

Donald Lewis MacKeen, M.S., Ph.D.

PRIMARY ACTIVITY:

CEO:

MacKeen Consultants Ltd (MCL), founded 1980 .

DEO Corporation, founded 1983

Address

MacKeen Consultants Ltd / DEO Corporation

542 Fallbrook Drive

Venice FL 34292

Tel. 941-492-2560 email:dmackeen@mackeen.com

OTHER ACTIVITIES

Adjunct Assistant Professor, Center for Sight, Georgetown University Medical Center.

Chairman, Association for Vision and Ophthalmology; 2009 Exhibits Committee

EDUCATION:

Doctor of Philosophy, Graduate School of Arts and Sciences,

Northeastern University, 1972

Thesis: Investigation of the effects of carbon dioxide laser radiation on the rabbit eye.

Master of Science in Pharmacology, Graduate School of

Pharmaceutical Sciences, Northeastern University, 1966

Thesis: Solubilization and Partial purification of a Monamine oxidase.

Bachelor of Science, Massachusetts College of Pharmacy

FORMER ACTIVITIES:

Founding Member: District of Columbia Institutional Review

Board, Inc, Washington, DC

Board of Directors, Sjogren's Syndrome Foundation, Inc.'s Senior

Advisor for Government Affairs (4 terms completed 2004)

Director of Pharmaceutical Research, Burton Parsons

Inc., Washington DC 1973-1980

Assistant Professor of Pharmacology Department of Medicinal

Chemistry and Pharmacology, Northeastern University, 1970-1973

Research Associate, Department of Biophysics and Biomedical

Engineering Northeastern University, 1966-1971

Director of Research, Burton Parsons, Washington, D.C., 1972-80

Lecturer in Europe , Alcon Laboratories 1981

Adjunct Professor, Department of Engineering, Northeastern University, Boston
Massachusetts

Executive Secretary, National Foundation for Eye Research, Inc.

Founding Chairman, The Dry Eye Institute, Lubbock, TX

SBIR (NIH) Panel Member, Ophthalmic products. 1985

Cooperative Cataract Research Group

Dakryology Society

International Society of Eye Research

International Contact Lens Society

TRANSLATOR

Kontaktlinsen-komplikationen, Hans-Walter Roth, MD, Georg Thieme Verlag, Stuttgart
2002 ; English Title: *Contact Lens Complications, Etiology, Pathogenesis, Prevention,
Therapy* ; Thieme 2003

CO-CHAIRMAN:

The First International Tear Film Conference,
Lubbock Texas, November 7-10, 1984

Dry Eye Institute Meeting: The Tear Film, Reno, Nevada, June
7-9, 1985

Advisory Board Member and Session Chairman, The First Meeting of the International
Society of Dakryology, Budapest, Hungary June 21-23, 1987

Founding Member Lacrimal Gland Study Group Now Tear Film and Ocular Surface

Member of the National Health Council FDA Issue Team

Member International Society of Ocular Toxicology, Inc.

PRESENTER:

Presented at numerous conferences including ARVO, Tear Film Organization, German
Ophthalmological Society, CLAO, and for various Corporate meetings

CURRENT MEMBERSHIP:

American Academy of Ophthalmology

American Association for Research in Vision and Ophthalmology

Regulatory Affairs Professional Society

National Cathedral Society

Toastmasters

ASSOCIATE EDITORSHIP:

a) The Preocular Tear Film in Health, Disease, and Contact Lens Wear, Lubbock TX
1986 Dry Eye Institute pp. 987

b) Lacrimal Gland, Tear Film and Dry Eye Syndromes, 1994 Plenum Press NY. Pp.729

INVITED LECTURER FDA:

"Ophthalmic Drug Delivery Systems ", Food and Drug
Administration Seminar, Washington, DC, November 4, 1979

"The International Tear Film Symposium: Current overview of tear physiology and
ophthalmic preparations" FDA Seminar, FDA Center for Devices and Radiological
Health, Silver Spring MD, December 18, 1984

