DAVID R. JANERO, Ph.D.

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SUMMARY OF QUALIFICATIONS

Over 30 years of experience as results-oriented R&D and business leader and educator in drug discovery and development. Innovative scientist with excellent analytical, problem-solving, and communication skills and brand experience in key therapeutic markets. Design and profiling of new chemical entities as small-molecule and proteinbased therapeutics by integrating cell/molecular biology, medicinal chemistry, chemical biology, pharmacology, and drug discovery/development. Proven administrative, entrepreneurial, and research-strategy expertise in project and program management within and across varied therapeutic areas as part of "international big pharma," "startup/emerging biotech," and academia. Success in building R&D teams, contributing to scientific and medical advances in unmet therapeutic areas, and leading multiple discovery campaigns that have brought novel leads to the clinic and therapeutics to market. Strong background in target identification/validation; technology/model development and transfer; competitive intelligence; building and nurturing intra- and extramural multicenter collaborations and strategic research and business alliances; and implementing and critically evaluating technological and product opportunities among diverse constituencies. Established and actively maintained consultancies aimed at reducing translational risk; optimizing predictive preclinical testing and hit-to-lead strategies; improving development-candidate selection/profiling; supporting regulatory compliance and trial progression; leading academia-industry collaborations to leverage innovation output for drug and technology commercialization; and serving as expert witness. Committed to educating and mentoring scientists-in-training to help them reach their full potential and prepare them to earn and advance their place in the professional world.

PROFESSIONAL EXPERIENCE

NORTHEASTERN UNIVERSITY, Boston, MA

Visiting Professor and Graduate Program Director

2019-

Bouvé College of Health Sciences, Department of Pharmaceutical Sciences

- Chair Graduate Education Committee
- Guide and mentor graduate (MS, Ph.D.) students and ensure career readiness
- Create and monitor graduate-program learning outcomes and assessment plans: Medicinal Chemistry, Pharmacology, Pharmaceutical Sciences, Biomedical Sciences
- Teach scientific, business-development, and entrepreneurship courses
- Attract funding and collaborations to support educational and research initiatives

INDEPENDENT BIOPHARMA CONSULTANT

- Evaluate the therapeutic potential and positioning of potential leads and marketattractive commercial avenues
- Formulate and validate predictive R&D approaches with translational utility, including *in silico* tools, chemogenomic strategies, target identification and validation, drug design and optimization, *in vitro* and *in vivo* disease models, biomarker identification, and phenotypic/systems-biology analyses
- Construct and analyze critical-path business and product-development strategies
- Participate in decision-making from quantitative SAR through candidate differentiation and safety and efficacy testing
- Organize and direct efforts to solve formulation and ADMET problems and detect/combat adverse activities and (potential) side-effects at preclinical and development stages
- Help drive candidate selection for human trials and progression through regulatory and clinical-testing processes
- Establish formal R&D agreements, working relationships, and business strategies between academia and industry to facilitate and expedite lead optimization, development candidate profiling, drug repositioning, and clinical testing
- Plan, organize, edit, write, and execute institutional and governmental regulatory and business documents, grants (e.g., SBIRs, STTRs, Center Grants, Research Project Grants, NIH-RAID), R&D agreements (e.g., CRADAs), and allied presentations and journal publications
- Serve as expert witness regarding therapeutics, drug design/action, and pharmacology

NORTHEASTERN UNIVERSITY, Boston, MA

Assistant Director, Center for Drug Discovery	2007-2009
Deputy Director, Center for Drug Discovery	2010-2018

- Develop, coordinate, and teach state-of-the-art courses allied to the University's experiential learning approaches and Biotechnology Initiative
- Establish and maintain productive interactions among intramural departments, technology-transfer operations, and research centers of excellence within the institution's entrepreneurial ecosystem
- Mentor students, fellows, and professional staff and promote career development
- Attract funding from private, government, and commercial sources
- Serve as in-house authority on the biotechnology and pharmaceutical industries, entrepreneurship, and drug discovery and commercialization
- Attract and initiate novel R&D projects and University-industry collaborations with good strategic and technological fit for commercialization
- Oversee and expand the Center's intellectual-property interests and intellectual capital, including oversight of all research publications, patents, and grants
- Represent the Center and its R&D activities intramurally and externally

