



June 27, 2005

Sue Shallal, Ph.D.
Designated Federal Officer
U.S. EPA Science Advisory Board
Via e-mail: shallal.suhair@epa.gov

Re: PFOA Review Panel
*Submission of Pathology Working Group Report
on Mammary Tumors in Chronic Study of PFOA*

Dear Dr. Shallal:

We are submitting for the PFOA Panel's consideration a copy of a recently-completed Pathology Working Group (PWG) report examining the mammary findings from the 3M (Sibinski et al. 1983) chronic study on PFOA. (Experimental Pathology Laboratories, Inc., "Pathology Peer Review and Pathology working Group Review of Mammary Glands from a Chronic Feeding Study in Rats with PFOA," June 17, 2005.) The pathology review was a joint project of the 3M Medical Department and DuPont Haskell Laboratory.

The report concludes (p. 12):

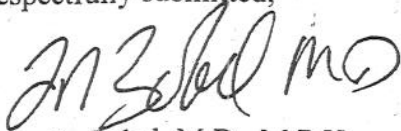
The PWG concluded that the incidence of mammary gland neoplasms in the study was not affected by chronic dietary administration of PFOA. The morphologic appearance, overall incidence and distribution of the neoplasms observed in treated and control animals were similar.

The chronic study included a control group and two dose groups which received 30 or 300 ppm in the diet. The slides were retained, and were made available to the reviewing pathologist, Dr. Gabrielle Willson. Dr. Willson reexamined all sections of mammary gland from all female rats in all dose groups. Dr. Jerry Hardisty of Experimental Pathology Laboratories then convened a Pathology Working Group including Dr. Willson, Dr. Ray Brown and Dr. Ernest McConnell to determine a consensus diagnosis for all neoplastic lesions diagnosed by either the original study pathologist or the reviewing pathologist and to determine the toxicologic significance of the incidence of mammary gland neoplasms present in the female rats in the PFOA study. The Pathology Working Group examined the slides without knowledge of the treatment group of the animals, and applied diagnostic criteria and nomenclature of the Society of Toxicological Pathologists (Mann et al. 1996).

The primary difference between the original reported findings and the PWG results involved findings initially reported as lobular hyperplasia which the PWG classified as fibroadenoma. There were minor differences in classification of other findings. Dr. David Gaylor performed statistical analyses on the findings for the PWG. The PWG report states:

- There were no statistically significant differences in the incidence of fibroadenoma, adenocarcinoma, total benign neoplasms or total malignant neoplasms between control and treated animals using Fisher's Exact Test for pairwise comparison.
- Combining benign and malignant neoplasms is not recommended. However, even if combined in this study, there was no significant difference between control and treated groups. (p. 11)
- None of the tumor types or combinations of tumor types exhibited statistically significant survival-adjusted dose-response trends. (p. 20)
- There was no increase in tumor multiplicity or incidence with dose between control and treated groups. (p. 11)
- The morphologic appearance of neoplasms in treated groups was similar to those observed in the control group, indicating that treatment did not affect the phenotype of the neoplasms in the study. (p. 11)
- The incidence of mammary gland neoplasms in the study is similar to historical control data for untreated Crl:CD female Sprague Dawley rats in 104-week studies, as reported in the literature. (pp. 11-12)

Respectfully submitted,



Larry R. Zobel, M.D., M.P.H.

Staff Vice President and Medical Director

Enclosure

cc: EPA AR-226 Docket

Dr. Jennifer Seed

Dr. Robert Rickard

Report Title

PATHOLOGY PEER REVIEW AND
PATHOLOGY WORKING GROUP REVIEW
OF MAMMARY GLANDS
FROM A CHRONIC FEEDING STUDY
IN RATS WITH PFOA

PWG REPORT

Data Requirement

N/A

Author

Jerry F. Hardisty, D.V.M.

Date

June 17, 2005

Performing Laboratory

Experimental Pathology Laboratories, Inc.
P.O. Box 12766
Research Triangle Park, NC 27709

Sponsor

DuPont-Haskell Laboratory for
Health and Environmental Sciences
1090 Elkton Road
P.O. Box 50
Newark, DE 19714

Project ID

EPL Project No. 129-060

VOLUME 1 OF 1

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PATHOLOGY PEER REVIEW AND
PATHOLOGY WORKING GROUP REVIEW
OF MAMMARY GLANDS
FROM A CHRONIC FEEDING STUDY
IN RATS WITH PFOA

CERTIFICATION OF GOOD LABORATORY PRACTICES

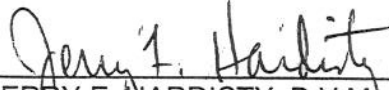
This Pathology Working Group Review (PWG) does not constitute a study. Therefore, Good Laboratory Practice Standards (40 CFR, Part 160) do not apply to this report. However, all appropriate documentation of the review process has been maintained.

Signature:

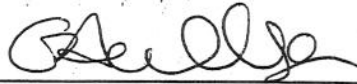
Jerry F. Hardisty
Dr. Jerry F. Hardisty
Author

June 17, 2005
Date

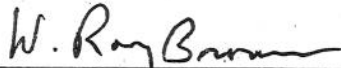
PWG PARTICIPANTS:



JERRY F. HARDISTY, D.V.M.
Diplomate ACVP
(Chairperson)



GABRIELLE A. WILLSON, B.V.M.S., MRCVS
F.R.C. Path
(Reviewing Pathologist)



W. RAY BROWN, D.V.M., Ph.D.
Diplomate ACVP
(Consulting Pathologist)



ERNEST E. MCCONNELL, D.V.M., M.S.
Diplomate ACVP, ABT
(Consulting Pathologist)

PATHOLOGY PEER REVIEW AND
PATHOLOGY WORKING GROUP REVIEW
OF MAMMARY GLANDS
FROM A CHRONIC FEEDING STUDY
IN RATS WITH PFOA

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PATHOLOGY PEER REVIEW AND
PATHOLOGY WORKING GROUP REVIEW
OF MAMMARY GLANDS
FROM A CHRONIC FEEDING STUDY
IN RATS WITH PFOA

EPL PROJECT NO. 129-060

NARRATIVE SUMMARY

INTRODUCTION

Hematoxylin and eosin stained and trichrome stained microscopic slides of mammary gland from female rats used in a chronic feeding study in rats with PFOA were received from DuPont Haskell Laboratory for Health and Environmental Sciences, Newark, Delaware by Experimental Pathology Laboratories, Inc. (EPL®), Research Triangle Park, North Carolina. The study was conducted by the 3M Corporation and the tissues from the study had previously been examined and the results reported by Dr. Robert Geil, the Study Pathologist (SP), for the 3M Corporation. A summary of the group design according to the protocol for the study is summarized in Table 1 below:

Table 1. Experimental Design for a Chronic Feeding Study
in Female Sprague-Dawley Rats with PFOA

Group No.	Dietary Level of Test Material (ppm)	Number of Female Rats	
		Interim Sacrifice	Terminal Sacrifice
1	Control (0)	15	50
6	Mid (30)	0	50
5	High (300)	15	50

Dr. Gabrielle Willson, the Reviewing Pathologist, reexamined all sections of mammary gland from all female rats in all groups, all previously reported mammary neoplasms and all previously reported subcutaneous neoplasms. Prior to the reexamination of the slides, the necropsy records were compared to the reported microscopic findings to ensure that all grossly described mammary and subcutaneous masses were sectioned and

examined microscopically. The purpose of the peer review was to validate the accuracy and consistency of the initial histopathologic examination and to identify the issues that needed to be addressed during the review. The preliminary review of the data indicated that all masses were sectioned and examined microscopically.

Following the reexamination of the histopathology findings of all sections of the mammary gland by the Reviewing Pathologist, a Pathology Working Group (PWG) was convened for the purpose of providing a consensus diagnosis for all neoplastic lesions involving the mammary gland which were diagnosed either by the Study Pathologist or the Reviewing Pathologist. The PWG members consisted of the Reviewing Pathologist, Dr. Willson, and the two consultant board-certified veterinary pathologists with extensive experience in the microscopic evaluation and interpretation of lesions observed in chronic toxicity and oncogenicity bioassay studies conducted in rodents. The original Study Pathologist was not available for the PWG meeting. The PWG's task was to provide a consensus diagnosis for each of the mammary gland neoplasms reported by either the Study or Reviewing Pathologist and to determine the toxicologic significance of the incidence of mammary gland neoplasms present in the female rats treated with PFOA in the diet.

Conduct of the Reviewing Pathologist's Examination

The mammary gland and all subcutaneous masses were evaluated for histopathologic changes during the Reviewing Pathologist's examination conducted by Dr. Willson. Although all microscopic findings in the mammary gland were reviewed, particular emphasis was given to neoplastic lesions. All slides containing sections of mammary tissue with a primary neoplasm of the mammary gland diagnosed by either the Study or Reviewing Pathologist were organized for the PWG review.

Conduct of the Pathology Working Group Review

The Pathology Working Group was chaired by Dr. Jerry F. Hardisty, Experimental Pathology Laboratories, Inc. (EPL®), who organized and presented the material to the panel of three pathologists. Curricula vitae for the PWG Chairperson and each of the PWG participants are present in Appendix C. The PWG review was performed on May 19, 2005, at Experimental Pathology Laboratories in the Research Triangle Park, North Carolina. Individuals attending or participating in the PWG review are listed below:

Dr. Jerry F. Hardisty, Diplomate, A.C.V.P.	(PWG Chairman)
Dr. Gabrielle Willson, FRC Path	(Reviewing Pathologist)
Dr. W. Ray Brown Diplomate, A.C.V.P.	(PWG Participant)
Dr. E.E. McConnell Diplomate, A.C.V.P.	(PWG Participant)
Dr. Steven R. Frame Diplomate, ACVP	(Observer)
Mr. Gerald Kennedy	(Observer)

The PWG examined coded slides without knowledge of treatment group. Each participant recorded his/her diagnoses and comments on worksheets which were prepared by the PWG Chairperson. The PWG examined the mammary gland only for neoplastic lesions and did not consider other lesions which may have also been present. Each lesion was discussed by the group, reexamined if necessary, and the final opinions were recorded on the Chairperson's worksheets. The consensus diagnoses of the PWG were reached when at least two of the three PWG participants were in agreement.

During the PWG review, the nomenclature and diagnostic criteria recommended by the Society of Toxicological Pathologists was used by the PWG to classify the proliferative lesions (Mann, et. al., 1996). A summary of the diagnostic criteria and nomenclature used by the PWG participants for proliferative lesions of the mammary gland of rats is presented below:

Nomenclature and Diagnostic Criteria for Proliferative Lesions of the Mammary Gland in Rats

LOBULAR HYPERPLASIA

- Dilatation of ducts or ductules usually present.
- Evidence of epithelial or glandular proliferation.
- May contain mild cellular pleomorphism and mitotic activity.

FIBROADENOMA

- Composed of glandular epithelium and fibrous connective tissue.
- Epithelium is generally single layered and uniform and may contain lipid vacuoles.
- Connective tissue distributed within and between lobules ranges from well-differentiated to dense hyalinized collagen with few interspersed fibrocytes.
- Epithelium often forms ductules, alveoli or small cysts.
- Focal areas of atypia and/or cellular pleomorphism may be present.
- Mast cells may be frequent.

ADENOMA

- Discrete nonencapsulated mass consists of proliferating alveolar structures in clusters separated by scanty connective tissue septa.
- Alveoli have a single layer of low cuboidal to columnar epithelium with small nuclei and a single nucleolus; epithelium often vacuolated.
- Alveolar lumina may be empty or filled with minimal secretion (tubular pattern) or may be widely distended by proteinaceous secretion (secretory pattern).
- Luminal surface of epithelium generally round, may be smooth or serrated.
- Focal areas of atypia and/or pleomorphism may be present.
- Papillary projections of epithelium may occur, either protruding into dilated ductal lumina (papillary pattern) or into cystic spaces which may be simple or multiloculated (cystic papillary pattern).

ADENOCARCINOMA

- May be noninvasive or invasive.

- May have distant metastases.
- Neoplastic epithelial cells from 1-4 or more layers thick.
- Uniform epithelial cells basophilic to eosinophilic with round to oval centrally located nuclei. Chromatin clumped, single small nucleolus. Numerous mitotic figures.
- Multiple branching papillae covered by cuboidal to columnar epithelium (papillary pattern).
- Closely packed, generally empty, tubular structures which may be round or elongated (tubular pattern).
- Neoplastic epithelial proliferation in a solid sheet with the formation of secondary lumina (cribriform pattern).
- Distended ductules lined by a multilayered epithelium surrounding a central core of necrotic tumor cells (comedo pattern).

ADENOCARCINOMA ARISING IN FIBROADENOMA

- Adenocarcinomatous change within a fibroadenoma.
- Histologic pattern of fibroadenoma component variable.
- Typical histologic appearance of adenocarcinoma present.

After the PWG completed the slide review and the diagnoses were recorded by the PWG Chairperson, the slides were decoded by treatment group. PWG consensus diagnoses for individual animals reviewed in each group are presented in Appendix A. A summary of the incidence of neoplasms in the mammary gland of female rats is tabulated in Table 2.

Table 2. Chronic Feeding Study in Female Sprague-Dawley Rats with PFOA:
Incidence of Mammary Gland Neoplasms in Female Rats

	Group 1		Group 6		Group 5**	
	SP	PWG	SP	PWG	SP	PWG
MAMMARY GLAND -- Number Necropsied	50	50	50	50	50	50
Adenocarcinoma (%)	8 (16%)	9 (18%)	14 (28%)	16 (32%)	5 (10%)	5 (10%)
Fibroadenoma (%)	8 (16%)	16 (32%)	13 (26%)	16 (32%)	19 (38%)	20 (40%)
Fibroadenoma, Multiple (%)	2 (4%)	2 (4%)	6 (12%)	6 (12%)	2 (4%)	3 (6%)
Adenoma (%)	3 (6%)	1 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
No. of Animals with Benign Tumors	13	19	19	22	21	23
No. of Animals with Malignant Tumors	8	9	14	16	5	5
No. of Animals with Both Benign and Malignant Tumors	2	2	4	7	3	3
No. of Animals with Mammary Tumors (Benign or Malignant)*	19	24	29	31	23	25

*Some affected had more than one tumor type.

