Curriculum Vitae

John-Michael Sauer, Ph.D.

Current Position:

I am currently the Program Officer of Biomarker Programs and Executive Director of the Predictive Safety Testing Consortium (PSTC) at the Critical Path Institute, and an adjunct Research Professor in the Department of Pharmacology at University of Arizona College of Medicine.

Education:

Doctor of Philosophy in Pharmacology and Toxicology (1996)

Interdisciplinary program in Pharmacology and Toxicology
The University of Arizona, Tucson, Arizona
Advisor: I. Glenn Sipes, Ph.D.
Dissertation: *All-trans-retinol modulation of chemically induced pulmonary and hepatic toxicity.*

Masters of Science in Biological Sciences (1991)

Department of Biological Sciences
Western Michigan University, Kalamazoo, Michigan
Advisor: Leonard J. Beuving, Ph.D.
Thesis: *An ultrastructural evaluation of 1-nitronaphthalene induced pulmonary toxicity in the rat.*

Bachelor of Science (1989)

Biomedical Sciences (major) and Chemistry (minor)
Western Michigan University, Kalamazoo, Michigan

Professional Experience:

Critical Path Institute (2013 to present)

Executive Director

Consortium Director of Predicative Safety Testing Consortium (PSTC), Critical Path Institute, Tucson, AZ.

June 2013 to Present: Responsible for leading a consortium of nineteen (19) pharmaceutical industry members under the advisement of the FDA, EMA, and PMDA with the goal of finding improved safety testing approaches and methods for direct application in drug discovery and development. PSTC is primarily focused on the regulatory qualification of translational safety biomarkers for use in both nonclinical and clinical studies. Currently, biomarkers for multiple target tissue are being evaluated including the kidney, liver, testis, heart, skeletal muscle, and vascular. Duties include direct supervision of a staff of project coordinators/managers, as well as general leadership responsibilities across the Critical Path Institute.

The University of Arizona (2015 to present)

Adjunct Research Professor

Research Professor, Department of Pharmacology, College of Medicine, Tucson, AZ.

March 2015 to Present: Faculty title as Research Professor, non-tenure eligible, in the research series, in the Department of Pharmacology, College of Medicine.

Pfizer-CovX (2012 to 2013)

Senior Director and CovX Leadership Team Member

Head of *In Vitro* Pharmacology and DMPK, Pfizer-CovX, San Diego, CA.

December 2012 to May 2013: Responsible for leading a group of drug disposition and *in vitro* pharmacology scientists involved in the discovery (SAR support) and development of peptide and protein

(ADC and CovX-body) therapeutics. Additional responsibilities included oversight of cross-functional projects teams, as well as, portfolio and talent management. Other duties included serving as the primary lead for CovX to access Pfizer's worldwide toxicology (DSRD) and ADME (PDM) capabilities.

Covance (2011 to 2012)

Executive Director and Site Scientific Head, Safety Assessment

Covance-Chandler Site Scientific Head, Covance Laboratories, Chandler, AZ.

August 2011 to July 2012: Responsible for the scientific rigor, quality and integrity of all experiments conducted at Covance-Chandler. Duties include direct oversight of study directors, study toxicologists, report coordinators and anatomical pathologists, as well as management of client relationships and interaction. Additional responsibilities include leadership of global projects and initiatives for *in vitro* ADME and toxicology.

Elan Corporation, plc (2005 to 2011)

Vice President, Global Research

Head of Lead Finding, Drug Metabolism and Pharmacokinetics and Nonclinical Safety Evaluation (LD&S), Elan Pharmaceuticals, South San Francisco, CA.

March 2008 to June 2011: Responsible for leading a group of drug disposition, toxicology, translational medicine, high throughput screening, and chemical inventory scientists. Additional responsibilities included leadership and/or oversight of cross-functional discovery and development teams.

Senior Director, Global Research

Head of Lead Discovery and Optimization

September 2005 to March 2008: Functional Area Leader of Screening, Compound Inventory, Drug Disposition, and Research Informatics. Responsible for the managing a group of drug metabolism & pharmacokinetic, *in vitro* pharmacology, chemical inventory, and database scientists.

Director, Global Research

Head of Drug Metabolism and Pharmacokinetics

January 2005 to September 2005: Responsible for the management of a group of ADME scientists, as well as advise cross-functional discovery and development teams.