2006 - present

NITROMED, INC., Lexington, MA

Last position held: Founding Senior Director, R&D

- Built and mentored interdisciplinary R&D teams that addressed market needs for sexual dysfunction, cardiovascular disease, hypertension, renal disease, oncology, metabolic syndrome, and inflammation
- Established from start-up and led the Company's *in vitro* and *in vivo* R&D in applied and translational biology to ensure timely compound pipeline progression, lead profiling, and development candidate flow
- Designed and implemented research and business strategies supporting corporate funding and clinical trials that led to a high-profile product launch and IPO
- Set corporate policy as R&D Committee and Scientific Advisory Board member
- Identified, critically evaluated, and championed novel extramural ventures and alliances that enriched corporate scientific and business profiles and expedited the business plan
- Supported clinical, regulatory, and licensing efforts as pharmacology advisor and spearheaded preclinical investigations toward next-generation products
- Key brand experience: BiDil[®] (heart failure)

NOVARTIS PHARMACEUTICALS, Summit, NJ

Last position held: Senior Research Fellow / Manager, R&D

1989 - 1994

- Implemented and fostered research programs that introduced and advanced drug candidates for hypertension, heart disease, diabetes, and oncology
- Devised and championed cutting-edge research approaches that improved compound targeting, pharmacokinetics, bioavailability, efficacy, and safety
- Managed productive R&D projects and teams that enhanced pipeline flow and broadened the pharmacological and safety profiling of clinical candidates
- Key brand experience: Starlix[®] (diabetes); Lescol[®], Valsartan[®], Losartan[®] (dyslipidemias/hypertension/heart disease); Femara[®] (oncology)

HOFFMANN-LA ROCHE, INC., Nutley, NJ

Last position held: Research Investigator, Pharmacology

1983 - 1989

- Recruited and supervised productive research teams in applied pharmacology, drug discovery and profiling, and lead optimization
- Established and managed R&D projects that successfully identified and advanced clinical candidates/drugs for bronchopulmonary, obesity, cardiovascular, immunodeficiency, dermatology, and anti-infective indications
- Launched extramural strategic alliances across several therapeutic areas that extended corporate R&D and product portfolios
- Key brand experience: Xenical[®] (obesity/metabolic syndrome); Accutane[®] (dermatology); Cardene[®] (cardiovascular disease/hypertension/heart failure); Rocephin[®] (anti-infective)

1994 - 2006

ACADEMIC AFFILIATIONS

NORTHEASTERN UNIVERSITY, Boston, MA	
Visiting Professor, Department of Pharmaceutical Sciences, Bouvé College of Health Sciences	2019-
<i>Professor (Adjunct Faculty),</i> Department of Pharmaceutical Sciences, Bouvé College of Health Sciences	2007-2018
Professor (Adjunct Faculty), Center for Drug Discovery	2007-2018
BOSTON UNIVERSITY, School of Medicine, Boston, MA	
Research Associate Professor, Biochemistry	1995 - 2010
Visiting Scientist, Whitaker Cardiovascular Institute and	
Department of Medicine	2003 - 2007

INTRAMURAL PROFESSIONAL ACTIVITIES

NORTHEASTERN UNIVERSITY, Boston, MA

Program Director, MS in Medicinal Chemistry

Member, Center for Drug Discovery, Scientific Advisory Board (ex officio)

Member, Center for Drug Discovery, Strategic Advisory Board (ex officio)

Member, Graduate Education Committee, Pharmaceutical Sciences

Member, Biotechnology Council

Member, Research Advisory Council

Member, Health Sciences Entrepreneurs

Grant-related Funding Activities

Member, Executive Committee and Curriculum and Research Oversight Committee, Pre- and Postdoctoral Training Program in Medications Development (NIH Grant DA-007312), 1/7/07-6/30/13

Scientific Coordinator, Endocannabinoid Sites as Therapeutic Target (NIH Grant P01 DA009158-15), 7/1/14-6/30/19

Co-PI, Chemistry and Pharmacology of Drugs of Abuse Conference Series (NIH Grant R13 DA040423), 7/1/15-6/30/20

Curent Member, Ph.D. Thesis Committees: L. Cantwell, X. Ma, P. Schaffer (Pharmaceutical Sciences)