** Two Group 5 female rats had fibroadenoma present in the interim sacrifice group.

DISCUSSION AND CONCLUSION

The results of the PWG Review generally supported the Reviewing Pathologist's findings. The primary difference between the original reported findings and the PWG results involved changes in the mammary gland that were initially reported as lobular hyperplasia by the Study Pathologist which the PWG felt had features more characteristic of mammary gland fibroadenoma. This difference involved six Group 1, two Group 6 and two Group 5 female rats. Although there were a few differences concerning the classification of benign

and malignant neoplasms, the majority of the other neoplasms reported by the Study Pathologist were confirmed during the PWG review of mammary gland neoplasms in female rats from this study.

Although the incidence of neoplasms varied among the control and treated groups, there were no statistically-significant differences when evaluated using the Fisher's Exact Test for pairwise comparison for fibroadenoma, adenocarcinoma, total benign neoplasms or total malignant neoplasms. The PWG noted that although it is not recommended that benign and malignant neoplasms be combined since there was no histologic evidence of tumor progression from benign to malignant (McConnell, 1986). However, even if combined in this study, there was no significant difference between control and treated groups. The only statistically significant difference (<0.01) involved a negative pairwise comparison in the incidence of adenocarcinoma in Group 6 (30 ppm) compared to Group 5 (300 ppm). Statistical analyses of mammary tumors in rat fed PFOA conducted by Dr. David W. Gaylor are presented in Appendix B.

There was no increase in tumor multiplicity or incidence with dose between control and treated groups. The morphologic appearance of the neoplasms present in treated groups was similar to those observed in the control groups indicating that treatment did not affect the phenotype of the neoplasms in the study. The incidence of mammary gland neoplasms observed in this study is similar to historical control data for mammary gland neoplasms in untreated Crl:CD female Sprague-Dawley Rats in 104 week studies in the open literature (Inveresk Research, 2002; Giknis and Clifford, 2001; Giknis and Clifford, 2004; Chandra, et al., 1992; McMartin, et al., 1992; Stevens, et al., 1994; and Sykes G, 1987) presented in Table 3.

Table 3. Historical Control Data In Untreated Crl:CD Female Sprague-Dawley Rats In 104 Week Studies

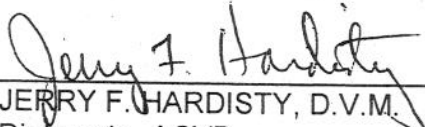
ADENOMA	FIBROADENOMA	ADENOCARCINOMA	REFERENCE
Average (Range)	Average (Range)	Average (Range)	
3.6% (0-18%)	47.2% (26-68%)	8.5% (0-20%)	Inveresk, 2002
8.4% (1.7-32.0%)	41.1% (13.3-61.2%)	23.7% (8.6-58.3%)	Giknis MLA and Clifford CB, 2001
6.9% (1.1-32.0%)	38.1% (13.3-62.3%)	22.2% (8.6-58.3%)	Giknis MLA and Clifford CB, 2004

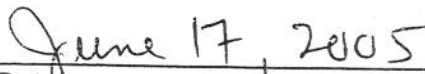
ADENOMA	FIBROADENOMA	ADENOCARCINOMA	REFERENCE
3.54% (NA)	18.96% (NA)	8.80% (NA)	Chandra M, et al., 1992
6.5% (2.9-11.4%)	31.3% (20.0-43.3%)	16.8% (6.7-30.0%)	McMartin DN, et al., 1992
1% (0-7)	33% (36-48)	17% (3-19)	Stevens, JT, et al., 1994, Atrazine
5% (0-15)	34% (2-75)	14% (0-25)	Stevens, JT, et al., 1994, Propazine
2% (3-11)	30% (20-43)	18% (7-30)	Stevens, JT, et al., 1994, Simazine
4% (0-31)	23% (11-57)	6% (3-16)	Stevens, JT, et al., 1994, Terbutylazine
1.9% (0-9.1%)	37.4% (24.2-54.0%)	14.1% (6.5-24.5%)	Sykes G, 1987. US EPA Administrative Record 226-1917

*NA = Not available

CONCLUSION

The PWG concluded that the incidence of mammary gland neoplasms in this study was not affected by chronic dietary administration of PFOA. The morphologic appearance, overall incidence and distribution of the neoplasms observed in treated and control groups were similar.


JERRY F. HARDISTY, D.V.M.
Diplomate, ACVP
Chairperson


Date

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Giknis MLA and Clifford CB (2004) Compilation of spontaneous neoplastic lesions and survival in Crl:CD® (SD) rats from control groups. Charles River Laboratories.

Inveresk Research (2002) Background Tumour Incidences CD Sprague-Dawley rats.

Mann PC, Boorman GA, Lollini LO, McMartin DN and Goodman DG (1996) Proliferative lesions of the mammary gland in rats, IS-2. In Guides for Toxicologic Pathology. STP/ARP/AFIP, Washington, D.C.

McConnell EE, Solleveld HA, Swenberg JA and Boorman GA (1986) Guidelines for combining neoplasms for evaluation of rodent carcinogenesis studies. JNCL, Vol. 76, No. 2., 283-289.

McMartin DN, Sahota PS, Gunson DE, Hsu HH and Spaet RH (1992) Neoplasms and related proliferative lesions in control Sprague-Dawley rats from carcinogenicity studies. Historical data and diagnostic considerations. Toxicologic Pathology, Vol. 20, Number 2, 212-225.

Stevens JT, Breckenridge CB, Wetzel LT, Gillis JH and Luempert III LG (1994) Hypothesis for mammary tumorigenesis in Sprague-Dawley Rats exposed to certain triazine herbicides. Journal of Toxicology and Environmental Health, 43:139-153.

Sykes G (1987) Two-year Toxicity/Carcinogenicity Study of Fluorochemical FC-143 in Rats. US EPA Administrative Record 226-1917. 1-6.

APPENDIX A

PWG Consensus Diagnoses for Individual Animals
Reviewed in Each Group

APPENDIX A

Chemical Name: PFOA Mammary Glands from the Chronic Feeding Study in Rats with PFOA

Animal No.	Study Pathologist's Diagnosis	Reviewing Pathologist's Diagnosis	Pathology Working Group Consensus Diagnosis
Group 1 (Female) – 0 ppm			
1R-4577	Lobular Hyperplasia	Fibroadenoma	Fibroadenoma
1R-4581	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4583	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4587	Lobular Hyperplasia	Fibroadenoma	Fibroadenoma
1R-4595	Lobular Hyperplasia	Fibroadenoma	Fibroadenoma
1R-4596	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4600	Lobular Hyperplasia	Fibroadenoma	Fibroadenoma
	Adenoma, Papillary	Adenocarcinoma	Adenocarcinoma
1R-4606	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4609	Carcinoma	No Slide	Adenocarcinoma*
		Fibroadenoma	Fibroadenoma
1R-4611	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4612	Fibroadenoma, Two	Fibroadenoma, Two	Fibroadenoma, Multiple
1R-4613	Lobular Hyperplasia	Fibroadenoma	Fibroadenoma
1R-4614	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4621	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4623	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4624	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4625	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4627	Adenocarcinoma	Adenocarcinoma and Fibroadenoma	Fibroadenoma
1R-4628	Adenoma, Papillary	Adenocarcinoma	Adenocarcinoma
1R-4633	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4634	Fibroadenoma, Two	Fibroadenoma, Two	Fibroadenoma, Multiple
1R-4635	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
	Adenoma	Adenoma	Adenoma
1R-4636	Lobular Hyperplasia	Fibroadenoma	Fibroadenoma
1R-4639	Fibroadenoma	Fibroadenoma	Fibroadenoma
*No slide available for reexamination, so defaulted to Study Pathologist's reported diagnosis.			

APPENDIX A

Chemical Name: PFOA Mammary Glands from the Chronic Feeding Study in Rats with PFOA

Animal No.	Study Pathologist's Diagnosis	Reviewing Pathologist's Diagnosis	Pathology Working Group Consensus Diagnosis
Group 6 (Female) – 30 ppm			
1R-4706	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4707	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4708	Fibroadenoma	Fibroadenoma, Two	Fibroadenoma, Multiple
1R-4710	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4711	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4712	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4714	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4717	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4718	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4719	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4720	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4721	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4723	Adenocarcinoma, Papillary	Adenocarcinoma, Papillary and Fibroadenoma	Adenocarcinoma and Fibroadenoma
1R-4726	Not Remarkable	Fibroadenoma	Lobular Hyperplasia
1R-4727	Fibroadenoma	Fibroadenoma, Two	Fibroadenoma, Multiple
1R-4729	Fibroadenoma, Two	Fibroadenoma, Two	Fibroadenoma, Multiple
1R-4730	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4731	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4732	Fibroadenoma, Two	Fibroadenoma, Two	Fibroadenoma, Multiple
1R-4734	Lobular Hyperplasia, Cystic	Fibroadenoma	Fibroadenoma
1R-4737	Fibroadenoma, Two	Adenocarcinoma and Fibroadenoma	Adenocarcinoma and Fibroadenoma
1R-4740	Lobular Hyperplasia	Fibroadenoma	Fibroadenoma
1R-4741	Lobular Hyperplasia	Fibroadenoma	Lobular Hyperplasia
1R-4742	Fibroadenoma, Two	Adenocarcinoma and Fibroadenoma	Adenocarcinoma and Fibroadenoma

APPENDIX A

Chemical Name: PFOA Mammary Glands from the Chronic Feeding Study in Rats with PFOA

Animal No.	Study Pathologist's Diagnosis	Reviewing Pathologist's Diagnosis	Pathology Working Group Consensus Diagnosis
1R-4743	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4744	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4745	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4746	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4747	Fibroadenoma, Two	Fibroadenoma, Two	Fibroadenoma, Multiple
1R-4748	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4750	Fibroadenoma, Two	Fibroadenoma, Two	Fibroadenoma, Multiple
1R-4753	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4754	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
Group 5 (Female) – 300 ppm			
1R-4641	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4644	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4645	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4646	Adenocarcinoma and Fibroadenoma	Adenocarcinoma and Fibroadenoma	Adenocarcinoma and Fibroadenoma
1R-4649	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4654	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4657	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4659	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4660	Fibroadenoma, Two	Fibroadenoma, Two	Fibroadenoma, Multiple
1R-4662	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4663	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4665	Lobular Hyperplasia, Moderate	Fibroadenoma	Fibroadenoma
1R-4673	Adenocarcinoma	Adenocarcinoma	Adenocarcinoma
1R-4677	Fibroadenoma, Two	Fibroadenoma, Two	Fibroadenoma, Multiple
1R-4679	Fibroadenoma	Fibroadenoma, Two	Fibroadenoma, Multiple
1R-4682	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4685	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4686	Fibroadenoma	Fibroadenoma	Fibroadenoma
1R-4694	Fibroadenoma	Fibroadenoma	Fibroadenoma

Chemical Name: PFOA
Mammary Glands from the Chronic Feeding Study in Rats with PFOA

18

APPENDIX B

Statistical Analyses of Mammary Tumors in Rats Fed PFOA

6/12/05

Statistical Analyses of Mammary Tumors in Rats Fed PFOA

David W. Gaylor, Ph.D.
Gaylor and Associates, LLC

Introduction

Female Sprague-Dawley rats were fed PFOA in a chronic bioassay. The incidence of animals with mammary tumors reported by the Pathology Working Group are listed in Table 1. The denominators are the effective number of animals at risk (adjusted for survival) as calculated by the National Toxicology Program Poly-3 procedure (Portier and Bailer, 1989).

Table 1. Incidence of mammary tumors in female rats fed PFOA.

Tumor type	0 ppm	30 ppm	300 ppm
Adenocarcinoma	9 / 40.4	16 / 43.4	5 / 41.4
Fibroadenoma	18 / 41.4	22 / 41.1	23 / 44.3
Adenoma	1 / 38.4	0 / 38.5	0 / 41.4
Fibroadenoma/Adenoma	19 / 41.7	22 / 41.1	23 / 44.3
Adenocarcinoma/ Fibroadenoma/Adenoma	24 / 42.9	31 / 44.7	25 / 45.3

Results

None of the tumor types or combinations of tumor types listed in Table 1 exhibited statistically significant survival adjusted dose-response trends. No statistically significant survival adjusted pair-wise increases in tumor incidence compared to controls were noted. All P-values exceeded 0.10.

References

Portier, CJ and Bailer, AJ. Testing for increased carcinogenicity using a survival-adjusted quantal response test. *Fundamental Appl. Toxicol.* 12: 731-737 (1989).

APPENDIX C

Curricula Vitae

JERRY F. HARDISTY
PRESIDENT/VETERINARY PATHOLOGIST

EDUCATION:

Iowa State University, Pre-Veterinary, 1965-1967
Iowa State University, D.V.M., 1971

Certified by the American College of Veterinary Pathologists, 1976
Adjunct Associate Professor at the School of Veterinary Medicine,
NC State University, 1983

PRESENT POSITION AND EXPERIENCE:

1998 - Present. President and Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for overall management and direction of contract research pathology laboratories in Virginia and North Carolina. The company serves both government and university research and the safety assessment programs of the pharmaceutical, chemical, and cosmetic industries.

1994 - 1998. Vice President, Operations and Pathologist, Experimental Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for overall management and direction of pathology research laboratories in North Carolina and Virginia.

