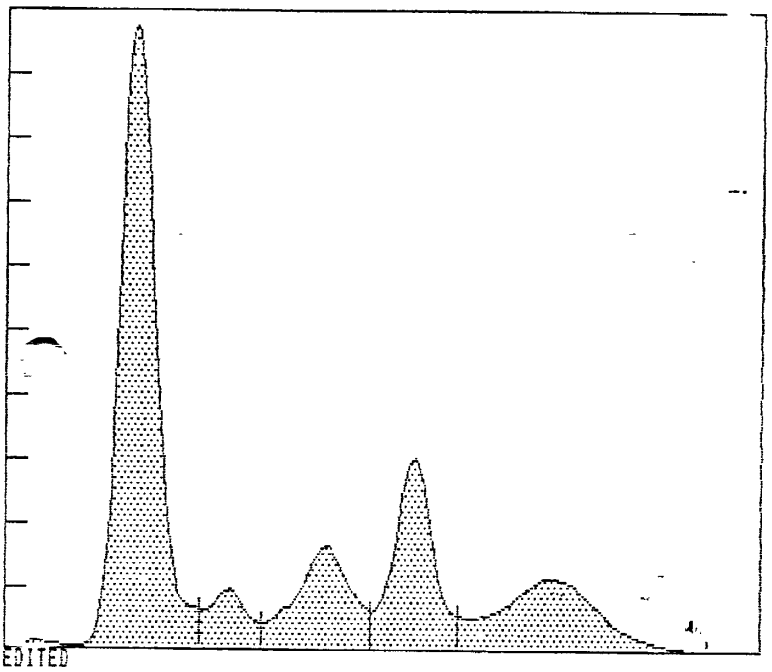
ATTACHMENT #5.12

SERUM PROTEIN ELECTROPHORESIS

[redacted]

Protein-16

02-01-1999 11:02:44



Patient Name : [redacted]
Specimen Date : 1-31-99
Specimen Time : 0600 [redacted]
Age : 47
Doctor : [redacted]
Location : [redacted]
Total : 6.8

Sample Number : [redacted]
Date Scanned : 02-01-1999
Time Scanned : 10:38:38

Fraction	%	gm/dl	gm/dl Range	
ALBUMIN	49.96	3.40	3.40	5.00
ALPHA 1	5.01	0.34	0.08	0.42
ALPHA 2	12.63	0.86	0.50	1.00
BETA	16.35	*1.11 hi*	0.80	1.10
GAMMA	16.06	1.09	0.70	1.60
Total Protein		6.80	6.00	8.40

A/G 1.00

INTERPRETATION:

_____Within normal limits. . . X Essentially normal. . . _____Abnormal. . .

CFSAN Project #13336
02/17-19/1999
MMA mma

ATTACHMENT # 4.16

Reviewed by: [redacted] Date: 2/1/99

000007

[redacted]

[redacted] 30-Jan-99

Room: [redacted] DOB: [redacted]

Clinical Data: CT BRAIN LOSS OF MUSCLE CONTROL L SIDE
D: 01/30/99 [redacted]

Exam: CT BRAIN C-

HISTORY: Left-sided numbness x two days with loss of left-sided muscle control.

TECHNICAL FACTORS: Axial 5 mm contiguous images were obtained from the foramen magnum through the skull vertex. Images are obtained in soft tissue and bone windows.

FINDINGS: Visualized orbits, paranasal sinuses and skull are unremarkable. There is a 12 mm hypodensity in the posterior aspect of the right putamen, possibly involving the posterior limb of the right internal capsule. This hypodensity is somewhat ill-defined. It is concerning for a lacunar infarct, either chronic or subacute in nature. There is no evidence of intracranial hemorrhage or mass. There is no evidence of mass effect or midline shift. A less than 5 mm hypodensity is noted in the left external capsule adjacent to the left putamen. This also may represent a small lacunar infarct.

IMPRESSION: 1. One cm irregular hypodensity, posterior aspect of the right basal ganglia, possibly involving the posterior limb of the right internal capsule, consistent with a chronic versus subacute lacunar infarct. Other causes of parenchymal hypodensity are felt less likely but cannot be excluded. Consider MRI in further evaluation of this finding.
2. Less than 5 mm hypodensity in the left external capsule. This could be artifactual, related to volume averaging or possibly represent a small lacunar infarct as well.

signed: [redacted], M.D.