INVITED LECTURER/ORGANIZER

"Update: Aspects of contact lens hazards" FDA Seminar FDA

Center for Devices and Radiological Health, Silver Spring MD,
October 23, 1985

"Schaeden bei v.T. -Tragen in den USA" D.L. MacKeen,

"Kontaktlinsen und AIDS", coauthor HW Roth, Wiesbadener
BVA-Tagung, Wiesbaden, W. Germany, November 20,1987

"Die Behandlungen des trochenen Auges mit dem modifizierten Punctum Plug" the 73
Tagung der Wuerttenbergischen Augenaerztlichen Vereinigung 23 April 1989
University of Tuebingen, Tuebingen, Germany

Program Monitor "Corneal topography and Imaging Session", CLAO Meeting, Las
Vegas, NV, Feb 1996

Panel Member Sjogrens Syndrome Foundation 'Meet the Experts' NIH June 1996

Acad. Rheumatology Meeting Orlando, FL

Organizing member, 2nd International Conference on the Lacrimal Gland, Tear Film and Dry Eye Syndromes, Bermuda, Nov. 1996

Co-chairman Physiology and Anatomy Session, European Contact Lens Ophthalmologists (ESCLO) Meeting, Ulm, Germany Sept. 13, 1996

Invited speaker, ESCLO/BVA Meeting "Contact lens hygiene in One-day Systems" Ulm, Germany Sept. 12, 1996

Invited speaker, Closing Summary Comments on the 2nd International Conference on the Lacrimal Gland, Tear Film and Dry Eyes Syndromes, Bermuda, Nov. 1996

Bascom Palmer Eye Hospital, Miami FL., Ocular Surface and Tear Workshop, "Drug delivery via the tear lipid layer May 16, 1997

Organizing committee 3rd International Conference on the Lacrimal Gland, Tear Film and Dry Eyes Syndromes, Maui, Hawaii Nov. 2000

Third International Dry Eye Symposium< Maui Hawaii, Nov 2000 "Simple Method Of Detecting The Anti-Inflammatory Action Of Topical Dry Eye Treatments",

BIBLIOGRAPHY

Gabay S. Valcourt A and MacKeen DL, "Preparation of a highly purified monoamine oxidase (MAO)" Fed. Proc. 25(2): 319 (1966)

Fine S Feigen L. MacKeen DL and Klein E, "Hazards and protective devices associated with 10.6u radiation." Proc. Ann. Conf. Engineer._ Med. Biol. 9:52 (1967)

Fine S. Edlow J MacKeen DL, Feigen L Ostrea E and Klein E
"Focal hepatic injury and repair produced by laser radiation"
Am. J. Pathol. 52(1): 155-176 (1968)

MacKeen DL, Fine S and Klein E,, "Toxic and explosive hazards associated with lasers". Laser Focus, Oct. 1968, pp 44-49

Feigen L, MacKeen DL and Fine S,, "A method for detecting and measuring frequency of surface vibrations using a helium-neon laser" Rev. Sci. Instrum. 40:381 (1971)

MacKeen DL, Fine S. Feigen L and Fine BS,, "Anterior chamber measurements on carbon dioxide laser corneal irradiation" Invest. Ophthalmol. 9(5): 366-371 (1970)

Fine S, MacKeen DL, Berkow JW and Fine BS, "Preliminary report of biologic testing of laser protective materials", *Am J Ophthalmol*, 71(4): 828-834 (1971)

MacKeen DL, Fine S, Aaron A and Fine BS, "Cataract production in rabbits with an ultraviolet laser." *Laser Focus* April. 1971 p 27

MacKeen DL and Fine S. "Effects of suprathreshold carbon dioxide laser irradiation of the weanling rabbit eye on lenticular concentrations of ascorbic acid and reduced glutathione. *Fed. Proc.* 32(3): 348 (1973)