1978 - 1994. Director and Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for the project management, direction and technical supervision of the North Carolina branch of EPL. Responsible for the microscopic evaluation of toxicological studies. Responsible for the National Toxicology Program's Pathology Quality Assessment Program and Operations of the NTP Archives.

1976 - 1978. Pathologist/Project Manager, Experimental Pathology Laboratories, Inc., Herndon, Virginia

Responsible for the management of EPL's Carcinogenesis Support Laboratory. Project Manager of a program to provide Tracor Jitco with Quality Assurance in the NCI Carcinogenesis Testing Program. Technical supervision of a program to provide pathology support services to the Carcinogenesis Program of the National Cancer Institute. Responsible for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies.

JERRY F. HARDISTY, D.V.M. – Continued**PRESENT POSITION AND EXPERIENCE – Continued**

1972-1976 Research Pathologist, Veterinary Pathology Branch, Biomedical Laboratory, Edgewood Arsenal, Maryland

Dr. Hardisty was a preceptee in the U.S. Army preceptorship program in Veterinary Pathology. During this time he performed gross and microscopic diagnoses of spontaneous disease and changes produced by experimental procedures in laboratory animals. He prepared reports describing and interpreting these experimental results.

During this time he was principal investigator for the reproductive, mutagenic, teratogenic studies performed at the laboratory. This work consisted of revising previous experimental protocols and designing new experimental protocols to be utilized at the laboratory. The experimental design employed required the gross examination of pregnant female rats and fetuses for evidence of fetal toxicity and teratogenesis. He trained biological technicians to perform timed matings in rats, examine serially sectioned fetuses for malformations, and to examine fetal skeletons for prenatal abnormalities.

1971-1972 Attending Veterinarian, Division of BioSensor Research, Walter Reed Army Institute of Research

Dr. Hardisty studied the radiographic and morphologic lesions of several musculoskeletal diseases of the German Shepherd Dog. In association with Dr. Wayne Riser, he investigated the pathogenesis and possible genetic relationship of canine hip dysplasia, eosinophilic panosteitis and ununited anconeal processes in an attempt to reduce their incidence through a selective breeding program.

PROFESSIONAL MEMBERSHIPS:

- Diplomate, American College of Veterinary Pathologists
- ACVP Subspecialty in Toxicologic Pathology
- American College of Toxicology
- Society of Toxicology
- Society of Toxicologic Pathologists
- British Society of Toxicologic Pathologists
- International Academy of Toxicologic Pathology
- American Veterinary Medical Association
- North Carolina Society of Toxicology
- Charles Louis Davis, D.V.M. Foundation
- The Society of Phi Zeta
- The Society of Gamma Sigma Delta
- The Fraternity of Alpha Zeta
- The Fraternity of Omega Tau Sigma
- American Association for the Advancement of Science

JERRY F. HARDISTY, D.V.M. – Continued**PROFESSIONAL ACTIVITIES:**

- Standardized System of Nomenclature and Diagnostic Criteria (SSNDC), The Society of Toxicologic Pathologists, 1987-1995.
- Executive Committee, The Society of Toxicologic Pathologists, 1994- 1998.
- Executive Committee Chairman, The Society of Toxicologic Pathologists, 1997-1998.
- Joint Committee for STPs/ILSI on International Standardization of Nomenclature and Diagnostic Criteria for Toxicologic Pathology, 1994-1995, Co-Chairman 1995-Present.
- President-Elect, The Society of Toxicologic Pathologists, 1999-2000.
- President, The Society of Toxicologic Pathologists, 2000-2001.
- Past President, The Society of Toxicologic Pathologists, 2001-2002.
- Long Range Planning Committee, American College of Toxicology, 2002.
- North American Director, International Academy of Toxicologic Pathology, 2002.
- FDA Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Sciences, FDA Center for Drug Evaluation and Research, 2003.

EDITORIAL REVIEW BOARD:

- International Agency for Research on Cancer (WHO), Classification of Rodent Tumors, Part II, The Mouse, 1995-2001.
- Editorial Review Board for *Fundamental and Applied Toxicology*, Society of Toxicology Board of Publications, 1996-1998.
- Editorial Review Board for *Toxicological Sciences*, Society of Toxicology Board of Publications, 1998-2004.
- Editorial Review Board for *Experimental and Toxicologic Pathology*, 2000.

PUBLICATIONS AND PAPERS:

Factors predisposing to urolithiasis in feedlot cattle. Hardisty JF and Dillman RC. The Iowa State University Veterinarian, Iowa State University, Ames, Iowa, 33(2), 77-81, 1971.

Reduction of frequency of hip dysplasia in military dogs. Riser WH, Hardisty JF and Castleberry MW. In Proceedings, Canine Hip Dysplasia Symposium and Workshop, OFA, Columbia, MO. 1972.

Genetic influence of the male on the incidence of canine hip dysplasia. Hardisty JF, Scalera SE., Castleberry MW and Riser WH. In Proceedings, Canine Hip Dysplasia Symposium and Workshop, OFA, Columbia, MO. 1972.

JERRY F. HARDISTY, D.V.M. – Continued**PUBLICATIONS AND PAPERS – Continued**

Evaluation of the effects of chemical compounds on the reproductive system of rats. Hardisty JF. Presented at the Biomedical Laboratory Review and Analysis, April 1975.

Reproductive studies with quint essence compounds. Hardisty JF, Presented at the Biomedical Laboratory Review and Analysis of Quint Essence, January 1976.

Effects of KZ/IP mixture on the reproductive system. Hardisty JF and Pellerin RJ. Edgewood Arsenal Technical Report, 1976.

Reproductive studies with diisopropylmethylphosphate in rats. Hardisty JF, Pellerin RJ, Biskup RF and Manthei JH. Edgewood Arsenal Technical Report ARCSL TR 77037, May 1977.

Quality assurance in pathology. Hardisty JF, Ward JM and Griesemer RA. NCI-NCTR Pathology Workshop, Bethesda, MD, June 1978.

Mononuclear cell leukemia in Fischer 344 rats. Hardisty JF. NCI-NCTR Pathology Workshop, Bethesda, MD, June 1978.

Quality assurance for pathology in rodent carcinogenesis tests. Ward JM, Goodman DG, Griesemer RA, Hardisty JF, Schueler RL, Squire RA and Strandberg JD. Journal of Environmental Pathology and Toxicology, 2, 371-378, Nov.-Dec. 1978.

Neoplasms and pigmentation of the thyroid gland in F-344 rats exposed to 2,4-diaminoaniline sulfate, a hair dye component. Ward JM, Stinson, SF, Hardisty JF, Cockrell BY and Hayden DW. Journal of the National Cancer Institute, Vol. 62, No. 4, April 1979.

Renal carcinogenic and nephrotoxic effects of the flame retardant TRIS[(2,3-dibromopropyl) phosphate] in F-344 rats and B6C3F1 mice. Reznik G, Ward JM, Hardisty JF and Russfield A. Journal of the National Cancer Institute, Vol. 63, No. 1, July 1979.

Correlation between gross observations of tumors and neoplasms diagnosed microscopically in carcinogenesis bioassays in rats. Kulwich BA, Hardisty JF, Gilmore CE and Ward JM. Journal of Environmental Pathology and Toxicology, 3, 281-287, December 1979.

Evaluation of procedures suggested for reducing the pathology workload in a carcinogenesis testing program. Hardisty JF, Ward JM, Douglas JF and Fears TR. Journal of Environmental Pathology and Toxicology, 3, 167-176, December 1979.

JERRY F. HARDISTY, D.V.M. – Continued**PUBLICATIONS AND PAPERS – Continued**

Cancer induction following single and multiple exposures to a constant amount of vinyl chloride monomer. Hehir RM, McNamara BP, McLaughlin J, Willigan DA, Bierbower G and Hardisty JF. Presented for the conference to re-evaluate the Toxicology of Vinyl Chloride Monomer, Polyvinyl Chloride and Structural Analogues on March 20-21, 1980, at the National Institute of Health, Bethesda, MD.

Cancer induction following single and multiple exposures to a constant amount of vinyl chloride monomer. Hehir RM, McNamara BP, McLaughlin J, Willigan DA, Bierbower G and Hardisty JF. *Environmental Health Perspectives*, 41, 63-72, October 1981.

Carcinogenesis bioassay of 2,6-Xylidine in rats. Hardisty JF, Montgomery CA and Kornreich M. *The Toxicologist*, Vol 3, No. 1, March 1983.

Chronic toxicity and oncogenicity bioassay of inhaled toluene in Fischer 344 rats. Gibson JE and Hardisty JF. *Fundamental and Applied Toxicology*, 3: 315-319, 1983.

Quality assurance in pathology for rodent carcinogenicity tests, by GA Boorman, CA Montgomery, JF Hardisty, SL Eustis, MJ Wolfe and EE McConnell. In: Handbook of Carcinogen Testing, (H Milman and E Weisberger, eds), pp. 345-357. New Jersey: Noyes Publications, 1985.

Systemic effects following inhalation of fog oil obscurant. Hardisty JF, Stead AG, Grose EC and Selgrade MJ. Presented at the North Carolina Chapter of the Society of Toxicology Meeting on February 2, 1985.

Factors influencing laboratory animal spontaneous tumor profiles. Hardisty JF. *Toxicologic Pathology*, 13, 91-104, 1985.

Pulmonary and hepatic health effects of inhalation of petroleum smoke. Grose EC, Stevens MA, Illing JW, Jaskot RH, Hardisty JF and Stead A. *The Toxicologist*, Vol 6, No. 1, March 1986.

National Toxicology Program Pathology Quality Assurance Procedures, by J.F. Hardisty and GA Boorman. In: Managing Conduct and Data Quality of Toxicology Studies, (BK Hoover, JK Baldwin and AF Uelner. NIEHS/NTP – CE Whitmire, CL Davies and DW Bristol, eds), pp 263-269. New Jersey: Princeton Scientific Publishing Co. Inc., 1986.

Pulmonary effects due to short term exposure to oil fog. Selgrade MJK, Hatch GE, Grose EC, Illing JW, Stead AG, Miller FJ, Graham JA, Stevens MA and Hardisty JF. *J. Toxicol. & Environ. Health* 21: 173-185, 1987.

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JERRY F. HARDISTY, D.V.M. – Continued**PUBLICATIONS AND PAPERS – Continued**

Chronic toxicity and oncogenicity study of 2,6 diethylaniline. TG Pullin, RW Naismith, JF Hardisty, EB Whorton Jr. and GL Ter Haar. *The Toxicologist*, Vol 8, No. 1, February 1988.

Peripheral nerve sheath tumors, rat, by D.M. Walker, V.E. Walker, J.F. Hardisty, KT Morgan and JA Swenberg. In: ILSI Monographs on Pathology laboratory animals, nervous system, Vol 6, (TC Jones, U Mohr and RD Hunt, eds), New York, Springer-Verlag, 1988.

Pulmonary effects due to subchronic exposure to oil fog. MK Selgrade, GE Hatch, EC Grose, AG Stead, FJ Miller, JA Graham, MA Stevens and JF Hardisty. *Toxicology and Industrial Health*, Vol 6, No. 1, 1990.

Thyroid gland, by JF Hardisty and GA Boorman. In: Pathology of the F344 Rat, (G Boorman, S Eustis, C Montgomery, M Elwell and W MacKenzie, eds), San Diego, Academic Press, 1990.

Oral cavity (pharynx, tongue, gingival teeth), esophagus and stomach, by HR Brown, JF Hardisty and SL Eustis. In: Pathology of the F344 Rat, (G Boorman, S Eustis, C Montgomery, M Elwell and W MacKenzie, eds), San Diego, Academic Press, 1990.

Toxicological pathology: a critical stage in study interpretation, by JF Hardisty and SL Eustis. In: Progress in Toxicology, (D Clayson, I Munro, P Shubik and J Swenberg, eds), Amsterdam, Elsevier, 1990.

Tumors of the skin in the HRA/Skh mouse after treatment with 8-methoxypsoralen and UVA radiation. JK Dunnick, PD Forbes, SL Eustis and JF Hardisty. *Fund. & Appl. Tox.*, Vol 16, 92-102, 1991.

Proliferative lesions of the mouse lung: Progression studies in Strain A mice. JF Foley, MW Anderson, GD Stoner, BW Gaul, JF Hardisty and RR Maronpot. *Experimental Lung Research*, Vol.17, 157-168, 1991.

Lesions of the rodent liver. Hardisty JF. Presented at the Dose Response Relationships for Hepatocarcinogenesis in Medaka Exposed to Waterborne N-Nitrosodietylamine. Workshop on December 15, 1993.

Procedures for peer review in toxicologic pathology. Hardisty JF. Presented at The Society of Toxicologic Pathologist 13th International Symposium on June 5-9, 1994.

Necropsy and histology in toxicologic pathology. Hardisty JF. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, July 27, 1994.

JERRY F. HARDISTY, D.V.M. – Continued

PUBLICATIONS AND PAPERS – Continued

A comparison of liver tumor diagnoses from seven PCB studies in rats. Moore John A, Hardisty Jerry F, Banas Deborah A and Smith, Mary Alice. *Regulatory Toxicology and Pharmacology*, Vol 20, 362-370, 1994.

Neoplastic lesions of questionable significance. Hardisty JF. Presented at the 1994 Toxicology Roundtable on October 3, 1994.

Use of nasal diagrams to record nasal lesions. Hardisty JF. Presented at the 1994 Toxicology Roundtable on October 4, 1994.

Morphologic assessment of pathologic changes in the rat larynx. Hardisty JF. Presented at the 1994 Toxicology Roundtable on October 4, 1994.

Pathology peer review and PWG. Hardisty JF. Presented at the 1995 Toxicology Roundtable in Nashville, TN on October 23, 1995.

Peer review in toxicology pathology. Ward JM, Hardisty JF, Hailey JR and Street CS. *Toxicologic Pathology* ISSN:0192-6233, Vol. 23, No. 2, 1995

Computerized pathology data – summary vs. individual. Hardisty JF. Presented at the 1995 Toxicology Roundtable in Nashville, TN on October 24, 1995.