Eli Lilly and Company (1997 to 2005)

Principal Research Scientist, Drug Disposition

Neuroscience Drug Discovery and Metabolism, Eli Lilly and Company, Indianapolis, IN.

February 2004 to January 2005: ADME scientist on cross-functional discovery and development teams, responsible for the conduct of all drug disposition and metabolism experiments needed for SAR optimization, clinical development and commercialization. This included the support of teams from Lead Generation to Commercialization.

Research Scientist, Drug Disposition

Discovery & Lead Optimization Drug Disposition

January 2002 to February 2004: ADME scientist on cross-functional discovery teams, responsible for the conduct of experiments needed for SAR optimization and the development of clinical candidates, in conjunction with medicinal chemists and biologists.

Senior Pharmacologist, Drug Disposition

Development and Commercialization

October 1997 to January 2002: ADME representative on cross-functional early and late stage development teams. Coordinated ADME activities needed for the development of clinical candidates. Prepare and implement ADME development and commercialization team plans in conjunction with other functional area representatives.

The University of Arizona (1996 to 1997)

Project Leader, National Toxicology Program Contract

Research Associate Scientist, Center for Toxicology, The University of Arizona, Tucson AZ.

January 1996 to October 1997: Scientific coordinator for all aspects of the National Toxicology Program (NTP) Chemical Disposition in Mammals (CDM) contract for Dr. I. Glenn Sipes (Contract Principle Investigator). Prepare and implement project plans, timelines and manage laboratory staff and resources.

International Research and Development Company (1989 to 1990)

QA Auditor, Quality Assurance

Auditor, Quality Assurance Department, International Research and Development Company. Mattawan, MI.

January 1989 to October 1990: Served as a QA report auditor responsible for insuring the accuracy of report content, as well as appropriate regulatory compliance.

Publications:

I have authored/co-authored numerous peer-reviewed manuscripts, reviews and book chapters, as well as many abstracts/platform presentations presented at national meetings. I have also authored several regulatory reports and submission documents (IND, NDA, and CTD) for international submission.

Manuscript, Reviews and Book Chapters

Sauer JM. 1991. An ultrastructural evaluation of 1-nitronaphthalene induced pulmonary toxicity in the rat. Western Michigan University, Kalamazoo, MI: Masters of Science Thesis.

Sauer JM, Hooser SB, Sipes IG. 1995. All-*trans*-retinol alteration of 1-nitronaphthalene-induced pulmonary and hepatic injury by modulation of associated inflammatory responses in the male Sprague-Dawley rat. *Toxicology and Applied Pharmacology,* 133:139-149.

Sauer JM, Sipes IG. 1995. Modulation of chemical-induced lung and liver toxicity by all-*trans*-retinol in the male Sprague-Dawley rat. *Toxicology*, 105:237-249.

Sauer JM, Sipes IG. 1995. All-*trans*-retinol modulation of nitronaphthalene-induced lung and liver injury the male Sprague-Dawley rats. *Proceedings of the Western Pharmacology Society*, 38:29-31.

Sauer JM, Hooser SB, Badger DA, Baines A, Sipes IG. 1995. Alterations in chemically induced tissue injury related to all-*trans*-retinol pretreatment in rodents. *Drug Metabolism Reviews,* 27:299-323.

Rosengren JR, **Sauer JM**, Hooser SB, Sipes IG. 1995. The interaction between retinol and five different hepatotoxicants in the Swiss Webster mouse. *Fundamental and Applied Toxicology*, 25:281-292.

Sauer JM. 1996. All-*trans*-retinol modulation of chemically-induced pulmonary and hepatic toxicity. The University of Arizona, Tucson, AZ: Doctoral Dissertation.

Badger DA, **Sauer JM**, Hoglen NC, Jolley CS, Sipes IG. 1996. The role of inflammatory cells and cytochrome P-450 in the potentiation of CCl_4-induced liver injury by a single dose of retinol. *Toxicology and Applied Pharmacology*, 141:507-519.

Sauer JM, Bao JQ, Smith RL, Kuester RK, Mayersohn M, Sipes IG. 1997. The disposition kinetics and metabolism of *trans*-methyl styryl ketone in female $B6C3F_1$ mice. *Drug Metabolism and Disposition*, 25:1184-1190.

