American Board of Toxicology

From: Kimberly Norman <kimberlygailnorman@gmail.com>
Sent: Wednesday, September 30, 2020 11:11 PM
To: American Board of Toxicology
Subject: Re: ABT Board of Director Nominations
Attachments: CV_ Kimberly Norman._Sept2020.doc

Hi Susie, below please find my self nomination letter and my CV attached. If any additional information is needed please reach out. Thanks, Kim

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Dear ABT Board of Directors Selection Committee,

I would like to be considered for an ABT Board of Directors position opening April 2021. I am interested in becoming a member of a working board, and can commit the time to participate in the three board meetings per year, extensive committee work as needed throughout the year, proctoring the certification examination in October, and supporting the ABT booth at the annual SOT meeting booth. I reside in Durham, NC, so it is convenient for me to participate in local board meetings, proctor the examination in Raleigh, and attend the 2021 summer meeting in Winston-Salem in July. I have been a Diplomate since 2013 with recertification in 2018, and became a European Registered Toxicologist in 2017.

I have experience working in various industries including a start-up biotechnology venture (Insight Genetics), a non-profit contract testing toxicology laboratory (Institute for In Vitro Sciences), and a large consumer goods company (Clorox/Burt's Bees), and feel that I could positively contribute to the board and help the ABT achieve its goals. My toxicology experience is primarily in in vitro toxicology testing methods. I served as a Study Director for eye irritation and skin irritation/sensitization studies for 7 years during which time I had the opportunity to work with international teams to develop, optimize, and deliver GLP methods for broader use within the industry, including the in vitro skin sensitization assays, KeratinoSens/LuSens and the Direct Peptide Reactivity Assay. I served as a member of the OECD Expert Committee for skin sensitization and helped to develop the test guidelines for the first generation of in vitro skin sensitization methods. I enjoy collaborating with others to achieve shared goals and appreciate opportunities to learn from experienced toxicologists, and mentor students and early career toxicologists. I participate in industry trade groups, and currently serve as the Chair of the Safety and Regulatory Toxicology Committee within the Personal Care Products Council, representing Clorox and subsidiary Burt's Bees.

I appreciate your consideration and have attached my CV for more details on my education and experience for your reference. Please reach out if any additional information would be useful.

Kind Regards, Kim

Kimberly Norman, PhD, DABT, ERT
Clorox- Global Stewardship
Associate Research Fellow (ARF)
Durham, NC 27703
(615)513-9981

On Wed, Sep 9, 2020 at 12:04 PM American Board of Toxicology <info@abtox.org> wrote:

> Diplomates are invited to nominate themselves or a fellow Diplomate for the seats on the Board of Directors becoming vacant in April of 2021. Please be aware that the ABT is a working board, and members have to be able to meet deadlines. Time requirements include participating in three board meetings per year, extensive committee work at certain times of the year, proctoring the certification examination

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SUMMARY OF QUALIFICATIONS

- Experienced, PhD level scientist with specialization in the safety and regulatory compliance of consumer goods, with concentration in cosmetics and OTC drugs. US board certified toxicologist, European registered toxicologist, and certification as Safety Assessor for cosmetics in the EU.
- Recognized industry leadership in the safety and regulatory compliance of personal care products. For >8 years have participated as a member on the Safety and Regulatory Toxicology Committee (SRTC) of leading industry trade association, Personal Care Products Council. Selected to serve as Vice-Chair in 2018 and currently serve as Chair of SRTC.
- Experienced in the toxicological evaluation of cosmetic ingredients and formulas, and managing technical and regulatory personnel. Demonstrated leadership in managing cosmetic regulatory tasks for domestic and international markets.
- Currently lead an Adverse Event Program (AE Chair) for a Fortune 500 company, with overall responsibility for >1,000 products sold across > 30 countries, with reporting needs across multiple domestic (FDA, EPA, CPSC) and international agencies. Experienced with FDA serious adverse event (SAE) reporting, and AE training for safety professionals and sales staff. Committed to continued product safety improvement through collaboration with Quality, Consumer Affairs, and Product Development. Global Stewardship representative on Corrective Action and Preventative Action (CAPA) team.
- Demonstrated communication skills through speaking engagements and publications. Invited speaking opportunities at US EPA Symposia, the Society of Toxicology (SOT) annual meeting, the American Contact Dermatitis Society (ACDS) annual meeting, the Personal Care Products Council Safety annual workshop, and the 15th International Conference on the Science of Botanicals. Co-authored peer-reviewed manuscripts with BASF, Procter & Gamble, Beiersdorf, Givaudan, and Johnson & Johnson on the safety assessment of ingredients.
- Proven ability to oversee complex projects and drive business results through coaching and mentorship of team members. Led assay validation studies from protocol development through laboratory execution to international regulatory guideline adoption and delivering a GLP method for broad use within the industry. Assigned tasks to a team of 8-10 laboratory technicians, matching team member skills with project needs to meet tight deadlines while maintaining stringent GLP quality standards. Managed non-technical team members, including Sales Specialist, Client Services Associate, and regulatory specialists. Experience hiring, onboarding, and managing employees.
- Strong technical skills and translation of complex technical information to practical application. Served as a Study Director on >300 *in vitro* and *in chemico* toxicology studies. As Study Director, I was responsible for study plan design and approval, as well as overseeing the execution of the laboratory procedures by laboratory staff, data analysis, and reporting. Recognized expert in the field of non-animal toxicology. Served on the Organization for Economic Co-operation and Development (OECD) Expert Panel for skin sensitization, assessing the scientific merit of proposed assays, and reviewing and optimizing international test guidelines. Awarded the 2016 Lush Prize for Young Researcher for leadership in validation of non-animal toxicology methods.