An evaluation of changes in the olfactory epithelium and liver peroxisome proliferation in mice after inhalation exposure to methylethylketoxime. Newton PE, Bolte HF, Lake BG, Derelanko M, Rinehart WE and Hardisty JF. *The Toxicologist*, Vol 30, No. 1, Part 2, March 1996.

Peer review of histopathology data. Hardisty JF. Presented at the American College of Toxicology 17th Annual Meeting in King of Prussia, PA on November 11, 1996.

Pathology peer review in assessing carcinogenicity studies. Hardisty JF. Presented at the American College of Veterinary Pathologists' Thirty- First Annual Meeting in Seattle, Washington on December 5, 1996.

Value of the mouse carcinogenicity bioassay (Summary). Hardisty JF. *Toxicologic Pathology* ISSN:0192-6233, Vol. 24, No. 6, 1996, pp. 720-721.

Interaction of consultants, contract laboratories and industry-Panel Discussion with HE Black, AM Dahlem, JF Hardisty, TG Terrell. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, May 19, 1997.

Controversial issues in anatomic pathology. JF Hardisty. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, May 20, 1997.

JERRY F. HARDISTY, D.V.M. – Continued**PUBLICATIONS AND PAPERS – Continued**

Phenolphthalein induces thymic lymphomas accompanied by loss of the p53 wild type allele in heterozygous p53-deficient (+) mice. Dunnick JK, Hardisty JF, Herbert RA, Seely JC, Furedi-Machacek EM, Foley JF, Lacks GD, Stasiewicz S and French JE. Toxicologic Pathology, Vol. 25, No. 6., 533-540, 1997.

Diagnostic dilemmas in toxicologic pathology. Hardisty Jerry. Presented at The 22nd Annual CL Davis DVM Foundation Continuing Education Symposium at North Carolina State University, College of Veterinary Medicine in Raleigh, North Carolina on June 14-18, 1998.

Thyroid and parathyroid glands, by JF Hardisty and GA Boorman. In: Pathology of the Mouse, (RR Maronpot, GA Boorman and BW Gaul, eds), Vienna, IL, Cache River Press, 1999.

Rodent leydig cell tumorigenesis: a review of the physiology, pathology, mechanisms, and relevance to humans. Jon C Cook, Gary R Klinefelter, Jerry F Hardisty, Richard M Sharpe and Paul MD Foster, Critical Reviews in Toxicology, 29(2): 169-261, 1999.

The nomenclature of cell death: recommendations of an ad hoc committee of Society of Toxicologic Pathologists. Levin S, Bucci TJ, Cohen SM, Fix AS, Hardisty JF, Legrand EK, Maronpot RR and Trump BF. Toxicol Pathol. 1999 Jul-Aug;27(4):484-490.

Controversial issues in anatomic pathology. Hardisty Jerry. Presented as a course entitled *Industrial Toxicology and Pathology* for the American Registry of Pathology at the Ramada Inn in Bethesda, MD on September 28, 1999.

Histopathology of nasal olfactory mucosa from selected inhalation toxicity studies conducted with volatile chemicals. Hardisty JF, Garman RH, Harkema JR, Lomax LG and Morgan KT. Toxicologic Pathology, Vol.27, No. 6, pp. 618-627, 1999.

Pathology Working Groups: Current Concepts. Hardisty JF. Presented at the 16th Annual Meeting of the Society of Quality Assurance in Montreal, Canada on October 9-13, 2000.

Blind Pathology – When and When Not. Hardisty JF. Presented at the 51st Annual Toxicology Roundtable Program in Asheville, NC on October 15-18, 2000.

Short-Term, Subchronic, and Chronic Toxicology Studies, by NH Wilson, JF Hardisty and JR Hayes. In: Principles and Methods of Toxicology, 4th Edition, (Wallace Hayes, ed), ISBN 1-56032-814-2, 2000.

Methods to identify and characterize developmental neurotoxicity for human health risk assessment. II: neuropathology. Garman RH, Fix AS, Jortner BS, Hardisty JF, Claudio L and Ferenc S. Environmental Health Perspectives, Vol. 109, pp. 93-100, March 2001.

JERRY F. HARDISTY, D.V.M. – Continued**PUBLICATIONS AND PAPERS – Continued**

A chronic inhalation toxicity/oncogenicity study of methylethylketoxime in rats and mice. Newton PE, Wooding WL, Bolte HF, Derelanko MJ, Hardisty JF and Rinehart WE. Inhalation Toxicology, 13:1093-1116, 2001.

Carcinogenic assessment of premafloxacin in rats and mice. White KA, Daniel EM, Botta JA, Clare LJ, Barnett D, Hildebrandt P, Hardisty JF and Lucas MJ. Presented as a poster for the Society of Toxicologic Pathology and the International Federation of Societies of Toxicologic Pathologists in Orlando, Florida on June 24-28, 2001.

Quality review procedures necessary for rodent pathology databases and toxicogenomic studies: The National Toxicology Program Experience. Boorman GA, Haseman JK, Waters WD, Hardisty JF and Sills RC. Toxicol. Pathol. 30, 88-92, 2002.

Inhalation toxicology of octamethylcyclotetrasiloxane (D₄) following a 3-month nose-only exposure in Fischer 344 rats. Burns-Naas LA, Meeks RG, Kolesar GB, Mast RW, Elwell MR, Hardisty JF and Thevenaz P. International Journal of Toxicology, ISSN 1091-5818, Vol. 21, No. 1, pp 39-53, 2002.

Diagnostic dilemmas in toxicologic pathology. Presented at the 5th Industrial Toxicology and Pathology Course and symposium in Chicago, IL on July 9, 2002.

Histologic artifacts & diagnostic dilemmas. Presented at the RTP Rodent Pathology Course, Research Triangle Park, NC on September 8-10, 2002.

Comparative prevalence, multiplicity, and progression of spontaneous and vinyl carbamate-induced liver lesions in five strains of male mice. Takahashi K, Dinse GE, Foley JF and Maronpot RR. Toxicologic Pathology, Vol 30, No. 5, pp 599-605, 2002.

Propylene glycol monomethyl ether (PGME): inhalation toxicity and carcinogenicity in Fischer 344 rats and B6C3F1 mice. Toxicologic Pathology, Vol 30, No. 5, pp 570-579, 2002.

An evaluation of changes and recovery in the olfactory epithelium in mice after inhalation exposure to methylethylketoxime. Newton PE, Bolte HF, Derelanko MJ, Hardisty JF and Rinehart WE. Inhalation Toxicology, 14:1249-1260, 2002.

The pathologist and pathology data. Hardisty JF. Presented at NIEHS, RTP, NC on February 29, 2002.

The pathologist and pathology data. Hardisty JF. Presented at the SOT Meeting in Nashville, TN on March 2002.

The pathologist and pathology data. Hardisty JF. Presented at FDA CEDR on May 31, 2001.

JERRY F. HARDISTY, D.V.M. – Continued**PUBLICATIONS AND PAPERS – Continued**

Histologic artifacts and diagnostic dilemmas. Hardisty JF. Presented at NCTR in Jefferson, AR on October 31, 2002.

The pathologist and pathology data. Hardisty JF. Presented at NCTR in Jefferson, AR on October 31, 2002.

The pathologist and pathology data. Hardisty JF. Presented at Health Canada in Ottawa, Canada on December 2, 2002.

Necropsy and histology techniques. Hardisty JF. Presented at FDA on January 9, 2003.

Current approaches to Peer Review and PWG. Hardisty JF. Presented at Battelle in Columbus, OH on June 5, 2003.

Characterization of intrathoracic mesothelioma in Fischer 344/N rats. Willson G, Clayton N, Hardisty J, and Pearce G. Presented as a poster for the Society of Toxicologic Pathology, 22nd Annual Meeting In Savannah, Georgia on June 15-19, 2003.

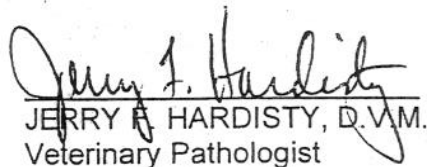
Transplacental carcinogenicity of azidothymidine in B6C3F1 mice and F344 rats. Walker DM, Hardisty JF, Ruecker FA, Funk KA, Wolfe MJ and Walker VE. Abstract No. 548. 2004 *Itinerary Planner*. Baltimore, MD: Society of Toxicology.

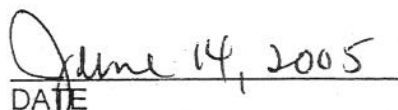
Comparison of automated software with conventional histopathology of liver step sections in an NTP Subchronic Bioassay. Willson GA, Joron TA, Lesniak D, Pearce G and Hardisty JF. Presented a poster at the STP Meeting in Salt Lake City, UT, June, 2004.

Automated Pathology Systems – Human Versus Machine Vision. Hardisty JF: Toxicology Roundtable, Augusta, MI. Sept. 2004.

Comparative hepatic toxicity: prechronic/chronic liver toxicity in rodents. Hardisty JF and Brix AE. *Toxicologic Pathology*, 33:35-40, 2005.

ACT/STP Pathology Course for Non-Pathologists. Hardisty JF. Speaker at ACT/STP Meeting, Lincolnshire, IL, May 10-13, 2005.


JERRY F. HARDISTY, D.V.M.
Veterinary Pathologist


DATE

**GABRIELLE A. WILLSON
VETERINARY PATHOLOGIST**

EDUCATION:

Glasgow University Veterinary School B.V.M.S., 1973-1977
MRC Path (Membership of the Royal College of Pathologists), 1985
FRC Path (Fellowship of the Royal College of Pathologists), 1995

PRESENT POSITION AND EXPERIENCE:

01/04 – Present. Veterinary Pathologist, Experimental Pathology Laboratories, Inc.,
Research Triangle Park, NC

Provides pathology support to CIIT, Centers for Health Research in Research Triangle Park, on a part-time basis. This involves interaction with staff at all levels and participation in many diverse areas ranging from the technical aspects of tissue processing and necropsy techniques to study design, photography, poster preparation, image analysis, confocal microscopy, electron microscopy and immunohistochemistry in addition to the routine necropsy and interpretation of pathological lesions.

09/00 - Present. Veterinary Pathologist, Experimental Pathology Laboratories, Inc.,
Research Triangle Park, NC

Duties as a staff pathologist in present position at EPL include histopathologic interpretation of tissues from various laboratory animals and audits of pathology data and specimens used for toxicity and carcinogenicity studies.

03/00 - 07/00 Anatomic Pathologist, IDEXX Veterinary Services, West
Sacramento, CA

Responsibilities included performing histopathology on research studies submitted by independent biotechnology companies, pharmaceutical companies and university departments. Also, in part, provision of diagnostic histopathology service for veterinary clinicians.

12/96 - 12/99 Veterinary Surgeon, The Animal Care Centre in Sharjah, United
Arab Emirates

Functioned in a clinical capacity as a veterinary surgeon.

10/91 - 12/96 Independent Toxicological Pathologist, Histo-Logic, Stalybridge,
Cheshire UK

GABRIELLE A. WILLSON, B.V.M.S., MRC Path, FRC Path - Continued**PRESENT POSITION AND EXPERIENCE - Continued**

Since August 1991, functioned as a consultant pathologist establishing Histo-Logic, an independent pathology consultancy. Performed pathology on a number of studies and also performed peer reviews of studies for Glaxo Wellcome (Ware). These studies were either performed in house (Ware) or at contract facilities and of necessity involved close liaison with the other scientists involved.

Read a variety of studies in rats, mice, dogs and minipigs for contract and other pharmaceutical laboratories in both the United Kingdom and elsewhere in Europe. Histo-Logic was accepted into the United Kingdom Department of Healths GLP Compliance programme.

10/77 - 06/91

Senior Pathologist, Unilever Research, Sharnbrook, Bedford UK

Responsibilities included postmortem and histological assessment of short, medium and long-term tests in rodents.

Acted as Study Director for all teratogenicity studies for several years conducted both in house and at contract laboratories.

Management of the Teratology Department with direct responsibility for a staff of four.

Achievements During This Period:

Completion of a large number of tests encompassing feeding, inhalation, intratracheal instillation, intrapleural and intraperitoneal injection, intravaginal instillation and topical application. Ultrastructural examination and histochemical assessment were frequently required as part of the evaluation process.

Sole responsibility for the histological assessment of a vast and complex intrapleural study investigating the lifetime effects of fibrous minerals.

Production of reports, most of which were submitted to Regulatory Authorities.

Overseeing a successful collaborative project with the Anatomy Department of Leicester University Medical School in the area of in-vitro techniques for the assessment of embryo culture. This technique was later transferred to the Environmental Safety Laboratory at Unilever where it was used in the assessment of potential teratogens.

Formal presentations of results of studies both within Unilever and to the operating companies.

Carrying out background research to maintain the health of the breeding colonies of rats, mice, guinea pigs, rabbits and investigation of specific problems.

GABRIELLE A. WILLSON, B.V.M.S., MRC Path, FRC Path - Continued**PRESENT POSITION AND EXPERIENCE - Continued**

07/77 - 10/77

Locum work, Henderson & Keywood Veterinary Surgeons
Surbiton, Surrey UK

Locum work in a busy small animal practice. Duties included consultations, surgical procedures, etc.

PROFESSIONAL MEMBERSHIPS:

Fellow of the Royal College of Pathologists
British Society of Toxicological Pathology
Charles Louis Davis, D.V.M. Foundation
Society of Toxicologic Pathology

PRESENTATIONS AND POSTERS:

Induced Mesothelioma in the Wistar Rat. Willson, G, presented at the Industrial Histology Discussion Group, 22nd Meeting, Llandudno, North Wales, September 1992.