Sauer JM, Smith RL, Bao JQ, Kattnig MJ, Kuester RK, McClure TD, Mayersohn M, Sipes IG. 1997. Oral and dermal absorption, disposition kinetics and the metabolic fate of *trans*-methyl styryl ketone in the male Fischer 344 rat. *Drug Metabolism and Disposition*, 25:732-739.

Sauer JM, Bao JQ, Smith RL, McClure TD, Mayersohn M, Pillai U, Cunningham ML, Sipes IG. 1997. The absorption, disposition kinetics, and metabolic pathways of cyclohexene oxide in the male Fischer 344 rat and female $B6C3F_1$ mouse. *Drug Metabolism and Disposition*, 25:371-378.

Sauer JM, Waalkes MP, Hooser SB, Kuester RK, McQueen CA, Sipes IG. 1997. Suppression of Kupffer cell function prevents cadmium induced hepatocellular necrosis in the male Sprague-Dawley rat. *Toxicology*, 121:155-164.

Sauer JM, Waalkes MP, Hooser SB, Baines AT, Kuester RK, Sipes IG. 1997. Role of metallothionein expression in the development of tolerance to cadmium hepatic toxicity induced by all-*trans*-retinol in the male Sprague-Dawley rat. *Toxicology and Applied Pharmacology*, 143:110-119.

Sauer JM, Eversole RR, Lehmann CL, Johnson DE, Beuving LJ. 1997. An ultrastructural evaluation of 1-nitronaphthalene induced acute target organ toxicity in the rat. *Toxicology Letters*, 90:19-27.

Sauer JM, Badger DA, Sipes IG. 1997. *The hepatotoxicity of vitamin A (all-trans-retinol)*. (IG Sipes, AJ Gandolfi, and CA McQueen, eds). Comprehensive Toxicology Series 9.34:493-503.

Sauer JM, Stine ER, Gunawardhana L, Hill DA, Sipes IG. 1997. *The liver as a target for chemical-chemical interactions.* (A.P. Li, ed). Drug-Drug Interactions, Scientific and Regulatory Perspectives, Advances in Pharmacology, 43:37-63.

Bao JQ, Smith RL, **Sauer JM**, Pillai U, Sipes IG. 1997. Simultaneous determination of cyclohexene oxide and its metabolites in rat plasma and urine by gas chromatography. *Journal of Chromatography B*, 696:59-68.

Badger DA, Kuester RK, **Sauer JM**, Sipes IG. 1997. Gadolinium chloride inhibits cytochrome P450: Relevance to chemical-induced hepatotoxicity. *Toxicology*, 121:143-153.

Hoglen NC, Abril E, **Sauer JM**, Earnest DE, McCuskey RS, Lantz RC, Mobley SA, Sipes IG. 1997. Modulation of Kupffer cell and blood monocyte activity by *in vivo* treatment with all-*trans*-retinol. *Liver*, 17:157-165.

Sauer JM, Bao JQ, Smith RL, Kattnig MJ, Kuester RK, Sipes IG. 1998. The metabolic and dispositional fate of 1,2-dibromo-2,4-dicyanobutane in the male Fischer 344 rat. *Drug Metabolism and Disposition*, 26:429-436.

Bao JQ, **Sauer JM**, Smith RL, Kuester RK, Kattnig MJ, Sipes IG. 1998. Biotransformation and macromolecular binding of 1,2-dibromo-2,4-dicyanobutane in rat blood. *Drug Metabolism and Disposition*, 26: 1001-1007.

Hoglan NC, Regan SP, Hensel JL, **Sauer JM**, Steup DR, Miller MLJ, Twerdok LE, Sipes IG. 1998. Alteration of Kupffer cell function and morphology by low melting point paraffin wax in female Fischer-344 but not Sprague-Dawley rats. *Toxicological Sciences*, 46:176-184.

Halladay JS, **Sauer, JM**, and Sipes, IG. 1999. Metabolism and disposition of [^{14}C]1-nitronaphthalene in male Sprague-Dawley rats. *Drug Metabolism and Disposition*, 27:1456-1465.

Burkey JL, **Sauer JM**, McQueen CA, Sipes IG. 2000. Cytotoxicity and genotoxicity of methyleugenol and related congeners – a mechanism of activation for methyleugenol. *Mutation Research*, 453: 25-33.