MacKeen DL, Szabo G and Fine S "The effects of UV laser radiation at 325 nm on the skin" *Yale J. Med* 1973

Szabo GT, MacKeen DL and Fine S, "The ultrastructural effects of ultraviolet laser radiation on skin" *Ann Italiani Dermatol. Clin Sperimen.* 28(2): 1974

MacKeen DL, Fine S and Fine BS, "Production of cataracts in rabbits with the UV laser " *Ophthalmic Res.* 5: 3176 (1973)

13) MacKeen DL and Fine BS, "Repair of epithelial abrasions in rabbit and rhesus monkey" *Invest. Ophthal* , Suppl April 1975 p 40

Green K and MacKeen DL 'Chloramphenicol retention on and penetration into the eye", *Invest ophthalmol* 15: 220-222 (1976)

MacKeen DL and Labaw, B," A method of fitting soft hydrophilic contact lenses to rabbits for long term experiments" *Int Contact Lens Clinic* July/August :65(1978)

MacKeen DL and Green, K "Chlorhexidine kinetics of hydrophilic contact lenses" *J Pharm Pharmacol* 30:714(1978) [Listed as suggested method in FDA Guidelines for contact lens testing from 1980 to date]

MacKeen DL and Green, K "Chlorhexidine kinetics of hard contact lenses" *J Pharm Pharmacol* 31: 7814(1979)

MacKeen DL, "on an in vitro method of simulating drug release from viscous eye drops" *Pharm Pharmacol* 31:872 (1979)

MacKeen, DL Translator of 'Kontaktlinsen' by Drs. HW Roth and M Roth-Wittig, published by Harper and Rowe, 1980

MacKeen DL,, "Aqueous formulations and Ointments in Ocular Pharmacology of the Anterior Segment , Ed.F Holly International Ophthalmology Clinic 3. 1980 Boston Little Brown, publishers

Lee WR, Murray SR, Williamson J and MacKeen DL "Human conjunctival mucin: a quantitative study of normal and diseased (KCS) tissue" A. v. Graefe's Archiv f. Ophthalmol. 215:209-221 (1981)

MacKeen DL, Kopp SJ, Greiner JV and Glonek T, "Effects of verapamil on metabolism of the crystalline lens: a phosphorus-31 nuclear magnetic resonance spectroscopic study" Invest Ophthalmol Suppl. 25(3): 104 (1984)

Roth HW and MacKeen DL "AIDS: Ein Risiko fuer Kontaktlinsenanpasser und Patient" Der Augenspiegel 31(12): 4-8 1985.

MacKeen DL, "Testing the Tears" Contact Lens Spectrum Feb 1986, pp 37-38

MacKeen DL, "Measuring Tear Qualities", Contact Lens Forum July 1986, pp 48-50

MacKeen DL, "Contact Lens Solutions: The Pharmacist's Role". Amer.Pharm. 26 (10): 27(1986)

MacKeen DL and Fine SF,, "Scattering of Near UV Radiation within Gel Contact Lens material", Invest Ophthalmol Suppl 28(3):164(1987)

Roth HW and MacKeen DL, "Experience with silicone punctum plugs in dry eye patients" Dakryology Meeting Budapest June 21, 1987

MacKeen, DL, "Schaden beim Tragen von v.T. Linsen in den USA" Z. prakt. Augenheilkd 9:92-94 (1988)

MacKeen, DL and Roth HWI "Kontaktlinsen und AIDS", Z. prakt.. Augenheilkd. 9: 102-104 (1988)

Bush,JF, Huff,LW and MacKeen, DL."Laser-assisted contact angle measurements." Am. J. Optom. Phys. Optics 65: 722-728 (1988)

MacKeen, DL.Cavanagh HD, Homano, H and Hideji IF, "Overnight Swelling and Deswelling of Rabbit Corneas in Response to RGP and Soft Contact Lens Wear". Invest Ophthalmol Suppl 30(3):480(1989)