Spontaneous and Induced Pathology of the Salivary Glands and Oesophagus. Willson G, presented at the BSTP Modular Education Programme in Toxicological Pathology, Cambridge, England, July 20, 1993.

Cardiovascular System: Spontaneous Rodent Pathology. Willson, G., presented at the BSTP Modular Education Programme in Toxicological Pathology, Cambridge, England, July 9-12, 2001.

Hepatoblastomas in Mice in the US National Toxicology Program (NTP) Studies. Turusov VS, Torii M, Sills RC, Willson GA, Herbert RA, Hailey JR, Haseman JK and Boorman GA, presented at the STP Meeting in Denver, CO, June 2-6, 2002.

Characterization of Intrathoracic Mesothelioma in Fischer 344/N Rats. Willson G, Clayton N, Hardisty J and Pearce G. Presented as a poster for the Society of Toxicologic Pathology, 22nd Annual Meeting in Savannah, Georgia on June 15-19, 2003.

Toxicologic Pathology of the Integumentary System and the Mammary Gland. Willson G. Presented to the Health Products and Food Branch, Office of Continuing Education, Ontario, Canada on January 20, 2004.

The Use of Automated Pathology Software to Confirm the Results of Pathological Evaluation of NTP Studies. Pearce G, Joron TA, Lesniak D, Willson GA and Hardisty JF, presented a poster at the STP Meeting in Salt Lake City, UT, June, 2004.

GABRIELLE A. WILLSON, B.V.M.S., MRC Path, FRC Path - Continued**PUBLICATIONS AND PAPERS:**

Comparison of Automated Pathology Software with Conventional Histopathology of Liver Step Sections in an NTP Subchronic Bioassay. Willson GA, Joron TA, Lesniak D, Pearse G and Hardisty JF, presented a poster at the STP Meeting in Salt Lake City, UT, June, 2004.

Module 13: Musculoskeletal System, Skin, Subcutis and Mammary Gland. Willson G (organized the programme), BSTP Modular Education Programme in Toxicological Pathology, Cambridge, England, July 5-9, 2004.

Corneal Lipoidosis in a Dog with Bilateral Thyroid Carcinoma. Harrington GA and Kelly DF. Vet Pathol. 1980 Jul;17(4):490-3.

A Lymphomatoid Granulomatosis of the Lungs in Young Dogs. Lucke VM, Kelly DF, Harrington GA, Gibbs C and Gaskell CJ. Vet Pathol. 1979 Jul;16(4):405-12.

Hepatoblastomas in Mice in the US National Toxicology Program (NTP) Studies. Turusov VS, Torii M, Sills RC, Willson GA, Herbert RA, Hailey JR, Haseman JK and Boorman GA. Toxicologic Pathology, Vol. 30, No. 5, pp 580-591.



GABRIELLE A. WILLSON, B.V.M.S.,
M.R.C.V.S., FRC. Path.

September 1st 2004

Date

CURRICULUM VITAE - 2004

NAME

W. Ray Brown, D.V.M., Ph.D.
Diplomate, American College of Veterinary Pathologists

PRESENT POSITION

Consultant in Toxicologic, Pharmacologic & Experimental Pathology
President, Research Pathology Services, Inc.
438 East Butler Avenue, New Britain, PA 18901
Telephone: 215-345-7070 Fax: 215-345-4326 e-mail: WRBRPS@concentric.net

EDUCATION

	<u>Degree</u>	<u>Year</u>
Pennsylvania State University University Park, Pennsylvania	B.S.	1961
New York State College of Veterinary Medicine Cornell University Ithaca, New York	D.V.M.	1964
New York State College of Veterinary Medicine Cornell University - Veterinary Pathology Ithaca, New York	Ph.D.	1967

PREVIOUS POSITIONS

Independent Consultant in Toxicologic, Pharmacologic and Experimental Pathology	1973 - present
Director of Toxicology and Pathology Merck Institute for Therapeutic Research West Point, Pennsylvania	1972 - 1973
Director of Pathology Merck Institute for Therapeutic Research West Point, Pennsylvania	1970 - 1972
Senior Research Fellow of Pathology Merck Institute for Therapeutic Research West Point, Pennsylvania	1969 - 1970
Research Fellow of Pathology Merck Institute for Therapeutic Research West Point, Pennsylvania	1967 - 1969

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W. Ray Brown, D.V.M., Ph.D.

PREVIOUS POSITIONS (Continued)

Laboratory Instructor, Veterinary Pathology 1964 - 1967
New York State College of Veterinary Medicine
Cornell University
Ithaca, New York

NIH Trainee in Veterinary Pathology 1964 - 1967
New York State College of Veterinary Medicine
Cornell University
Ithaca, New York

ACADEMIC AFFILIATION

Assistant Professor, Department of Pathology
Jefferson Medical College
Thomas Jefferson University
Philadelphia, Pennsylvania

PROFESSIONAL SOCIETIES

American College of Veterinary Pathologists
American Veterinary Medical Association
Pennsylvania Veterinary Medical Association
International Academy of Pathology
American Society of Veterinary Clinical Pathologists
Society of Toxicology
Society of Toxicologic Pathologists
International Union of Pharmacology (Section of Toxicology)
Charles Louis Davis, DVM Foundation
Sigma Xi
Phi Zeta National Veterinary Honorary Society
Omega Tau Sigma Professional Veterinary Society

OTHER SPECIALTY

Director, Electron Microscopy Laboratory
Department of Safety Assessment
Merck Institute for Therapeutic Research
West Point, Pennsylvania

CONTINUING EDUCATION/PROFESSIONAL MEETINGS

American College of Veterinary Pathologists Annual Meeting Baltimore, MD - October 31-November 3	1989
Mouse Pulmonary Carcinogenesis Symposium National Toxicology Program - NIEHS Research Triangle Park, NC - March 27-28	1990
Society of Toxicology Annual Meeting Miami Beach, FL - February 12-15	1990
American College of Veterinary Pathologists Annual Meeting Phoenix, AZ - December 10-13	1990
Society of Toxicology Annual Meeting Dallas, TX - February 25-28	1991
Drug Information Association Recent Considerations on the Design, Interpretation and Evaluation of Rodent Carcinogenicity Studies Rockville, MD - September 30-October 1	1991
American College of Veterinary Pathologists Annual Meeting Orlando, FL - December 9-13	1991
Society of Toxicology Annual Meeting Seattle, WA - February 24-27	1992
Society of Toxicologic Pathologists XI International Symposium Toxicologic Pathology of the Hematopoietic System Phoenix, AZ - May 31-June 4	1992
National Research Council Role of Toxicologic Pathology in Safety Assessment Washington, DC - February 8-9	1993

Curriculum Vitae - 2004

W. Ray Brown, D.V.M., Ph.D.

CONTINUING EDUCATION/PROFESSIONAL MEETINGS (Continued)

Society of Toxicology Annual Meeting New Orleans, LA - March 15-19	1993
Society of Toxicologic Pathologists XII International Symposium Regulations Governing Toxicologic Pathology Washington, DC - June 27-July 1	1993
Growth Factors and Tumor Promotion: Implications for Risk Assessment (7 th International Conference on Carcinogenesis and Risk Assessment) Austin, TX - December 1-4	1993
International Life Sciences Institute 5 th Workshop on Mouse Liver Tumors Arlington, VA - November 7-9	1994
Society of Toxicology Annual Meeting Baltimore, MD - March 5-9	1995
Society of Toxicologic Pathologists 14 th International Symposium San Diego, CA - June 11-15	1995
Staging of Rat Testes Two-day short course by Dr. L. Russell Rohm and Haas Company Spring House, PA - February 26-27	1996
Mid-Atlantic Chapter, Society of Toxicology Spring Scientific Meeting Kenilworth, NJ - April 25	1996
Society of Toxicologic Pathologists 15 th International Symposium Toxicologic Pathology and Risk Assessment St. Louis, MO - June 9-13	1996
American College of Toxicology Annual Meeting Valley Forge, PA - November 11-13	1996

CONTINUING EDUCATION/PROFESSIONAL MEETINGS (Continued)

Society of Toxicology Annual Meeting Cincinnati, OH - March 9-13	1997
Society of Toxicologic Pathologists 16 th International Symposium Toxicologic Pathology of the Kidney and Urinary Bladder Beaver Creek, CO - June 22-26	1997
American College of Veterinary Pathologists Annual Meeting Albuquerque, NM - November 16-21	1997
Society of Toxicology Annual Meeting New Orleans, LA - March 14-18	1999
Society of Toxicology Annual Meeting Philadelphia, PA - March 19-23	2000
Society of Toxicology Annual Meeting Nashville, TN - March 17-21	2002
Charles Louis Davis, DVM Foundation Alternatives to the Rodent Biosassay in Assessing Carcinogenicity New Brunswick, NJ - April 5	2002
American College of Veterinary Pathologists Annual Meeting New Orleans, LA - December 7-11	2002
Charles Louis Davis, DVM Foundation Dermatopathology Symposium New Orleans, LA - December 7	2002
American College of Veterinary Clinical Pathologists Annual Meeting New Orleans, LA - December 7-11	2002

CONTINUING EDUCATION/PROFESSIONAL MEETINGS (Continued)

Charles Louis Davis, DVM Foundation
Gastrointestinal Toxicologic Pathology
New Brunswick, NJ - April 25

2003

PATHOLOGY WORKING GROUP (PWG) PARTICIPANT

- National Toxicology Program
- Dioxin- Re-evaluation of hepatic tumors from the 1978 Kociba rat study (1990)
- Dioxin- Participant at the Banbury Conferences (Cold Spring Harbor) on the results of the re-evaluation of the rat liver tumors (1990)
- PCBs-Re-evaluation of the rodent liver tumors from the Aroclor 1254 and 1260 and Clophen A30 and A60 chronic/oncogenicity rat studies (1991)
- Several industrial-sponsored PWGs on chemicals, agrochemicals and pharmaceuticals

HISTOPATHOLOGY PEER REVIEW

Peer review of histopathology slides and data have been and are being performed for several domestic and international pharmaceutical and chemical companies, trade groups, and consortiums on toxicity and carcinogenicity studies.

EXPERIENCE IN TOXICOLOGY AND PATHOLOGY

Activities as a consultant in toxicologic and pharmacologic pathology have included the design, supervision, evaluation, and reporting of toxicity and carcinogenicity studies involving various chemical and potential therapeutic or biologic substances. Laboratory animals used in these studies include rodents (rats, mice, hamsters, guinea pigs, rabbits), cats, dogs, non-human primates (Rhesus, cynomolgus and African green monkeys and marmosets), various avian species (chickens, ducks, turkeys, quail), and miniature swine. The types of experiments in the areas of involvement have been oral toxicity experiments, inhalation exposure studies, parenteral studies (intravenous, intramuscular, dermal, ocular and subcutaneous irritation studies), carcinogenicity experiments, reproduction/teratology studies, and histologic evaluation for safety tests of various vaccine preparations.

Responsibilities in these various experiments have included evaluation, interpretation and detailed reporting of antemortem data (clinical signs of toxicologic and pharmacologic effects), electrocardiology, hematology, serum biochemistry, urinalysis, and postmortem data (organ weights), gross and microscopic tissue examinations, histochemistry and electron microscopy.

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W. Ray Brown, D.V.M., Ph.D.

Reporting of the above data has included preparation of summarizations of the methods and results, conclusions, and safety assessment of the various agents based on the results. These reports are written in appropriate formats for submission to international and domestic regulatory agencies, e.g., suitable for submission for Investigational New Drug (IND) and New Drug Application (NDA) with the Food and Drug Administration, U. S. Department of Agriculture, National Cancer Institute and Environmental Protection Agency.

In addition to primary project participation and monitoring, peer review experience has included selection as the Society of Toxicology Task Force pathologist to perform an independent pathology review of the urinary bladder and hepatic neoplasms in the FDA/NCTR ED₀₁ mouse carcinogenicity study and participation in several select panels and committees for review and interpretative opinions on pathology slides and data for various sponsors, as well as international and domestic regulatory agencies. Many of these reviews and representations have involved findings and interpretation of hepatic and endocrine toxicity and potential oncogenicity.

Curriculum Vitae - 2004

W. Ray Brown, D.V.M., Ph.D.

PUBLICATIONS:

1. Christian, M.S. and Brown, W.R., Control Primordial Follicle Counts in Multigeneration Studies in CRL Sprague-Dawley ("Gold Standard") Rats, *Toxicologic Sciences*, 66:1-S, 233 (2002).
2. York, R.G., Brown, W.R., Girard, M.F., and Dollarhide, J.S., Two-Generation Reproduction Study of Ammonium Perchlorate in Drinking Water (in press).
3. Cruzan, G., Cushman, J.R., Andrews, L.S., Granville, G.C., Johnson, K.A., Bevan, C., Hardy, C.J., Coombs, D.W., Mullins, P.A. and Brown, W.R., Chronic Toxicity/Oncogenicity Study of Styrene in CD-1 Mice by Inhalation Exposure for 104 Weeks. *J. Applied Toxicology* 21:185-198 (2001).
4. Cruzan, G., Cushman, J.R., Andrews, L.S., Granville, G.C., Johnson, K.A., Hardy, C.J., Coombs, D.W., Mullins, P.A. and Brown, W.R., Chronic Toxicity/Oncogenicity Study of Styrene in CD Rats by Inhalation Exposure for 104 Weeks. *Toxicol. Sci.* 46:266-281 (1998).
5. Forbes, P.D., Takizawa, T., Hashimoto, K., Yamashita, S., Hoberman, A.M., Sambuco, C.P., Brown, W.R., and Parker, R.M., 78-Week Photocarcinogenesis Study of Grepafloxacin and Comparator Articles Administered Orally to Hairless Mice. *Toxicological Sciences*, 42:1-S, 50-51, 1998.
6. Sambuco, C.P., Powers, W. J., Dempster, M., Hoberman, A.M., Forbes, P.D., Brown, W.R., Stahle, P.L., Streeter, A.J. and Parker, R.M., 13-Week Subchronic Phototoxicology Study of levofloxacin, A Quinolone Antibiotic, Administered Orally to Hairless Mice. *Toxicological Sciences*, 42:1-S, 51, 1998.
7. Parker, R.M., Powers, W.J., Dempster, A.M., Hoberman, A.M., Sambuco, C.P., Brown, W.R., Stellar, S.M., Streeter, A.J. and Forbes, P.D., 120Month Oral (Gavage) Photocarcinogenicity Study of Levofloxacin in Hairless Mice. *Toxicological Sciences*, 42:1-S, 51, 1998.
8. Manley, A., Brown, W.R., and Mennear, J.: Dichlorvos and Mononuclear Cell Leukemia in Fischer 344 Rats: Lack of Effect of Chronic Administration on Progression of the Disease. *International Journal of Toxicology*, 16:1-7, 1997.
9. Brown, W. R.: Comparative Histopathologic Evaluation of Animal Studies: Murine Studies with L-tryptophan and Constituents. *Journal of Rheumatology* (23, Supplement 46), 99-110 (1996).
10. Patterson, D.R., Hamlin, M.H., Hottendorf, G.H., Gough, A. and Brown, W.R., Proliferative lesions of the adrenal glands in rats. In *Guides for Toxicologic Pathology, STP/ARP/AFIP* (1995).
11. Brown, W. R., Fetter, A. D., Van Ryzin, R.J. and Langloss, J.M.: Effects of Calcitonin on the Rat Pituitary. *Toxicologic Pathology* 21(1): 81-86 (1993).