[redacted]

CFSAN Project #13336
02/17-19/1999
MMA

ATTACHMENT # 4.19

[redacted]

[redacted]

Room: [redacted] DOB: [redacted]
Clinical Data: D: [redacted] 1/30/99
STROKE

30-Jan-99
[redacted]
30-Jan-99/17:59

CFSAN Project #13336
02/17-19/1999
MMA mmr

ATTACHMENT # 4.17

Exam: MRI BRAIN W & W/O CONTR

1. MRI BRAIN
2. HEAD AND NECK MRA.

CLINICAL DATA: Patient admitted with stroke symptoms with left arm and leg numbness and weakness of two days duration.

TECHNICAL FACTORS: The following sequences were obtained;

1) Localizing sagittal T1 weighted whole brain images.
2) Axial proton density whole brain images.
3) Axial T2 weighted whole brain images.
4) Axial T1 weighted whole brain images.
5) Axial post gadolinium enhanced whole brain T1 weighted images.
6) Coronal T1 weighted IV contrast enhanced images were obtained through the basal ganglia.

In addition to standard MRI images of the brain, the following MR angiography sequences were obtained;

1) 3D time of flight MR angiography of the intracranial vasculature with MIP reconstructions.
2) 2D time of flight MR angiogram performed of the neck vessels with MIP reconstructions.

MRI BRAIN

FINDINGS: There is an moderate area of abnormal signal intensity, involving the right posterolateral basal ganglia including the putamen, extending along the lateral thalamus and external capsule into the deep right periventricular white matter as it progresses superiorly. There is a similar but much smaller 5 mm focus of abnormal signal intensity seen in the left posterolateral putamen as well. No enhancement is seen associated with either of these lesions, and there is no significant mass effect. The remainder of the brain is unremarkable. No additional focal lesions are demonstrated. There is no hemorrhage or mass.

MR ANGIOGRAM

FINDINGS:

RIGHT CAROTID: The cervical carotid is unremarkable. There is no measurable stenosis of the carotid bifurcation. Intracranially, anterior and middle cerebral branches filled and are unremarkable. There is a fetal origin of posterior cerebral artery.

(cont'd)

[redacted]

[redacted]

[redacted]

(continued - MRI BRAIN W & W/O CONTR)

LEFT CAROTID: The left carotid in the neck demonstrates a patent bifurcation without measurable narrowing. Distally the internal carotid artery is unremarkable without narrowing, aneurysm, or other focal lesion. Again, there is a fetal origin of the posterior cerebral artery.

VERTEBRAL BASILAR CIRCULATION: Both vertebral arteries demonstrate antegrade flow towards the head and the neck. They are somewhat small and supply small basilar artery which ends in the superior cerebellar arteries bilaterally and demonstrates no aneurysm or stenosis. There is some mild irregularity of the proximal basilar arteries.

IMPRESSION: 1. Moderate deep basal gangliar and white matter infarct of a subacute nature in the right posterior putamen, external capsule, and deep white matter adjacent to the thalamus.
2. Very small left posterior putamen subacute infarct. The overall appearance suggests watershed infarct in this patient, perhaps related to small vessel disease or slow flow.
3. No major vessel stenosis is demonstrated on the MRA.

signed: [redacted]

[redacted]

[redacted]

CFSAN Project #13336
02/17-19/1999
MMA MMM

ATTACHMENT # 4.18

Exam: MRI BRAIN W & W/O CONTR

30-Jan-99

[redacted]

[redacted]

[redacted]

PERIPHERAL VASCULAR LABORATORY

PATIENT NAME: [redacted]

REFERRING PHYSICIAN: [redacted], M.D.

Non-invasive Cerebrovascular Examination

INDICATIONS: This patient has sustained symptoms suggesting a possible cerebrovascular accident. She is referred for evaluation of suspected carotid arteriosclerosis as a possible etiology.

STUDIES PERFORMED:
1. Carotid artery duplex scan.
2. Vertebral artery duplex scan.