Cavanagh HD, Ichikawa H MacKeen DL Kazai A and Jester JV," Corneal Swelling Responses Differ with Extended Wear in Naive and Adapted Subjects with High Dk RGP Contact Lenses" Invest Ophthalmol Suppl 30(3):481(1989)

Ichikawa, H Kozai.A MacKeen DL and Cavanagh HD, "Corneal Swelling Responses with Extended Wear in Naive and Adapted Subjects with Menicon RGP Contact Lenses" CIAO J 15(3):192-195 (1989)

Roth HW and DL MacKeen "Erste Erfahrungen mit dem Disposable-Lens System" Der Augenspiegel 35, 2:5-7 (1989)

Ichijima I, MacKeen DL, Hamano H, Jester J and Cavanagh HD, "Swelling and deswelling of rabbit corneas in response to rigid gas permeable, hydrogel and elastomer contact lens wear." CLAO Journal 15(4):290-297 (1989)

MacKeen, DL and Roth HW "Successful maintenance of dry eye contact lens wearers with the punctum flow controller", Proceedings of the VIIth International Contact Lens Symposium, Singapore, March 1990

Roth HW and MacKeen DL, "Therapeutic uses of disposable contact lenses", Proceedings of the VIIth International Contact Lens Symposium Singapore, March 1990

Cavanagh HD, Hamano H, MacKeen DL and Lemp MA., "Tear lactate dehydrogenase levels: a new method to assess effects of contact lens wear in a rabbit model and man, Invest Ophthalmol.31(4): 406 (1990)

MacKeen DL, Cavanagh HD, Ohashi J., and Lemp MA. "Clinical results of extended wear with a new high Dk rigid gas permeable contact lens in humans' Invest Ophthalmol.31(4): 407 (1990)

MacKeen, DL and Mircheff, A, 'Air pollution and the dry eye" presented at Second Meeting of the International Dakryology Society, Amsterdam, 25 July 1990

MacKeen DL and Roth HW, A method and apparatus for modulating the flow of lacrimal fluid through a punctum and associated canaliculus U.S. Patent 4,915,684, April 10, 1990 Kreiner C, Fink R, MacKeen, DL" New methods in the detection of silicone oil impurities" Silicone in Medical Decices, Conference Feb 1-2, 1991 Baltimore, USDPH p.319

Green, K, MacKeen, DL, Slagle T and Cheeks T., " Tear Potassium contributes to maintenance of corneal thickness" Ophthalmic Research 24: 99-102 1991

MacKeen, DL. Fachdev,M. Ballou, V and Cavanagh, HD, "Results of a prospective multicenter clinical trial to assess the safety and efficacy of Menicon SFP rigid lenses for extended wear in human subjects" CLAO J 18 (3): 183-186 (1992)

MacKeen, DL US Patent 5,290,572 Ophthalmic composition for treating dry eye (1994) Assigned to DEO Corporation

Roth, HW and MacKeen DL , Micropachometric differentiation of dry eye syndromes in Lacrimal Gland and Dry Eye Syndromes pp505-512 Plenum Press, NY 1994

MacKeen, DL US Patent 5,366,739 Method of ophthalmic drug delivery (1994) Assigned to DEO Corporation

MacKeen DL Roth HW " Revolutionary method of ocular drug delivery IOVS 36(4): S166 (1995)

MacKeen, DL and Roth, HW, A preliminary report on a new method for the treatment of dry eye, Practical Optometry 6(3): 131-134 (1995)

MacKeen DL Roth HW and MacKeen PD, Supracutaneous treatment of dry eye patients with calcium carbonate, in Lacrimal gland , tear film and dry eye syndromes 2 Sullivan Ed. Plenum Press NY 1998

MacKeen DL Roth HW and MacKeen PD, Supracutaneous treatment of dry eye patients with calcium carbonate, in Lacrimal gland , tear film and dry eye syndromes 2 Sullivan Ed. Plenum Press NY 1998