Curriculum Vitae - 2004

W. Ray Brown, D.V.M., Ph.D.

PUBLICATIONS (Continued)

12. McGee, J. H., Butler, W.H., Willigan, D. A., Brown, W. R., and Sofia, R. D.: Critique of the Toxicology and Carcinogenesis Studies of Iodinated Glycerol in F344/N Rats and B6C3F1 Mice. *Regulatory Toxicology and Pharmacology* 18, 169-180 (1993).
13. Newberne, P. M., Carlton, W. W., and Brown, W. R.: Histopathological Evaluation of Proliferative Liver Lesions in Rats Fed *trans*-Anethole in Chronic Studies. *Food and Chemical Toxicology* 27(1): 21-26 (1989).
14. Hagan, J. V., Fisher, J. R., Brown, W. R. and Baldwin, R. C.: Comparison of the Two-Week Whole-Body and Nose-Only Inhalation Toxicity of Mancozeb in Rats. *The Toxicologist* 7(1): 196 (1987).
15. Mizens, M., Brown, W. R., Laveglia, J., Killeen, J. C. and Ignatoski, J. A.: Combined 30-Day Feeding Study and One-Generation Reproduction Study in Rats with Ethyl 5-Cyano-3,4-Diphenyl-6-OXO-1[6H]-Pyridazine-acetate (DS-29399). *The Toxicologist* 4:17 (1984).
16. Ford, W. H., Auletta, C. S., Brown, W. R., Laveglia, J., Killeen, J. C. and Ignatoski, J. A.: A 30-Day Toxicity Study in Dogs with Ethyl 5-Cyano-3,4-Diphenyl-6-OXO-1[6H]-Pyridazine-acetate (DS-29399). *The Toxicologist* 4:18 (1984).
17. Gongwer, L. E., Auletta, C. S., Rinehart, W. E., and Brown, W. R.: Mannitol II: Lifetime Feeding Study of A-132-1320 in Three Strains of Female Rats, Report of ICI Americas, Inc., Wilmington, DE and Bio/dynamics, Inc., East Millstone, NJ. Docket No. 74-21185 (4 volumes), Dockets Management Branch, FDA, Rockville, MD (1978).
18. Emery, J. B., House, J. A., and Brown, W. R.: Cross-Protective Immunity to Canine Adenovirus Type 2 by Canine Adenovirus Type 1 Vaccination. *American Journal of Veterinary Research* 39(11): 1778-1783 (1978).
19. Goldlust, M. B., Rich, L. G., and Brown, W. R.: Immune Synovitis in Rabbits. Effects of Differing Schedules for Intra-articular Challenge with Antigen. *American Journal of Pathology* 91(2): 329-343 (1978).
20. Apostolou, A., Saidt, L., and Brown, W. R.: Effect of Overnight Fasting of Young Rats on Water Consumption, Body Weight, Blood Sampling, and Blood Composition. *Laboratory Animal Science* 26(6): [Part 1], 959-960 (1976).
21. Zwickey, R. E., Brown, W. R. *et al.*: Preclinical Toxicology Studies of Carbidopa and Levodopa. *Toxicology and Applied Pharmacology* 29: 181-195 (1974).
22. Brown, W. R., Rubin, L., Hite, M. and Zwickey, R. E.: Experimental Papilledema in the Dog Induced by a Salicylanilide. *Toxicology and Applied Pharmacology* 21(4): 532-541 (1972).
23. Brown, W. R.: Significance of Spontaneous Diseases of the Central Nervous System in Laboratory Animals used in Pharmacology Research. *The Laboratory Animal in Drug Testing. Fifth International Committee on Laboratory Animals Symposium, Hanover Germany, 1972.*

Curriculum Vitae - 2004

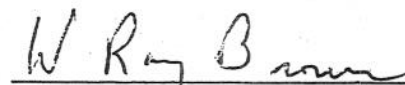
W. Ray Brown, D.V.M., Ph.D.

PUBLICATIONS (Continued)

24. Watson, L. S., Riley, R. L., Connelly, M. T., Russo, H. F., Brown, W. R. and Baer, J. E.: The Electrolyte Excretion Pattern of Amiloride Following Ureteral Retrograde Intraluminal Injection. *Federation Proceedings* 30: 337 (1971).
24. VanArman, C. G., Carlson, R. P., Brown, W. R. and Itkin, A.: Indomethacin Inhibits the Local Schwartzman Reaction. *Proceedings of the Society for Experimental Biology and Medicine*, 134(1): 163-168 (1970).
25. Whitlock, R. H. and Brown, W. R.: Chronic Cholangiohepatitis in the Dairy Cow. *Cornell Veterinarian* LIX(4): 515-524 (1969).
26. Brown, W. R., Krook, L. and Pond, W. G.: Atrophic Rhinitis in Swine. A nutritional disease. *Der Tierzuchter* 20: 546-647 (1968).
27. Scott, M. L., Olson, G., Krook, L., Brown, W. R.: Selenium-responsive Myopathies of Myocardium and of Smooth Muscle in the Young Poult. *Journal of Nutrition* 91(4): 573-583 (1967).
28. Brown, W. R., Krook, L., Pond, W. G.: Atrophic Rhinitis in Swine. Etiology, Pathogenesis and Prophylaxis. *Cornell Veterinarian* LVI, Supplement No. 1, 1-128 (1966).
29. Brown, W. R., Krook, L. and Pond, W. G., A New Look at Atrophic Rhinitis. *Modern Veterinary Practice* 47(9): 39-45, August 1966.
30. Krook, L., Pond, W. G. and Brown, W. R.: Dietary Calcium and Phosphorus and Atrophic Rhinitis. I. Nutrition. *Proceedings of the 57th Annual Meeting of the American Society for Animal Science*. *J. Animal Science* 24: 892 (1965).
31. Pond, W. G., Krook, L. and Brown, W. R.: Dietary Calcium and Phosphorus and Atrophic Rhinitis. *Proceedings for the 1965 Cornell Nutrition Conference for Feed Manufacturers*. Buffalo, New York (1965).

Book Chapter

1. Brown, W. R., Implications of the Reexamination of the Liver Sections from the TCDD Chronic Rat Bioassay in "Biological Basis for Risk Assessment of Dioxins and Related Compounds", Banbury Report 35, Gallo, M. A., Scheuplein, R. J., and van der Heijden, C. A. (eds.), Cold Spring Harbor Laboratory Press, 1991, pp. 13-26.


W. Ray Brown, DVM, PhD
Veterinary Pathologist

May 17, 2004
Date

1 June 2003

CURRICULUM VITAE

Name: Ernest E. McConnell, DVM, MS (Path)
3028 Ethan Lane
Raleigh, NC 27613

Date & Place of Birth: November 14, 1937
Orrville, Ohio

Citizenship: United States

Education:

1955 - 1957 - Preveterinary Medicine, The Ohio State University
1957 - 1961 - D.V.M., The Ohio State University
1964 - 1966 - M.S., Department of Pathology, Michigan State University
1965 - 1967 - Resident, Veterinary Pathology Division, Armed Forces Institute of Pathology,
Washington, DC

Board Certification:

Diplomate, American College of Veterinary Pathologists, 1968
Diplomate, American Board of Toxicology, 1980

Brief Chronology of Employment:

Jun 1961 - Aug 1961 Small Animal Practitioner, Becker Small Animal Hospital, Columbus, OH
Aug 1961 - Aug 1961 First Lieutenant, U.S. Air Force, Gunter AFB, Montgomery, AL
Oct 1961 - Sep 1964 Base Veterinarian, Hill Air Force Base, Ogden, UT
Sep 1964 - Sep 1965 Graduate Student, Department of Pathology, Michigan State University, East Lansing, MI
Sep 1965 - Oct 1967 Resident, Veterinary Pathology Division, Armed Forces Institute of Pathology, Washington, DC
Oct 1967 - May 1969 Veterinary Pathologist, Aerospace Pathology Branch, Armed Forces Institute of Pathology, Washington, DC
May 1969 - Aug 1972 Veterinary Pathologist, Geographic Pathology Division, Armed Forces Institute of Pathology, Washington, DC with duty in the Pathology Department, Veterinary Research Institute, Onderstepoort, Republic of South Africa

Aug 1972 - Aug 1974 Chief, Pathology Branch, Toxic Hazards Div., 6570 Aerospace Medical Research Lab.,
Wright-Patterson AFB, OH

Aug 1974 - Nov 1978 Veterinary Pathologist (Grade 05), U.S. Public Health Service, Research Pathologist and
Head, Comparative Pathology Section, National Institute of Environmental Health Sciences (NIEHS), Research Triangle Park, NC.

Nov 1978 - Jan 1984 Veterinary Director (Grade 06), NIEHS, Chief, Chemical Pathology Branch, Toxicology
Research and Testing Program, Research Triangle Park, NC

Sep 1983 - Jan 1985 Veterinary Director (Grade 06). NIEHS, Acting Director, Toxicology Research and Testing Program, Research Triangle Park, NC

Jan 1985 - Oct 1988 Veterinary Director (Grade 06). NIEHS, Director, Division of Toxicology Research and
Testing Program, Research Triangle Park, NC

Oct 1988 - present President, ToxPath, Inc., 3028 Ethan Lane, Raleigh, NC

Military Service:

Aug 1961 - Aug 1974: U.S. Air Force

Aug 1974 - Oct 1988: U.S. Public Health Service

Current Society Memberships:

American Veterinary Medical Association

American Association for the Advancement of Science

American College of Veterinary Pathologists

American Board of Toxicology

American Registry of Pathology, AFIP

Commissioned Officers Association, U.S. Public Health Service

North Carolina Chapter of the Society of Toxicology

Society of Toxicology

Society of Toxicologic Pathologists

Charter Member, Alumni Society, Armed Forces Inst. of Pathology

Honors & Special Scientific Recognition:

Distinguished Citizens Award, Hill AFB, Utah, 1964

National Defense Service Medal, 1967

U.S. Air Force Meritorious Service Medal, Wright-Patterson AFB, Ohio, 1974

Adjunct Associate Professor, School of Veterinary Medicine, North Carolina State University, 1978 to present

U.S. Public Health Service Commendation Medal, NIH, Washington, DC, 1978

Study Section-Agent Orange, Veterans Administration, June 1982

Chairman, Natural Exposure Study of Animals in Environmental Health Research Workshop, National Research

Council, National Academy of Sciences, April 1985

U.S. Public Health Outstanding Service Medal, NIH, Washington, DC, 1985
 Panelist-Speaker, Conference on the Implications of the Bhopal Tragedy, The Workers Policy Project, Newark, New Jersey, March 1985
 Task Force Leader, Study of Chemical Tracking Agent (NPPD) used by the Soviet KGB, Moscow, 1985
 Panel Member, IARC Working Group on the Evaluation of the Carcinogenic Risk of Chemicals to Humans -
 Some Chemicals Used in Plastics and Elastomers, Lyon, France, June 1985
 Study Director for the NTP Methyl Isocyanate Study, 1985
 Board Member, American Board of Toxicology, 1985-1989
 Panel Member, Refractory Ceramic Fiber Animal Studies, TIMA, 1986
 Panel Member, IARC Working Group on the Evaluation of the Carcinogenic Risk of Chemicals to Humans - Silica
 and Some Silicates, Lyon, France, June 1986
 Panel Member, DHHS Committee to Coordinate Environmental and Related Programs "Report on Cancer Risks
 Associated with the Ingestion of Asbestos", 1987.
 President, American Board of Toxicology, 1987-1988
 Panel Member, Health Consequences of Occupational Exposure to Man-Made Mineral Fibers, TIMA, London, England,
 January 1987
 Panel Member, IARC Working Group to update IARC Monographs: Chemicals and Industrial Processes Associated with
 Cancer in Humans, Lyon, France, March 1987
 Vice Chairman, IARC Working Group on Man-Made Mineral Fibers and Radon, Lyon, France, June, 1987
 Panel Member/Rapporteur, IPCS/MARC Task Group Meeting on Man-Made Mineral Fibers, London, England,
 September 1987
 Distinguished Alumnus, College of Veterinary Medicine, The Ohio State University, June, 1988
 Panel Member, National Research Council, Board on Environmental Studies and Toxicology, Subcommittee on
 "Animals as Monitors of Environmental Hazards", 1987-1989
 Co-Chairman, Review of EPA Cancer Assessment Guidelines, 1988-1989
 Consultant, SAB (Drinking Water Committee and Environmental Health Committee, Environmental Protection Agency,
 1988.
 Member, Committee on Toxicology, National Research Council, Board on Environmental Studies on Toxicology,
 1989-1994.
 Lecturer, Brookings Institute, 1989
 Panel Member (ad hoc), EPA-FIFRA Scientific Advisory Panel, 1989
 Panel Member/Rapporteur, IPCS/MARC Task Group Meeting on Benzene, Hannover, Germany, December, 1991.
 Panel Member, EPA-FIFRA Scientific Advisory Panel, 1992-2000
 FDA Group Recognition Award, Nitrofurantoin Hearing Team, 1992.
 Panel Member, IPCS Task Group Meeting on Synthetic Organic Fibers, London, England, September, 1992.
 Panel Member, WHO European Programme for Occupational Health, "Validity of Methods for Assessing the
 Carcinogenicity of Man-Made Fibers", Copenhagen, Denmark, 1992
 Chairman, EPA-FIFRA Scientific Advisory Panel, 1993-
 Member, EPA Science Advisory Board Executive Committee, 1993-1999

Panel Member, EPA Science Advisory Board, Dioxin Review Committee (Health Panel), 1995

Panel Member/Rapporteur, IPCS/MARK Task Group Meeting on Phosgene, London, England, March, 1996.