FINDINGS: B-mode imaging of the carotid bifurcation vessels bilaterally demonstrated no evidence of significant atherosclerotic disease. Flow velocities were normal in all vessels studied with no significant flow disturbance at either bifurcation. Analysis of the vertebral arteries was remarkable for antegrade flow bilaterally with normal wave forms and flow velocities.

CONCLUSIONS:
1. No evidence of significant atherosclerotic plaque at either carotid artery bifurcation.
2. Antegrade flow, bilateral vertebral art[redacted]

[redacted] M.D.

PAT: [redacted] DIC: [redacted] M.D.
EVD: 01/31/99 D: 01/31/99 T: 02/01/99
C: [redacted]
TYPIST: [redacted] JOB # [redacted] BATCH: [redacted]

CFSAN Project #13336
02/17-19/1999
MMA mma

ATTACHMENT # 4.9

PT NAME: [redacted] DATE: 01/31/99 MR#: [redacted]
PHYSICIAN: [redacted] ACCT#: [redacted]

PERIPHERAL VASCULAR LAB REPORT

COPY

[redacted]

[redacted]

COPY

ECHOCARDIOGRAM REPORT

CARDIOLOGIST: [redacted] M.D.

REFERRING PHYSICIAN: [redacted] M.D.

PROCEDURE PERFORMED: Transesophageal Echocardiogram

INDICATIONS: TIA.

MEDICATIONS: 4 mg of intravenous Versed, 15 mg of intravenous Demerol, topical Cetacaine spray.

FINDINGS:
1. Normal left ventricular size and function globally and segmentally.
2. Normal appearance of the right atrium, left atrium and left atrial appendage.
3. Normal appearance of the right ventricle.
4. No significant pericardial effusion.
5. Normal structural appearance of the tricuspid, mitral, aortic and pulmonic valves.
6. Mild atheromatous narrowing of the descending thoracic aorta.

DOPPLER FINDINGS:
1. Competent tricuspid valve.
2. Trace mitral regurgitation.
3. 1+ aortic insufficiency, pressure half time could not be assessed.
4. Competent pulmonic valve.
5. No evidence for interatrial shunting.

Two 10 cc injections of sonicated saline was performed in the peripheral vein in the left side with dense opacification of the right sided heart structures with no evidence for right to left shunting.

CONCLUSION:
1. Normal left ventricular systolic function.
2. Mild aortic insufficiency.

CFSAN Project #13336
02/17-19/1999
MMA mma

ATTACHMENT # 4.11

PT. NAME: [redacted] MR#: [redacted] ADMIT#: [redacted]
PHYSICIAN [redacted] DATE: 01/31/99

ECHOCARDIOGRAM REPORT

[redacted]

COPY

ECHOCARDIOGRAM REPORT

3. Mild atheromatous narrowing of the thoracic aorta.
4. No obvious source for cardiac thromboembolus noted.

[redacted]

[redacted] D: 01/31/99 T: 01/31/99

JOB: [redacted] C. [redacted] Batch: [redacted]

DIC.: [redacted], M.D.

cc: [redacted] M.D.

CFSAN Project #13336
02/17-19/1999
MMA mma

ATTACHMENT # 4.12

PT. NAME [redacted] MR#: [redacted] ADMIT#: [redacted]
PHYSICIAN: [redacted] DATE: 01/31/99

[redacted] (47 yr) ROUTINE RECORD

Female Caucasian

Room [redacted]
Loc [redacted]

Vent. rate	68	BPM
PR interval	140	
QRS duration	92	ms
QT/QTc	384/408	ms
P-R-T axes	4 -15	14

Normal sinus rhythm
Moderate voltage criteria for LVH, may be normal variant
Nonspecific T wave abnormalities, (flat or low voltage)
Borderline ECG
No previous ECGs available