M.S. Thesis Mentorships Completed

L. Lindsley (Pharmaceutical Sciences) May, 2010 "Neutral Antagonists as G Protein Coupled Receptor-directed Medicines"

S. Mallipeddi (Pharmaceutical Sciences) May, 2012 "In Vitro Expression of Human Cannabinoid 1 Receptor for Ligand-assisted Binding Site Characterization"

J. Raghav (Pharmaceutical Sciences) July, 2014 "A Soft-drug Approach for Cannabinoids"

K. Raja (Medicinal Chemistry) August, 2017 "Novel Allosteric Modulators of the α7 Nicotinic Acetylcholine Receptor"

Ph.D. Thesis Mentorships Completed

R. Sharma (Pharmaceutical Sciences) May, 2011 "Cannabinergic Analogs with Controlled Detoxification as Potential Therapeutics"

M. D'Souza (Pharmaceutical Sciences) May, 2012 "Novel Cannabidiol and Anandamide Analogs"

I. Karageorgos (Pharmaceutical Sciences) August, 2012 "The Mechanism of Monoacylglycerol Lipase Inactivation: A Study Using Nuclear Magnetic Resonance Spectroscopy and Mass Spectrometry"

R.G. Kini (Pharmaceutical Sciences and Inflammation and Tissue Protection Institute) August, 2012

"Mechanism of A2A Adenosine Receptor-mediated Immunosuppression in Inflamed Tissue Microenvironment"

M. Subramanian (Pharmaceutical Sciences and Inflammation and Tissue Protection Institute) August, 2012 "Mechanism of Adenosinergic Regulation of T-cell Mediated Acute Hepatitis"

S. Tai (Pharmaceutical Sciences) August, 2012 "Behavioral Pharmacology of Cannabinoids: Towards an Animal Model for Studying Cannabinoid Dependence/Withdrawal"

M. Nasr (Pharmaceutical Sciences) May, 2013 "Impact of Conformational Dynamics on the Molecular Enzymology of Human Monoacylglycerol Lipase as Drug Target"

M. Trivedi (Pharmaceutical Sciences) June, 2013 "Redox/Methylation Signaling: A Novel Epigenetic-based Mechanism of Opioid Drug Action"

G. Chopda (Pharmaceutical Sciences) August, 2013 "Cannabinoid-mediated Diuresis in Mice" D. Deshpande (Pharmaceutical Sciences, Pharmaceutics, Drug Delivery) August, 2013

"Multimodal Omega-3 Fatty Acid Oil-containing Nanoemulsion-based Therapeutic Strategy for the Treatment of Endothelial Dysfunction in Coronary Artery Disease"

A. Jamal-Allial (Pharmaceutical Sciences, Statistics, Epidemiology) August, 2013 "Serum 25(OD)D Concentrations and Cardiovascular Disease Risk Associations Among Older Puerto Ricans"

M. Johnson (Pharmaceutical Sciences) December, 2014 "Analysis of the Structure and Function of Endocannabinoid Hydrolyzing Enzymes Using Biophysical and Nanomedical Techniques"

K. Hu (Pharmaceutical Sciences) August, 2016 "Distribution of Exogenous Radiolabeled Anandamide and Related Compounds in the Mouse Brain"

S. Mallipeddi (Pharmaceutical Sciences) December, 2016 "Biochemical and Biophysical Study of Cannabinoid 1 and Cannabinoid 2 Receptors"

A. Aly (Pharmaceutical Sciences) May, 2017 "An Intranasal GDNF Gene Therapy Approach for Treating Parkinson's Disease"

A. Korde (Pharmaceutical Sciences) May, 2017 "Ligand Binding-site Characetrization of Human Cannabinoid Receptors"

M. Silva (Pharmaceutical Sciences and Tissue Protection and Inflammation Institute) June, 2017

"Driving the Germinal Center Reaction toward Subdominant Epitopes: A Potential Vaccination Strategy to Neutralize HIV"

G. Rajarshi (Pharmaceutical Sciences) July, 2017 "Characterization of the Endocannabinoid Enzyme Monoacylglycerol Lipase by Mutagenesis, Kinetics Analyses, and Nuclear Magnetic Resonance Spectroscopy"