MacKeen, PD, Roth HW and MacKeen, DL Treatment of dry eyed contact lens wearers with DEO, IOVS 37(3):S72, 1996

MacKeen DL Roth HW and Doane MA Ocular drug delivery by the LLD (lower lid delivery)Method IOVS 37(3):S77 1996

MacKeen DL Kontaktlinsen Hygiene bei disposable Systemen" Der Augenspiegel 42(9):17 (1996)

MacKeen, DL US Patent 5,595,764 Ophthalmic Composition for treating dry eye (1997) Assigned to DEO Corporation

MacKeen, DL, Roth,HW and MacKeen PD, Supracutaneous drug delivery to the eye" Presented at the 2nd International Symposium on Experimental and Clinical Ocular Pharmacology and Pharmaceutics, Munich, Germany, Sept 12, 1997

MacKeen, DL, Doane, MA and Roth HW," Fluorescent history of supracutaneous drug delivery to the pre-ocular tear film" IOVS 38(4)"S151 (1997)

MacKeen DL "Methods of Ophthalmic Drug Delivery" assigned to DEO Corporation, Australian Patent No. 986932, Sept 4, 1997

MacKeen, DL, Roth, HW, Doane MA and MacKeen, AAF, "Investigations of a new Ophthalmic drug delivery" Eye World, 3(4):64-66 April 1998

Isreb, MA, Greiner, JV, Korb, DR,Glonek T, Reddy,CC, Lee, EK, Kushak SL, Hearn D, and MacKeen DL," Human, rat and rabbit tear film lipid layer and interference pattern observations' IOVS 39(4): S532 (1998)

MacKeen DL Roth HW and MacKeen PD, Supracutaneous treatment of dry eye patients with calcium carbonate, in Lacrimal gland , tear film and dry eye syndromes 2 Sullivan Ed. Plenum Press NY 1998

MacKeen, D,L. Composition for Treating Dry Eye" assigned to DEO Corporation U.S. Patent 5,830,508

MacKeen, DL, "Composition for the treatment of dry eye syndrome" European Pat. 630 254 Jan 27,1999 Assigned to DEO Corporation

MacKeen, DL, "Method of Ophthalmic Drug Delivery", Canadian Patent 2,129,635. May 27,1999 assigned to DEO Corporation

MacKeen, D.L. "Metodo para aplicar farmaco oftalmico" Mexican patent No. 9307760 Issued September 3, 1999 to DEO Coporation

MacKeen, DL, "Zusammensetzungen zur Behandlung des trockenen Auges" German patent No. 693-23303 T2 to DEO Corporation

MacKeen, DL & Roth H-W "Simple Method Of Detecting The Anti-Inflammatory Action Of Topical Dry Eye Treatments", Presented at Third International Dry Eye Symposium< Maui Hawaii, Nov 2000. Scheduled for publication in Lacrimal Gland, Tear Film, and Dry Eye Syndromes 3, Plenum Press

MacKeen DL "Potential New Treatments For Dry Eye" Part I Contact Lens Spectrum 16(2): 21-26 Feb (2001) [First of a 3 part series]

MacKeen DL "Potential New Treatments For Dry Eye" Part II Contact Lens Spectrum 16(3): 22-30 Mar (2001)

MacKeen DL "Potential New Treatments For Dry Eye" Part III Contact Lens Spectrum 16(4): 40-43 Apr (2001)

MacKeen, D.L. Composition for treating dry eye US Pat. 6,254,893 B1 July 3, 2001

MacKeen,D.L AND Roth H W "Simple method of detecting the anti-inflammatory action of topical dry eye treatments" *Third International Conference on the Lacrimal Gland, Tear Film and Dry eye Syndromes** November 15-18,2000

MacKeen DL & Doane, M, "Video history of supracutaneous movement from the lid skin into the preocular tears" Presented at the TFOS meeting Puerto Rico, 2004 Abstract in The Ocular Surface, Jan 2005, Vol.3 (1) S32