CFSAN Project #13336
02/17-19/1999
MMA MmA

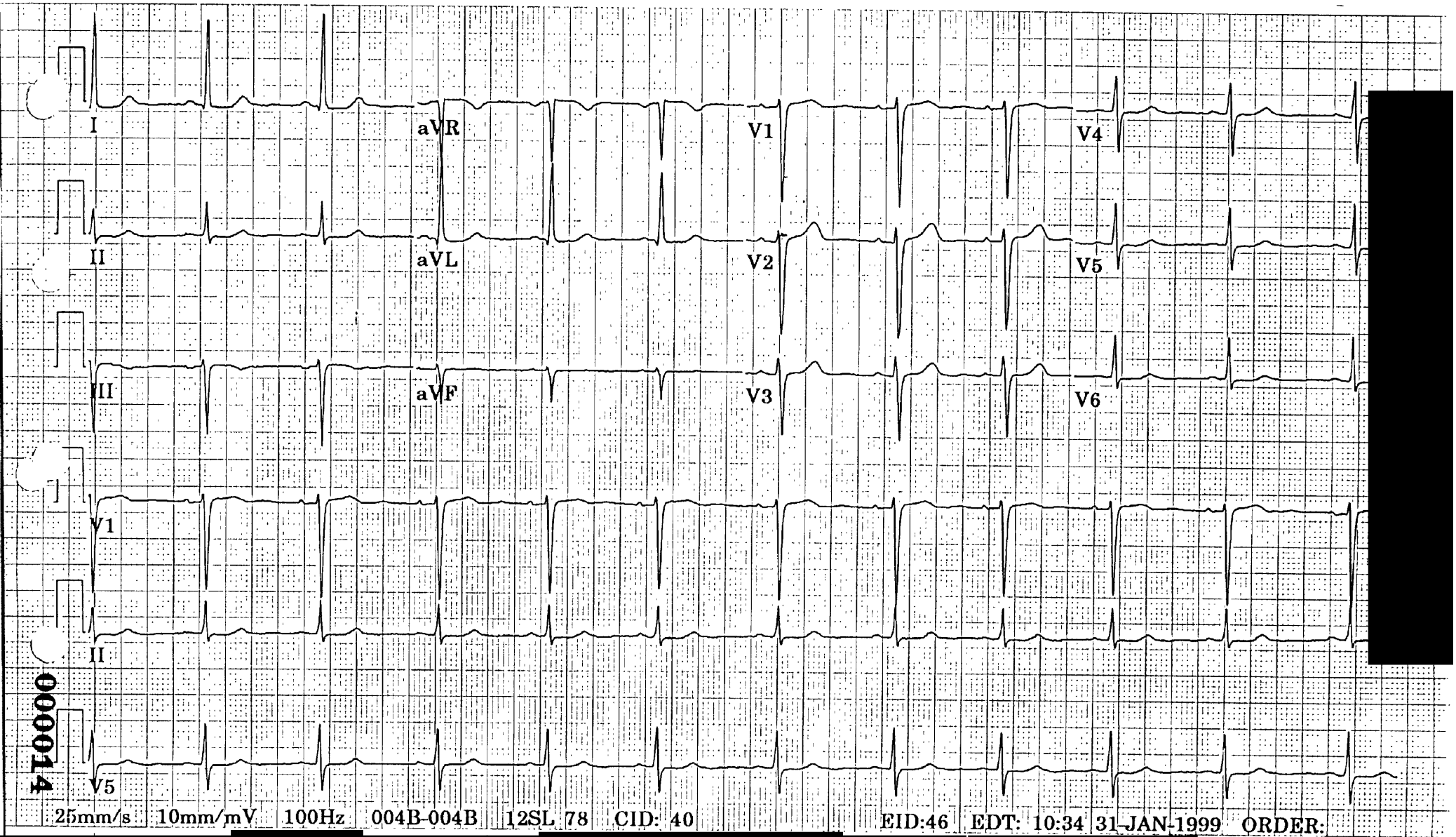
CONFIRMED

Meds: Unknown

ATTACHMENT # 4.13

Referred by: [redacted]

Confirmed by: [redacted], M. D.



[redacted]

Memorandum to ARMS # 13336.

Date: 5/26/99

From: Medical Officer, Clinical Research and Review Staff, Office of Special Nutritionals, HFS-452

Subject: Medical Records Placed in Permanent Storage.

The following types and amounts of records (more than 20 pages total) were place in permanent storage on this date because they were not considered essential for interpretation of this adverse event.

Approx Pages	Type of Records
30	Nursing notes
	Dietitian notes
5	Respiratory therapy/occupational therapy/physical therapy notes
	Clergy notes
	Medication records
5	Physician's orders
	Vital signs, fluids, input/output records
	Ventilator records
4	Hospital administrative records (e.g., insurance information, living will, etc)

V Cheeseman
for H. Slifman