Wilson CR, **Sauer JM**, Hooser SB. 2001. Taxines: A review of the mechanism and toxicity of yew (Taxus spp.) alkaloids. *Toxicon*, 39:175-185.

Porter AC, **Sauer JM**, Knierman MD, Becker GW, Berna MJ, Bao J, Nomikos G, Carter P, Bymaster FP, Leese A, Felder CC. 2002. Virodamine: Characterization of a novel endocannabinoid with antagonist activity at the CB1 receptor. *Journal of Pharmacology and Experimental Therapeutics,* 301:1020-1024.

Belle DJ, Ernest S, **Sauer JM**, Smith BP, Thomasson HR, Witcher JW. 2002. Effect of potent CYP2D6 inhibition by paroxetine on atomoxetine pharmacokinetics. *Journal of Clinical Pharmacology*, 42:1-9.

Sauer JM, Ponsler GD, Long AJ, Mattiuz E, Witcher JW, Thomasson HR, Desante K. 2003. Disposition and metabolic fate of atomoxetine hydrochloride: The role of CYP2D6 in human disposition and metabolism. *Drug Metabolism and Disposition*, 31:98-107.

Mattiuz EL, Ponsler GD, Barbuch RJ, Wood PG, Mullen JH, Shugert RL, Li Q, Wheeler WJ, Kuo F, Conrad PC, **Sauer JM**. 2003. Disposition and metabolic fate of atomoxetine hydrochloride: Pharmacokinetics, metabolism, and excretion in the Fischer 344 rat and beagle dog. *Drug Metabolism and Disposition*, 31:88-97.

Chalon S, Desager JP, DeSante K, Frye RF, Witcher JW, Long A, **Sauer JM**, Golnez JL, Smith BP, Thomasson H, Horsmans Y. 2003. Effect of liver impairment on the pharmacokinetics of atomoxetine and its metabolites. *Clinical Pharmacology & Therapeutics*, 73:178-191.

Witcher JW, Long AJ, **Sauer JM**, Heiligenstein JH, Wilens T, Biederman J, Spencer T. 2003. Atomoxetine pharmacokinetics in children with attention deficit hyperactivity disorder. *Journal of Child and Adolescent Psychopharmacology,* 13:53-64.

Wilson CR, **Sauer JM**, Carlson GP, Wallin R, Ward MP, Hooser SB. 2003. Species comparison of vitamin K_1 2,3-epoxide reductase activity. *Toxicology*, 189:191-198.

Sauer JM, Long AJ, Ring B, Gillespie JS, Sanburn NP, Desante KA, Petullo D, VandenBranden MR, Jensen CB, Wrighton SA, Smith BP, Thomasson HR, Witcher JW. 2004 Disposition and Metabolic Fate of Atomoxetine Hydrochloride: Clinical Drug-Drug Interaction Prediction and Outcome. *Journal of Pharmacology and Experimental Therapeutics*, 308:410-418.

Wheeler WJ, Bymaster FP, Calligaro DO, Clodfelter DK, Conrad PC, Heath PC, Kuo F, McGill JM, Murff RE, O'Bannon DD, **Sauer JM**, Wong DT. 2004. *Strattera™ (Atomoxetine HCl), an inhibitor of the norepinephrine transporter 1. The preparation of C-14 labeled atomoxetine and two of its metabolites 2. The preparation and biological evaluation of some additional putative metabolites of atomoxetine*. In: Dean, D.C.; Filer, C.N. and McCarthy, K.E., editors. Synthesis and Applications of Isotopically Labelled Compounds, Volume 8. New York (NY): John Wiley and Sons. p. 357-360.

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Witcher JW, **Sauer JM**, Chalon S. *Strattera®, a CYP2D6 Substrate: Clinical Development and Dose Strategy*. 2006. In: Krishna R. and Howard D., editors. Dose Optimization in Drug Development, Drugs and Pharmaceutical Sciences Series Marcel. New York (NY): Dekker. 161:247-258.