EDUCATION

August 2008 **Ph.D.: Cell and Developmental Biology**
Vanderbilt University, Nashville, TN
Thesis Advisor: James Sligh M.D., Ph.D.
Thesis title: Genetic and Biochemical Studies of Mitochondria in Skin Cancer.

May 2002 **B.S.: Biology, Cellular and Molecular Concentration,**
Magna Cum Laude, Chancellor's Award (4 year full-tuition scholarship)
Troy University, Troy, AL

PROFESSIONAL CERTIFICATIONS (all current)

November 2013 Diplomate of the American Board of Toxicology (DABT)
April 2017 European Registered Toxicologist (ERT)
February 2017 Certificate received for training course completion and examination passed for "Safety Assessment of Cosmetics in the EU" (Vrije Universiteit Brussel)

RESEARCH AND PROFESSIONAL EXPERIENCE

Associate Research Fellow- Global Stewardship
Clorox (location: Burt's Bees subsidiary headquarters), Durham, NC, September 2020 to present

Same responsibilities as below, with increased leadership responsibilities for Clorox safety and toxicology program activities and safety assessments across all brand categories, including cosmetics, OTC drugs, dietary supplements, foods, and cleaning and laundry.

Senior Scientist- Global Stewardship
Clorox (location: Burt's Bees subsidiary headquarters), Durham, NC, January 2017 to present

In my current position, I am responsible for overall management of the Clorox Adverse Events Program. As Chair of the AE program, I ensure all required AE reporting is conducted per relevant regulatory guidelines, lead monthly meeting with the AE Committee, escalate product safety issues as necessary, and work cross-functionally on continued product safety improvement. I work with a team of regulatory professionals in the Global Stewardship (GS) department to maintain a robust safety and regulatory compliance program for Clorox products under FDA regulation (Burt's Bees cosmetics and OTC drugs, foods, and dietary supplements). I have two direct reports, and lead the regulatory team meetings. I represent GS on cross functional product development and commercialization teams, providing expert guidance on global regulatory requirements and safety assessments. Responsibilities include ensuring global compliance of cosmetic and OTC products in domestic and select international markets, conducting raw material and formula reviews, and reviewing claims, packaging/labeling and marketing communication materials, and post-market surveillance. I have subject matter expert responsibilities for product safety across FDA regulated products, including ingredient, formulation, and packaging assessments. Support internal and external inquiries for safety and regulatory issues. Experience hiring, onboarding, and managing employees.

Manager, Client Development
Institute for In Vitro Sciences, Inc., Gaithersburg, MD, December 2015 to December 2016

In December 2015, I was promoted to the Manager of Client Development as a dual title alongside my role as a Senior Toxicologist/Study Director. In my role as a Study Director, I had increasing responsibility for managing client relationships, identifying and developing new business opportunities, and expanding the presence of the company which lead to my promotion in this business development area. In this role, I managed a Sales Specialist and a Client Services Representative. As the Manager of Client Development, I worked with my team on customer relationship management (CRM) software adoption and usage, roll-out of a new company website with updated design and content, improved client experience, and increasing revenue to meet targets. I fostered strategic partnerships with industry partners, regulatory agencies, and NGOs. I worked with the scientific team to identify unmet scientific support needs and build experimental tools to deliver these methods under GLP-compliance, and share these capabilities with our stakeholders.

Senior Toxicologist/Study Director
Institute for In Vitro Sciences, Inc., Gaithersburg, MD, December 2014 to December 2016

Same duties as previous position (see below) with added focus on the regulatory acceptance of alternative methods and collaboration with validation and regulatory authorities. Continued participation in OECD validation activities and interaction with US EPA and FDA to promote use of alternative methods for classification and labeling purposes. New responsibilities include training of Study Directors in various assays and interactions with clients, and further advancement and development of the skin sensitization assessment program. In December 2015, I was additionally promoted to the Manager of Client Development.