B. Garg (Pharmaceutical Sciences) July, 2017 "Investigating the Role of α7 Nicotinic Receptors in Inflammation"

T. Hall (Pharmaceutical Sciences) August, 2017 "Investigation into Fatty Acid Ethyl Esters in Mouse Brain after Ethanol Treatment: Detection, Quantification, and Potential Toxicity"

C. Miyabe-Shields (Pharmaceutical Sciences) January, 2018 "Biochemical Characterization of Human Alpha/Beta-hydrolase Domain Containing 6 as Therapeutic Target"

Q. Ye (Pharmaceutical Sciences) May, 2018 "The Role of Brain Iron Loading in Redox-Epigenetic Regulation of Psychiatriclike Behavior" J. Gleba (Pharmaceutical Sciences) May, 2019

"A Mechanism-based Forensic Investigation into the Postmortem Redistribution of Morphine"

K. Bugda Gwilt (Pharmaceutical Sciences) May, 2019 "Trace Aminergic Regulation of Gastrointestinal Inflammation: A Novel Strategy for Ulcertive Colitis"

Ph.D. Qualifying Examination Committees Completed

H. Zhou (Chemistry and Chemical Biology) September, 2011 "Ligand-assisted Protein-structure Characterization: Binding and Functional Motifs of Ligands of the CB2 Cannabinoid Receptor"

B. Garg (Pharmaceutical Sciences) December, 2014 "The Anti-inflammatory Role of α 7 Nicotinic Acetylcholine Receptor and its Ligands"

S. Mallipeddi (Pharmaceutical Sciences) December, 2014 "Biochemical and Biophysical Studies of Cannabinoid 1 and 2 Receptors"

A. Korde (Pharmaceutical Sciences) December, 2014 "Ligand Binding-site Studies of the Human Cannabinoid Receptor"

Q. Ye (Pharmaceutical Sciences) August, 2016 "The Role of Brain Iron Loading in Redox-Epigenetic Regulation of Psychiatriclike Behavior"

J. Gleba (Pharmaceutical Sciences) September, 2016 "A Mechanism-based Forensic Investigation into the Postmortem Redistribution of Morphine"

K. Gwilt (Pharmaceutical Sciences) November, 2017 "Trace Amine Associated Receptor 1 as Anti-inflammatory Drug Target"

P. Schaffer (Pharmaceurtical Sciences) December, 2017 "Design and Development of Novel Cannabinoid Receptor Allostric Modulators"

L. Cantwell (Pharmaceutical Sciences) December, 2017 "Development of Novel, Subtype-selective GIRK1/2-channel Activators for Treating Neuropathic Pain"

Teaching/Lecture Service

"Chemistry and Biology of Drugs of Abuse" (course director)
"Receptor Pharmacology"
"Drug Design and Development"
"Biophysical Methods in Drug Discovery"
"Drug Discovery and Development Journal Club"
"Pharmacology Journal Club"
"Bio-organic and Medicinal Chemistry"

MASSACHUSETTS INSTITUTE OF TECHNOLOGY, Cambridge, MA Venture Mentoring Service	
Member (completed five-year term)	2006 - 2011
Ad-hoc	2012 -
NATIONAL SCIENCE FOUNDATION, Washington, DC	
Advisor, Industrial Innovation and Partnerships Programs	2013 -
NEW YORK ACADEMY OF SCIENCES, New York, New York	
Advisor, Program for STEM Scientist Professional Development	2017 -
Editorial Board Member, Free Radical Biology and Medicine	1992 - 2000
Editorial Board Member, Expert Opinion on Drug Discovery	2011- 2013
Editor-in-Chief, Expert Opinion on Drug Discovery	2013-
Editorial Board Member, <i>Biomedicines</i>	2012 - 2017
Editorial Advisor, Elsevier/Academic Press	2012 -
Member, Federation of American Societies for Experimental Biology	1991 -
Member, American Society for Pharmacology	
and Experimental Therapeutics	1991 -
Member, New York Academy of Sciences	2010 -
Member, Yale Boston Biomedical Group	2012 -
Board Member, Boston Area Neurosciences Group	2012 -
Boston Chapter Head, Society for Neuroscience	2012 - 2017