Truong AP, Aubele DL, Probst GD, Neitzel ML, Semko CM, Bowers S, Dressen D, Hom RK, Konradi AW, Sham HL, Garofalo AW, Keim PS, Wu J, Dappen MS, Wong K, Goldbach E, Quinn KP, **Sauer JM**, Brigham EF, Wallace W, Nguyen L, Hemphill SS, Bova MP and Basi G. 2009. Design, synthesis, and structure–activity relationship of novel orally efficacious pyrazole/sulfonamide based dihydroquinoline γ-secretase inhibitors. *Bioorganic & Medicinal Chemistry Letters*, 19: 4920-4923.

Bowers S, Probst GD, Truong AP, Hom RK, Konradi AW, Sham HL, Garofalo AW, Wong K, Goldbach E, Quinn KP, **Sauer JM**, Wallace W, Nguyen L, Hemphill SS, Bova MP and Basi G. 2009. *N*-Bridged bicyclic sulfonamides as inhibitors of γ-secretase. *Bioorganic & Medicinal Chemistry Letters*, 19: 6952-6956.

Sealy JM, Truong AP, Tso L, Probst GD, Aquino J, Hom RK, Jagodzinska BM, Dressen D, Wone DWG, Brogley L, John V, Tung JS, Pleiss MA, Tucker JA, Konradi AW, Dappen MS, Toth G, Pan H, Ruslim L, Miller J, Bova M, Sinhad S, Quinn KP and **Sauer JM**. 2009. Design and synthesis of cell potent BACE-1 inhibitors: Structure–activity relationship of P1′ substituents. *Bioorganic & Medicinal Chemistry Letters*, 19: 6386-6391.

Hom RK, Bowers S, Sealy JM, Truong AP, Probst GD, Neitzel ML, Neitz RJ, Fang L, Brogley L, Jing W, Pan H, Yao N, Artis DR, Quinn K, **Sauer JM**, Powell K, Ren Z, Bard F, Yednock TA, and Griswold-Prenner I. 2010. Design and synthesis of disubstituted thiophene and thiazole based inhibitors of JNK. Bioorganic & medicinal chemistry letters. 10/2010; 20(24):7303-7.

Ye XM, Konradi AK, Smith J, Xu Y, Dressen D, Garofalo AW, Marugg J, Sham HL, Troung AP, Jagodzinski J, Pleiss M, Zhang H, Goldbach E, **Sauer JM**, Brigham EF, Bova M, and Basi G. 2010. Discovery of a Novel Sulfonamide-Pyrazolopiperidine Series as Potent and Efficacious Gamma-Secretase Inhibitors. *Bioorganic & Medicinal Chemistry Letters*, 20:2195-9.

Ye XM, Konradi AW, Smith J, Aubele DL, Garofalo AW, Marugg J, Neitzel ML, Semko CM, Sham HL, Sun M, Truong AP, Wu J, Zhang H, Goldbach E, **Sauer JM,** Brigham EF, Bova M, and Basi GS. 2010. Discovery of a novel sulfonamide-pyrazolopiperidine series as potent and efficacious gamma-secretase inhibitors (Part II). *Bioorganic & Medicinal Chemistry Letters*, 20:3502-6.

Mattson MN, Konradi AW, Neitzel ML, Quincy DA, Semko CM, Garofalo AW, Pleiss MA, Sham HL, Basi GS, Brigham EF, Goldbach EG, Zhang H, and **Sauer JM**. 2010. Discovery of Sulfonamide-Pyrazole g-Secretase Inhibitors. *Bioorganic & Medicinal Chemistry Letters*, 20:2148-50.

Truong AP, Probst GD, Sealy JM, Bowers S, Wone DW, Dressen D, Hom RK, Konradi AW, Sham HL, Wu J, Peterson BT, Ruslim L, Bova MP, Kholodenko D, Motter RN, Bard F, Santiago P, Ni H, Chian D, Soriano F, Cole T, Brigham EF, Wong K, Zmolek W, Goldbach E, Samant B, Chen L, Zhang H, Nakamura DF, Quinn KP, Yednock TA, and **Sauer JM**. 2010. Design of an orally efficacious hydroxyethylamine (HEA) BACE-1 inhibitor in a preclinical animal model. *Bioorganic & Medicinal Chemistry Letters*, 20:6231-6.