Panel Member, IPCS/MARK Task Group Meeting on Chloroethers, London, England, March, 1996.

Panel Member, National Research Council, Commission on Life Sciences, Subcommittee on "Toxicological and Performance Aspects of Oxygenated Motor Vehicle Fuels", 1996

Panel Member, EPA Scientific Advisory Board, Committee on Environmental Health, Ad Hoc member for Neurotoxicology Guidelines; Chair - Thyroid Carcinogenesis Guidelines, 1996

Panel Member, EPA Food Quality Protection Act Advisory Board, 1996

Member, ILSI Risk Science Institute Working Group on Dose Selection, 1996

Panel Member, EPA Science Advisory Board, EPA Proposed Guidelines for Carcinogenic Risk Assessment, 1997

Panel Member, IPCS Workshop on Issues in Cancer Risk Assessment, Hannover, Germany, January 1998 and January, 1999.

CoChair, EPA SAB/SAP Joint Meeting 'Testing of Pesticides in Human Subjects', Dec 1998 and Nov 1999.

CoChair, EPA SAB/SAP Joint Meeting 'Endocrine Disruptors', March 1999.

Panel Member, National Research Council, Commission on Life Sciences, Subcommittee on "Review of the US Navy's Exposure Limits for Manufactured Vitreous Fibers", 1999-2000.

Invited Expert Testimony on Trichloroethylene, Australian Solicitor General, Melbourne, Australia, Nov. 1999.

Panel Member, International Conference of the World Health Organization. "Advancing Knowledge on Regulating Tobacco Products", Oslo, Norway, February, 2000.

Moderator, 2000 Society of Toxicology "Issue" Session, "The Value and Ethics of Using Human Data for the Registration of Pesticides", Philadelphia, PA, March 2000.

Chair, Review of the Toxicology Program, Lovelace Respiratory Research Institute, Albuquerque, NM, April 2001.

Rapporteur, ILSI Agricultural Chemical Safety Assessment, Workgroup #1, April, 2001.

Session Chair, Risk Assessment Methods, "2001 Asbestos Health Effects Conference", Oakland, CA, May 2001.

Member, Lovelace Respiratory Research Institute's "Research Programs Oversight Committee", 2002-

Member, ATSDR Expert Panel on Health Effects of Asbestos and Synthetic Fibers (SVF: The Influence of Fiber Length. New York, NY. 29-30 October 2002.

Testimony before NRC/NAS Committee on the Use of Third Party Toxicity Research with Human Research Participants. Washington, DC. 19 March 2003.

Member, International Symposium on the Health Hazard Evaluation of Fibrous Particles Associated with Taconite and the Adjacent Duluth Complex.

Member, EPA Asbestos Mechanisms of Toxicity Workshop, Chicago, IL. 12-13 June 2003.

Chair, Subcommittee on Emergency and Continuous Exposure Guidance Levels for Selected Submarine Contaminants. National Academy of Sciences. 2003-2005.

Member, ILSI HESI Technical Committee on Agricultural Chemical Safety Assessment. 2003-2004.

Editorial Boards:

Medical Research Council of Canada, 1982-1984
Environmental Health Perspectives, 1983-1990
Drug and Chemical Toxicology, 1986-1994
Fundamental and Applied Toxicology, 1989-1995
Inhalation Toxicology, 1995-

Reviewer:

Science
Annals of Occupational Hygiene
Toxicological Sciences

Papers Published:

1. McConnell, E.E.: Case for diagnosis. Yaba monkey virus. Military Medicine 132:838, 869, 1967.
2. McConnell, E.E.: Garner, F.M. and Kirk, J.H.: Hartmanellosis in a bull. Pathologia Veterinaria 5:1-6, 1968.
3. McConnell, E.E., Cashell, I.G. and Garner, F.M.: Visceral leishmaniasis with ocular involvement in a dog. JAVMA 156:197-203, 1970.
4. McConnell, E.E., Van Rensburg, I.B.J. and Van Wyk, J.A.: A case of adenocarcinoma of the olfactory mucosa of a sheep of possible infectious origin. J.S. African Vet. Med. Assoc. 41:9-12, 1970.
5. Van Rensburg, I.B.J., Roos, C.J. and McConnell, E.E.: Diverticulosis in a cow. J.S. African Vet. Med. Assoc. 41:76, 1970.
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3. "Experiences with Animals at the Kruger National Park," Veterinary Faculty, Onderstepoort, September 1970.
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20. "The Toxicology of Dibenzofurans and Dibenzodioxins," 45th Meeting of the Interagency Collaborative Group on Environmental Carcinogenesis, National Cancer Institute, Bethesda, MD, May 1979.
21. "Comparative Toxicity of Technical and Analytical Pentachlorophenol in Cattle," NIEHS Science Fair, North Carolina State University, Raleigh, NC, June 1979.
22. "The Lesions Induced by Related Halogenated Aromatics in Various Species of Animals," 1979 Wildlife Disease Association Meeting, University of Oklahoma, Norman, OK, August 1979.
23. "Essentials of Routine Pathotoxicology Evaluation," Consensus Development of Immunotoxicology Meeting, NIEHS, Research Triangle Park, NC, November 1979.
24. "Toxicopathological Syndrome Induced by Related Halogenated Polycyclic Hydrocarbons," Ohio Agricultural Research and Development Center, Wooster, OH, August 1980.
25. "The National Toxicology Program," Conservative Trends in Laboratory Animal Science, Eighth Annual District IV AALAS Seminar, Raleigh, NC, March 1981.
26. "NTP Testing Results with Emphasis on Bioassays of DEHP, DEHA and Butyl Benzyl Phthalate," Phthalate Ester Conference, Washington, DC, June 1981.
27. "Effects of Subchronic Chlordecone Exposure on the Fertility of Female Rats," North Carolina Chapter of the Society of Toxicology, Research Triangle Park, NC, January 1982.
28. "Evaluation of Pathology Requirements," Third Annual Meeting of the American College of Toxicology, Washington, DC, December 1982.
29. "NIEHS Asbestos Feeding Study - Hamsters and Rats," Summary Workshop on Ingested Asbestos, USEPA, Cincinnati, OH, November 1982.
30. "Histopathology Workload in Carcinogenesis Bioassays - How much is necessary?" The Toxicology Forum Annual Winter Meeting, Arlington, VA, February 1983.
31. "Proliferative Lesions of the Exocrine Pancreas in Male F344 Rats - The Effect of Corn Oil," The Toxicology Forum 1983 Annual Winter Meeting, Arlington, VA, February 1983.
32. "Toxic Oil Syndrome," WHO Meeting, Madrid, Spain, March 1983.
33. "An Improved Protocol for Bioassay Studies," 2nd International Symposium of the Society of Toxicologic Pathologists, Crystal City, VA, May 1983.
34. "Chronic Toxicity of PCBs and Related Compounds in Various Animal Species," CCERP Conference on Potential Health Effects of Polychlorinated Biphenyls and Related Persistent Halogenated Hydrocarbons, NIEHS, Research Triangle Park, NC, September 1983.
35. "Toxicity of PCBs, Polychlorinated Dibenzofurans and Dibenzodioxins," International Workshop on Occupational Hazards Caused by Polychlorinated Biphenyls (PCBs) and Chlorobenzenes in Capacitors and Transformers, Espoo, Finland, September 1983.

36. "Dioxins in the Environment," Human Health and Toxicity Workshop, Michigan State University, East Lansing, MI, December 1983.
37. "Toxic and Carcinogenic Responses in Experimental Animals Administered Dibenzo-p-dioxins and Dibenzofurans," Federation of American Societies for Experimental Biology, St. Louis, MO, April 1984.
38. "Lesions in Animals Exposed to EDB," North Carolina Chapter of the Society of Toxicology Spring Meeting, Durham, NC, April 1984.
39. "Studies on the Bioavailability in Guinea Pigs of Dioxin in Soil," Society of Toxicology Meeting, Atlanta, GA, March 1984.
40. "NTP Program Update," European Toxicology Forum, Geneva Switzerland, September 1984.
41. "The Response of NTP to the Recommendations of the Ad Hoc Panel," 15th Conference on Environmental Toxicology, Dayton, Ohio, October 1984.
42. "National Toxicology Program Status and New Initiatives," The Toxicology Forum 1985 Annual Winter Meeting, Washington, D.C., February 1985.
43. "Relevant Non-Statistical Bioassay Issues," Symposium on long-term Animal Carcinogenicity Studies: A Statistical Perspective, American Statistical Association, Washington, D.C., March 1985.
44. "The Short and Long Term Health and Environmental Impacts," Conference on the Implications of the Bhopal Tragedy, The Workers Policy Project, Newark, New Jersey, March 1985.
45. "Ad Hoc Report on Chemical Carcinogenesis Testing and Evaluation," Environmental Health Seminar, University of Cincinnati, Ohio, May 1985.
46. "Challenges and Opportunities for Pathologists in the National Toxicology Program," ILSI Histopathology Seminar on the Reproductive System of Laboratory Animals, Hanover, Germany, September 1985.
47. "The Justification for Combining Benign and Malignant Tumors (or Not Combining Them) in Statistical Analysis Lesions in the Rat," ILSI Histopathology Seminar on the Reproductive System of Laboratory Animals, Hanover, Germany, September 1985.
48. "Methyl Isocyanate - Preliminary Study Results," ILSI Histopathology Seminar on the Reproductive System of Laboratory Animals, Hanover, Germany, September 1985.
49. "Overview of the National Toxicology Program in the United States and Findings in Selected Studies," C.L. Davis Sixth Annual Symposium, Cheshire, England, September 1985.
50. "Carcinogenesis Studies Results from the U.S. National Toxicology Program and the U.S. National Cancer Institute: 1976-1985," Collegium Ramazzini, Living in a Chemical World, Bologna, Italy, October 1985.
51. "Methylene Chloride, Methylchloroform and Trichloroethylene," Collegium Ramazzini, Living in a Chemical World, Bologna, Italy, October 1985.
52. "Liver Foci Formation During Aflatoxin Carcinogenesis in Rat: A Quantitative Study," Collegium Ramazzini, Living in a Chemical World, Bologna, Italy, October 1985.

53. "The Toxicity of Methyl Isocyanate in Rats and Mice," New Delhi and Madras, India, February 1986.
54. "Response to the Integration of Recommendations of the Ad Hoc Panel on Carcinogenesis Testing and Evaluation," Society of Toxicology Annual Meeting, New Orleans, La., 1986.
55. "NTP Strategy for Combining Neoplasms for Evaluation of Carcinogenesis Studies," Office of Pesticides & Toxic Substances Seminar Program, EPA, Washington, D.C., April 1986.
56. "Environmental Toxicology in the Mid-Eighties: Interfacing with the Toxicologist," FASEB 70th Annual Meeting, St. Louis, Missouri, April 1986.
57. "NTP's Response to the Ad Hoc Panel Recommendations," FEMA Annual Meeting, Palm Beach, Florida, April 1986.
58. "Studies on the Toxicity of Methyl Isocyanate, the Chemical Responsible for the Bhopal Disaster," North Carolina State University Microbiology Seminar Series, Raleigh, North Carolina, April 1986.
59. "Options for Aggregation of Incidence Data," Interdisciplinary Discussion Group on Carcinogenicity Studies (ILSI NF), Chapel Hill, North Carolina, June 1986.
60. "NTP Evaluation of Experimental Studies," The Toxicology Forum 1986 Annual Summer Meeting, Aspen, Colorado, July 1986.
61. "NTP Response to the Report of the Ad Hoc Panel on Chemical Carcinogenesis Testing and Evaluation," The Toxicology Forum 1986 Annual Summer Meeting, Aspen, Colorado, July 1986.
62. "Inhalation Study of Wollastonite in Rats," SAE's 4th Annual Colloquium on Brakes, Atlantic City, NJ, October, 1986.
63. "Considerations in Determining the Estimated Maximum Tolerated Dose," Pharmaceutical Manufacturers' Association Drug Safety Subsection meeting, Nashville, TN, November, 1986.
64. "Current Status of the Issue of Maximum Tolerated Dose (MTD) within the U.S. National Toxicology Program," 26th Annual Meeting of the Society of Toxicology, Washington, D.C., February, 1987.
65. "Federal Perceptions of Board Certification," Spring Meeting and Reception for Members of Association of Government Toxicologists, Bethesda, MD, May, 1987.
66. "Gavage Studies in Mice and Rats," Paradichlorobenzene Symposium (Sponsored by CIIT and Chlorobenzene Producers Association), Washington, D.C., July 1987.
67. "NTP Database," Meeting of the Ad Hoc Working Group on Carcinogenicity Testing, Washington, D.C., July 1987.
68. Rapporteur at Mouse Liver and Rat Kidney Tumors Workshop, EPA Science Advisory Board, Environmental Health Committee and Halogenated Organics Subcommittee, Washington, D.C., August 1987.
69. "Toxicology Learned the Hard Way," Principles of Toxicology, Boston Univ., August, 1988.