SELECT EXTRAMURAL PROFESSIONAL ACTIVITIES

REVIEWER (ad-hoc) for leading biochemistry, physiology, pharmacology, medicinal chemistry, and clinical journals, international private and government granting institutions, and biomedical publishers

EDUCATION

JOHNS HOPKINS UNIVERSITY, School of Medicine, Baltimore, MD National Institutes of Health **Postdoctoral Fellow**, Physiological Chemistry

YALE UNIVERSITY, School of Medicine, New Haven, CT Biomedical Sciences Program **Ph.D.**, Cell Biology and Molecular Medicine

BOSTON UNIVERSITY, Boston, MAB.A. summa cum laude, Phi Beta KappaBiology major, Chemistry minor; research honors, Molecular Genetics

BIBLIOGRAPHY

Research Publications

- Janero, D.R. and R.J. Barrnett. 1981. Analytical prenyl pigment separation from a total green-plant lipid extract. Anal. Biochem. 111:283-290.
- Janero, D.R. and R.J. Barrnett. 1981. Analytical separation of green-plant and animal neutral lipids by thin-layer chromatography. J. Chromatogr. 216:417-422.
- *Janero, D.R.* and R.J. Barrnett. 1981. Thylakoid membrane biogenesis in *Chlamydomonas reinhardtii* 137⁺. Cell cycle variations in the synthesis and assembly of polar glycerolipid. *J. Cell Biol.* 91:126-134.
- Janero, D.R. and R.J. Barrnett. 1981. Cellular and thylakoid-membrane glycolipids of *Chlamydomonas reinhardtii* 137⁺. J. Lipid Res. 22:1119-1125.
- Janero, D.R. and R.J. Barrnett. 1981. Cellular and thylakoid-membrane phospholipids of *Chlamydomonas reinhardtii* 137⁺. J. Lipid Res. 22:1126-1130.
- *Janero, D.R.* and R.J. Barrnett. 1982. Comparative analysis of diacylglyceryltrimethylhomoserine in *Ochromonas danica* and in *Chlamydomonas reinhardtii*. *Phytochemistry* 21:47-50.
- Janero, D.R. and R.J. Barrnett. 1982. Cardiolipin of *Chlamydomonas reinhardtii* 137⁺. *Phytochemistry* 21:1151-1153.
- *Janero, D.R.* and R.J. Barrnett. 1982. Isolation and characterization of an ether-linked homoserine lipid from the thylakoid membrane of *Chlamydomonas reinhardtii* 137⁺. *J. Lipid Res.* 23:307-316.
- Janero, D.R. and R.J. Barrnett. 1982. Sterol synthesis in *Chlamydomonas reinhardtii* 137⁺. Cell-cycle variations. *Biochim. Biophys. Acta* 710:242-247.
- *Janero, D.R.* and R.J. Barrnett. 1982. Thylakoid membrane biogenesis in *Chlamydomonas reinhardtii* 137⁺. II. Cell-cycle variations in the synthesis and assembly of pigment. *J. Cell Biol.* 93:411-416.
- *Janero, D.R.* and R.J. Barrnett. 1982. Thylakoid membrane biogenesis in *Chlamydomonas reinhardi* 137⁺. Cell-cycle variations in the synthesis of phospholipids of non-photosynthetic membranes. *Exp. Cell Res.* 138:451-454.
- Jelsema, C.L., A.S. Michaels, *D.R. Janero* and R.J. Barrnett. 1982. Membrane lipid metabolism in *Chlamydomonas reinhardtii* 137⁺ and y-1. Biochemical localization and characterization of acyltransferase activities. *J. Cell Sci.* 58:469-488.
- Siuta-Mangano, P., *D.R. Janero* and M.D. Lane. 1982. Association and assembly of triglyceride and phospholipid with glycosylated and unglycosylated apoprotein of very low density lipoprotein in the intact liver cell. *J. Biol. Chem.* 257:11463-11467.