Probst GD, Bowers S, Sealy JM, Stupi B, Dressen D, Jagodzinska BM, Aquino J, Gailunas A, Truong AP, Tso L, Xu YZ, Hom RK, John V, Tung JS, Pleiss MA, Tucker JA, Konradi AW, Sham HL, Jagodzinski J, Toth G, Brecht E, Yao N, Pan H, Lin M, Artis DR, Ruslim L, Bova MP, Sinha S, Yednock TA, Gauby S, Zmolek W, Quinn KP, and **Sauer JM**. 2010. Design and synthesis of hydroxyethylamine (HEA) BACE-1 inhibitors: structure-activity relationship of the aryl region. *Bioorganic & Medicinal Chemistry Letters*, 20:6034-9.

Truong AP, Probst GD, Aquino J, Fang L, Brogley L, Sealy JM, Hom RK, Tucker JA, John V, Tung JS, Pleiss MA, Konradi AW, Sham HL, Dappen MS, Toth G, Yao N, Brecht E, Pan H, Artis DR, Ruslim L, Bova MP, Sinha S. Yednock TA, Zmolek W, Quinn KP, and **Sauer JM.**. 2010. Improving the permeability of the hydroxyethylamine BACE-1 inhibitors: structure-activity relationship of P2' substituent. *Bioorganic & Medicinal Chemistry Letters*, 20:4789-94.

Neitzel ML, Aubele DL, Marugg JL, Jagodzinski JJ, Konradi AW, Pleiss MA, Szoke B, Zmolek W, Goldbach E, Quinn KP, **Sauer JM**, Brigham EF, Wallace W, Bova MP, Hemphill S, Basi G. 2011. Amino-caprolactam γ-secretase inhibitors showing potential for the treatment of Alzheimer's disease. *Bioorganic & Medicinal Chemistry Letters*, 21: 3715-20.

Neitz RJ, Konradi AW, Sham HL, Zmolek W, Wong K, Qin A, Lorentzen C, Nakamura D, Quinn KP, **Sauer JM**, Powell K, Ruslim L, Chereau D, Ren Z, Anderson J, Bard F, Yednock TA, and Griswold-Prenner I. 2011. Highly selective c-Jun N-terminal kinase (JNK) 3 inhibitors with in vitro CNS-like pharmacokinetic properties II. Central core replacement. *Bioorganic & medicinal chemistry letters*, 21:3726-9.

Bowers S, Truong AP, Neitz RJ, Hom RK, Sealy JM, Probst GD, Quincy D, Peterson B, Chan W, Galemmo RA, Tonn G, Quinn KP, **Sauer JM**, Wright S, Powell K, Ruslim L, Ren Z, Bard F, Yednock TA, and Griswold-Prenner I. 2011. Design and synthesis of brain penetrant selective JNK inhibitors with improved pharmacokinetic properties for the prevention of neurodegeneration. *Bioorganic & Medicinal Chemistry Letters*, 21; 5521-7.

Matsui A, Azuma J, Witcher JW, Long AJ, **Sauer JM**, Smith BP, DeSante KA, Read HA, Takahashi M, and Nakano M. 2012. Pharmacokinetics, Safety, and Tolerability of Atomoxetine and Effect of CYP2D6*10/*10 Genotype in Healthy Japanese Men. *Journal of Clinical Pharmacology*, 52:388-403.

Quinn K, Gullapalli RP, Merisko-Liversidge E, Goldbach E, Wong A, Liversidge GG, Hoffman W, **Sauer JM**, Bullock J and Tonn G. 2011. A Formulation Strategy for Gamma Secretase Inhibitor ELND006 (BCS Class II): Development of a Nanosuspension Formulation with Improved Oral Bioavailability and Reduced Food Effects in Dogs. *Journal of Pharmaceutical Sciences*, 101:1462-74.

Nguyen L, Wright S, Lee M, Ren Z, **Sauer JM**, Hoffman W, Zago W, Kinney GG, and Bova MP. 2012. Quantifying Amyloid Beta (Aβ)-Mediated Changes in Neuronal Morphology in Primary Cultures: Implications for Phenotypic Screening. *Journal of Biomolecular Screening*, 17:835-42.

Bradshaw JM, Nguyen L, Wallace W, Li C, **Sauer JM**, Bard F, and Bova MP. 2012. Monitoring Signaling by the p75(NTR) Receptor Utilizing a Caspase-3 Activation Assay Amenable to Small-Molecule Screening. *Assay and Drug Development Technologies,* 10:353-64.

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