70. "Mouse Liver Tumors: The Problem," Mouse Liver Carcinogenesis Conference, Austin, TX, November, 1988.
71. "Biology Issues in the Statistical Evaluation of Rodent Carcinogenicity Studies," Course on Biostatistics, International Agency for Research on Cancer, Lyon, France, December, 1988.
72. "Pitfalls in Carcinogenesis Testing," North Carolina State University, Graduate Course VMS 643 "Rodent Toxicologic Pathology", December, 1988.
73. "Maximum Tolerated Dose: The Debate," Brookings Institute, Washington, D.C., May, 1989 and Research Triangle Chapter, Society for Risk Analysis, Research Triangle Park, NC, May, 1989.
74. "The Search for Adequate Bioassay Data: Crude Biology Versus Statistics," Trace Substances in Environmental Health, Annual Meeting of the Society for Environmental Geochemistry and Health, Cincinnati, OH, May, 1989.
75. "Animal Bioassays: Using Protocols and Interpreting Results," Regional Risk Assessment Workshops, Workshop 1, Chicago, IL, June, 1989; Atlanta, GA, December 1989.
76. "Target Organ Toxicity in Carcinogenesis," Annual Summer Toxicology Forum, Aspen, CO, July, 1989.
77. "Toxicity Testing and Evaluation - Practical Considerations," International Training Workshop on Risk Assessment and Management, Chulabhorn Research Institute, Bangkok, Thailand, December 1989.
78. "Update on the Search for Adequate Bioassay Data: Crude Biology Versus Statistics," Annual Meeting of the Society of Toxicology, Miami, FL, February, 1990.
79. "Biological Effects of Dietary Restriction: An International Conference", Washington, D.C., March 1990.
80. "Principles of Route-to-Route Extrapolation," (Rapporteur), Hilton Head, SC, March 1990.
81. "Molecular Mechanisms of Fiber Cytotoxicity and Carcinogenesis," Banbury Center, Cold Spring Harbor Laboratory, NY, March 1990.
82. "NTP Carcinogens - Interpretational Problems," International Workshop: Early Indicators of Non-genotoxic Carcinogenesis, World Health Organization, Brussels, Belgium, June 1990.
83. "Principles of Carcinogenesis," School of Pharmacy, Campbell University, Buies Creek, NC, October, 1990.
84. "Comparative Responses in Carcinogenesis Bioassays as a Function of Age at First Exposure," Similarities and Differences Between Children and Adults: Implications for Risk Assessment, ILSI/RSI, Hunt Valley, MD, November, 1990.
85. "Ethylene Thiourea: A Case Study," Similarities and Differences Between Children and Adults: Implications for Risk Assessment, ILSI/RSI, Hunt Valley, MD, November 1990.
86. "Problems and Considerations in the Design and Interpretation of Rodent Carcinogenesis Studies", Lectures as part of "Toxicologic Pathology" course, VMS 643, College of Veterinary Medicine, NCSU, December, 1990.

87. "Toxicologic Studies", Man-made Mineral Fibers: Status of Health Risk Assessment", Johns Hopkins University, March, 1991.
88. "Fiber Toxicity - Background and Historical Perspective", Society of Toxicologic Pathologists, Research Triangle Park, May 1991.
89. "Animal Bioassay Issues/Use of QRA", International Society of Regulatory Toxicology and Pharmacology workshop "A Review of Risk Assessment and OMB's Report on its Application in Regulatory Agencies", Crystal City, VA, June 1991.
90. "The Design, Conduct and Interpretation of Fiber Toxicity Studies", A. L. Bortree Lecture Series, Veterinary Science Dept., Pennsylvania State University, PA, September 1991.
91. "Fiber Toxicology in Experimental Animals: Results of Studies with Natural and Man-Made Mineral Fibers", Intramural Fiber Research Workshop, National Institute for Occupational Safety and Health, Morgantown, WVA, September 1991.
92. "Conduct and Interpretation of Inhalation Studies of the Toxicity and Carcinogenicity of Man-Made Fibers", Workshop: Approaches to Evaluating the Toxicity and Carcinogenicity of Man-Made Fibers. Durham, NC, November 1991.
93. "Man-Made Fibers: Review of Toxicology Data", '92 Annual Toxicology Forum, Washington, D.C., February 1992.
94. Invited testimony before the German MAK Commission on MMVF's. Munich, Germany, May 1992.
95. "Man-Made Fibres: Validity of Methods for Assessment of Carcinogenicity of Fibres", WHO Regional Office for Europe, Copenhagen, 19-20 May, 1992.
96. "Evaluation of Reduced Protocols for Carcinogenicity Testing of Chemicals", EPA, Washington, DC, 22-23 Sept 1992.
97. "Comparative Pathology of Chrysotile and Crocidolite Asbestos", TIMA/NAIMA Fiber Science Workshop, St. Petersburg, FL, 20 Jan 1993.
98. "Relationship Between Pulmonary Fibrosis and Cancer", TIMA/NAIMA Fiber Science Workshop, St. Petersburg, FL, 20 Jan 1993.
99. "The Toxicologic Pathologist in 2000 A.D.: Needs for Industry, Government and Academia", Role of Toxicologic Pathology in Safety Assessment. National Academy of Science, Washington, DC, 10 Feb 1993.
100. "A Comparison of the Effects of Chrysotile and Crocidolite Asbestos in Rats after Inhalation", Toxicologic and Carcinogenic Effects of Solid Particles in the Respiratory Tract. 4th International Inhalation Symposium, Hannover, Germany, 3 March 1993.
101. "Styrene/styrene oxide - Results of animal carcinogenicity studies", International Symposium on Health Hazards of Butadiene and Styrene, Helsinki, Finland, 21 April 1993.
102. "The Impact of Toxicity Studies in the Regulatory Process", Dept. of Toxicology Seminar Series, Michigan State University, 3 June 1993.

103. "The Toxicopathology of Inhaled Fibers", Department of Pathology, Michigan State University, 3 June 1993.
104. "Peer Review in Carcinogenicity Bioassays - Uses/Abuses", Society of Toxicologic Pathologists 12th International Symposium, Alexandria, VA, 28 June 1993.
105. McConnell, E.E., Kamstrup, O., Musselman, R., Hesterberg, T.W., Chevalier, J. and Thevenaz, P. Chronic Inhalation Study of Size-separated Man-made Vitreous Fibers in Fischer 344/N Rats. 24th International Congress on Occupational Health, Nice, France, 30 October 1993.
106. McConnell, E.E. Invited expert testimony before the German Ministry of the Environment on MMVF's. Berlin, Germany, 9-10 December 1993.
107. McConnell, E.E. "Fiber-induced pathology in experimental animals. Physiology and Cell Biology Conference, University of Rochester Pulmonary and Critical Care Unit, 20 December 1993.
108. McConnell, E.E. "Talc: Consumer Uses and Health Perspectives" Panel Discussant, International Society of Regulatory Toxicology and Pharmacology, Bethesda, MD, 31 Jan - 1 Feb 1994.
109. McConnell, E.E. "Advantages and limits of in vivo screening tests", Assessment of Toxicity of Man-made Fibres, Paris, France, 3 Feb. 1994.
110. McConnell, E.E. "Inhalation Studies: Methodologies Used and Current Studies", Symposium on Synthetic Vitreous Fibers: Scientific and Public Policy Issues. Crystal City, VA, 2-3 March 1994.
111. McConnell, E.E. "Historical Review of the Bioassay and Future Directions", Design and Interpretation of Animal Carcinogenicity Studies, Great Lakes Discussion Group of the Society of Toxicologic Pathologists, Cincinnati, OH, 24 March 1994.
112. McConnell, E.E. Panel member "Workshop on Data Needs for Cancer Risk Assessment of MTBE", Baltimore, MD, 4 March 1995.
113. McConnell, E.E. "Maximum Tolerated Dose versus Lung Burden: A Pathologists Point of View", Particle Overload in the Rat Lung: Relevance for Human Risk Assessment. MIT Toxicology Symposium, Cambridge, MA, 29-30 March 1995.
114. "Dose Selection in Inhalation Studies", U.S. EPA Workshop, Chapel Hill, NC, 9-10 May 1995.
115. "U.S. EPA Science Advisory Board Dioxin Reassessment Review", Herndon, VA, 15-16 May 1995.
116. "FIFRA SAP Review, Chairman, Aquatic Risk Assessment and Mitigation, Crystal City, VA, 17 July 1995.
117. "EUROTOX-SOT DEBATE "Dose Setting for Carcinogenicity Studies Should be Based on the Maximum Tolerated Dose", Prague, Czech Republic, 29 Aug 1995 and Anaheim, CA 12 March 1996.
117. "Results of Life-time Inhalation Studies of Glass, Mineral and Slag Wools and Refractory Ceramic Fibres in Rodents", Symposium on the Health Effects of Fibrous Materials (excluding asbestos) Used in Industry, Sydney, Australia, 30-31 October, 1995.
118. "The Rodent Bioassay in Perspective", 10th International Conference on Carcinogenesis & Risk Assessment, Austin, TX, 4 December 1996.

119. McConnell, E.E., Müller, W., Hesterberg, T.W., Thevenaz, P. and Axten, C. A comparison of the effects of chrysotile and amosite asbestos in hamsters after inhalation: Interim results. Society of Toxicology Annual Meeting, Cincinnati, OH, 1997.
120. McConnell, E.E. Selecting Doses for Chronic Rodent Bioassays. Brookings Institution. Washington, D.C. 3 April 1997.
121. McConnell, E.E. Regulatory Toxicology: lecture for "Principles of Pharmacology", Medical College of Virginia, 28 April, 1997.
122. McClain, M. and McConnell, E.E. "Workshop on Screening Methods for Endocrine Disruptors in the Thyroid Function: Thyroid Histopathology and Serum Hormone Analysis" Duke University, Durham, NC, 24 June 1997.
123. McConnell, E.E. Update on the 10X Childrens Safety Factor. Pesticide Program Dialogue Committee, Alexandria, VA 16 April 1998.
124. McConnell, E.E. Cancer and Non-Cancer Responses to Inhaled Fibers, Validity of Animal Models for Human Respiratory Diseases. Lovelace Respiratory Research Insititue symposium, Santa Fe, NM, 29 September 1998.
125. McConnell, E.E. A Science-based Paradigm for the Classification of Synthetic Vitreous Fibers. 7th International Symposium on Particle Toxicology. Maastricht, The Netherlands. 13-15 October 1999.
126. McConnell, E.E. Similarities and Dissimilarities of Mesotheliomas Induced by Asbestos and SV40. Experimental Pathology Branch, National Institute of Environmental Health Sciences (NIH), RTP, NC. 27 October 1999.
127. McConnell, E.E. A Comparison of Asbestos and Simian Virus 40 Induced Mesotheliomas in Animals. Defense Research Institute's 20th Annual Asbestos Medicine Meeting, Las Vegas, NV. 12 November 1999.
128. McConnell, E.E. A Science-based Approach to the Classification of Synthetic Vitreous Fibers. 26th International Congress on Occupational Health, Singapore, 30 August 2000.
129. McConnell, E.E. Foot and Mouth Disease: A Review Lesions. North Carolina State University, April, 2001 and National Institute of Environmental Health Sciences, NIH, 6 June 2001.
130. McConnell, E.E. Animal Cancer Studies of Sodium Nitrite: Historical Review and Recent National Toxicology Program Bioassay Rresults. Institute of Food Technologists annual meeting, New Orleans, LA, 24 June 2001.
131. McConnell, E.E. Animal Testing and Chrysotile. Defense Research Institute's 22nd Annual Asbestos Medicine Meeting, Phoenix, AZ. 2 November 2001.
132. McConnell, E.E. Anthrax in South Africa. National Institute of Environmental Health Sciences, Research Triangle Park, NC. 14 November 2001.
133. McConnell, E.E. Anthrax in South Africa. College of Veterinary Medicine, NCSU, Raleigh, NC. 17 November 2001.

134. McConnell, E.E. "The Value of Human Testing of Pesticides." Pesticide Testing in Humans: Ethics and Public Policy. New York Academy of Medicine., NYC, NY. 27 February 2002.
135. McConnell, E.E. "Human Data in Risk Assessment", Current Topics in Pesticide Toxicology: An Intensive Workshop. North Carolina State University, 9 April 2002.
136. McConnell, E.E. "Science and Politics in Human Testing of Pesticides", Pesticides in the Molecular Age. 11th North American ISSX Meeting, 25 October 2002.
137. McConnell, E.E. "How do Animal/Experiment Data Augment our Understanding of Human Health Effects?" ATSDR Expert Panel on Health Effects of Asbestos and Synthetic Fibers (SVF: The Influence of Fiber Length. New York, NY. 29-30 October 2002.
138. McConnell, E.E. "The Value of Human Testing." NRC/NAS Committee on the Use of Third Party Toxicity Research with Human Research Participants. Washington, DC. 19 March 2003.
139. McConnell, E.E. "Ingestion Studies of Asbestos and Non-Asbestos Particles in Experimental Animals to Evaluate Carcinogenic Potential." International Symposium on the Health Hazard Evaluation of Fibrous Particles Associated with Taconite and the Adjacent Duluth Complex.
140. McConnell, E.E. "Influence of Fiber Type, Size and Exposure in the Cancer and Non-cancer Response to Asbestos Fibers (Animal Studies)." Asbestos Mechanisms of Toxicity Workshop, Chicago, IL. 12-13 June 2003.