- *Janero, D.R.* and M.D. Lane. 1983. Sequential assembly of very low density lipoprotein apolipoproteins, triacylglycerol, and phosphoglycerides by the intact liver cell. *J. Biol. Chem.* 258:14496-14504.
- *Janero, D.R.* and B. Burghardt. 1988. Protection of rat myocardial phospholipid against peroxidative injury through superoxide (xanthine oxidase)-dependent, iron-promoted Fenton chemistry by the male contraceptive gossypol. *Biochem. Pharmacol.* 37:3335-3342.
- *Janero, D.R.* and B. Burghardt. 1988. Analysis of cardiac membrane phospholipid peroxidation kinetics as malondialdehyde: non-specificity of thiobarbituric acid-reactivity. *Lipids* 23:452-458.
- *Janero, D.R.*, B. Burghardt and C. Burghardt. 1988. Specific binding of 1-<u>0</u>-alkyl-2acetyl-<u>sn</u>-glycero-3-phosphocholine (platelet-activating factor) to the intact canine platelet. *Thrombosis Res.* 50:789-802.
- *Janero, D.R.*, C. Burghardt and D. Feldman. 1988. Amphiphile-induced heart musclecell (myocyte) injury: effects of intracellular fatty acid overload. *J. Cell. Physiol.* 137:1-13.
- Janero, D.R., B. Burghardt and C. Burghardt. 1988. Radioligand competitive binding methodology for the estimation of platelet-activating factor (PAF) and the evaluation of PAF-receptor antagonism using intact canine platelets. J. Pharmacol. Meth. 20:237-253.
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- *Janero, D.R.* and B. Burghardt. 1989. Cardiac membrane malondialdehyde and vitamin E levels in normotensive and spontaneously hypertensive rats. *Lipids* 24:33-38.
- *Janero, D.R.* and B. Burghardt. 1989. Thiobarbituric acid-reactive malondialdehyde formation during superoxide-dependent, iron-catalyzed lipid peroxidation: influence of peroxidation conditions. *Lipids* 24:125-131.
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- Janero, D.R. and B. Burghardt. 1989. Prevention of oxidative injury to cardiac phospholipid by membrane-active stabilizing agents. *Res. Commun. Chem. Pathol. Pharmacol.* 63:163-173.

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- Janero, D.R., B. Burghardt, R. Lopez and M. Cardell. 1989. Influence of cardioprotective cyclooxygenase and lipoxygenase inhibitors on peroxidative injury to myocardial membrane phospholipid. *Biochem. Pharmacol.* 38:4381-4387.
- Janero, D.R. and B. Burghardt. 1989. Oxidative injury to myocardial membrane: direct modulation by endogenous alpha-tocopherol. J. Mol. Cell. Cardiol. 21:1111-1124.
- *Janero, D.R.*, N. Cohen, B. Burghardt and B. Schaer. 1990. Novel 6-hydroxychroman-2-carbonitrile inhibitors of membrane peroxidative injury. *Biochem. Pharmacol.* 40:551-558.
- Janero, D.R. and C. Burghardt. 1990. Solid-phase extraction on silica cartridges as an aid to platelet-activating factor enrichment and analysis. J. Chromatogr. 526:11-24.
- Janero, D.R., C. Burghardt and B. Burghardt. 1990. Production and release of plateletactivating factor by the injured heart-muscle cell (myocyte). *Res. Commun. Chem. Pathol. Pharmacol.* 67:201-218.
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- Janero, D.R., D. Hreniuk and H.M. Sharif. 1991. Hydrogen peroxide-induced oxidative stress to the mammalian heart-muscle cell (cardiomyocyte): lethal peroxidative membrane injury. J. Cell. Physiol. 149:347-364.
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- Janero, D.R., D. Hreniuk and H. Sharif. 1993. Hydrogen peroxide-induced oxidative stress to the mammalian heart-muscle cell (cardiomyocyte): nonperoxidative purine and pyrimidine nucleotide depletion. J. Cell. Physiol. 155:494-504.
- Ross, J., *D.R. Janero*, D. Hreniuk and L. Wennogle. 1993. Radioiodination of transforming growth factor- β (TGF- β) in a modified Bolton-Hunter reaction system. *J. Biochem. Biophys. Methods* 26:343-350.
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- Janero, D.R. and D. Hreniuk. 1996. Suppression of TCA cycle activity in the cardiac muscle cell by hydroperoxide-induced oxidant stress. *Am. J. Physiol.* 270:C1735-C1742.
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