Toxicologist II/Study Director
Institute for In Vitro Sciences, Inc., Gaithersburg, MD, June 2009 to December 2014

Manage all aspects of commercial toxicology studies. Assist commercial clients in developing appropriate *in vitro* toxicology programs for their products. Interact with industry, animal welfare groups and government as necessary to discuss use of *in vitro* methods. Serve as Study Director for the following *in vitro* toxicology endpoints: eye irritation, eye stinging, and skin sensitization. Participate in identifying, developing, and commercializing novel *in vitro* toxicology assays. Participate in producing manuscripts detailing IIVS' scientific activities. Organizing and/or participating in other IIVS programs as needed. Support IIVS marketing activities: prepare newsletter articles, IIVS webinar series, and preparation and review of IIVS marketing documents.

Scientist I
Insight Genetics, Nashville, TN, January 2009 to May 2009

Designed and performed experiments to develop novel DNA mutation screening technology to be used for cancer diagnostics and clinical trial patient screening. Prepared reports, written and oral, of results and participated in investor relations and grant writing to promote funding for start-up company.

Postdoctoral Fellow,
Vanderbilt University, Division of Dermatology Nashville, TN, June 2008 to October 2008

Principal Investigator: James Sligh M.D., Ph.D.
Continuation of a project started during graduate school to analyze genetic changes associated with skin cancer and UV radiation using human tissue samples. Designed studies and gained institutional review board (IRB) approval. Collaborated with clinical dermatology departments to obtain human research samples. Developed assays to evaluate mitochondrial DNA mutations in human skin cancers, photo-damaged skin, and blood. Managed project protocols, supplies, and budget.

PhD Candidate/Graduate Research Assistant
Vanderbilt University, Department of Cell and Developmental Biology, Nashville, TN, August 2002- May 2008

Principal Investigator: James Sligh M.D., Ph.D.
Designed and performed *in vitro* assays to evaluate the biological effects of ultraviolet light and immunosuppressive drugs on skin function in order to investigate the increased incidence of skin cancer in individuals taking these drugs. Thesis project explored the development of skin cancer in transplant recipients by determining the biological effects of widely used immunosuppressive drugs from Novartis, Fujisawa, and Wyeth. Research led to the formulation of a model to explain the phenomenon of increased skin cancer in transplant recipients taking Cyclosporine A.

SELECT APPOINTMENTS/MEMBERSHIPS/TRADE AFFLIATIONS

Safety and Regulatory Toxicology Committee (SRTC) - Personal Care Products Council (PCPC)
Served as member of OECD Expert Panel on Skin Sensitization
Review Committee member for Alternatives Research and Development Foundation (ARDF) Grants

SOT member and participation in SOT's In Vitro Toxicology Specialty Section
Member of American Society for Cellular and Computational Toxicology (ASCCT)
Volunteer for Washington D.C. Coalition for the Public Understanding of Science

PEER REVIEW ACTIVITIES

Reviewer: In Vitro Toxicology Journal
Reviewer: In Vitro Cellular and Developmental Biology
Reviewer: Toxicology and Applied Pharmacology
Reviewer: Chemical Research in Toxicology

SELECT INVITED SPEAKING ENGAGEMENTS

Cosmetic Packaging Safety Assessment.
SRTC Spring Meeting 2019, Washington, DC, May 14, 2019

Natural & Organic Cosmetics: Global Regulatory Landscape.
SRTC Fall Meeting 2017, Alexandria, VA, October 26, 2017

Current Approaches for Assessing Eye and Skin Safety of Cosmetics Using Non-Animal Methods.
Personal Care Products Council Safety Workshop, Newark, NJ, October 21, 2015

Conducting *In Vitro* Investigation of Skin Sensitization Potential.
Joint Symposia: PCRM and California EPA on "Advances in skin sensitization determination with *in vitro* and *in silico* models: What can they tell us?" California EPA Headquarters, Sacramento, CA, April 21, 2015

Using novel *in vitro* methods to predict the skin sensitization potential of botanical mixtures.
15th International Conference on the Science of Botanicals. University of Mississippi, Thad Cochran National Center for Natural Products Research, Oxford, Mississippi, April 13, 2015

Predicting Eye Stinging Using the Novel NociOcular Assay.
Third International Biotechnology Meeting, Queretaro, Mexico, March 27, 2015.

Integrated Testing Strategies for Skin Sensitization.
Second International Biotechnology Meeting, Queretaro, Mexico, February 21, 2014.

Novel *in vitro* Assays for Assessment of Pharmaceuticals.
Occupational Toxicology Roundtable Annual Meeting, Albuquerque, New Mexico, October 8, 2013

Screening Skin Sensitizers using the Novel *in vitro* Skin Sensitization Assay KeratinoSens.
American Contact Dermatitis Society 23rd Annual Meeting, March 15, 2012.

Refinement of the Applicability Domain and Predictivity of the KeratinoSens assay, a Novel *in vitro* Skin Sensitization Assay.
Platform Session: Alternatives to Mammalian Models in Skin Sensitization

SOT Annual Meeting, March 14, 2012

WEBINAR SPEAKING ENGAGEMENTS

Serious Eye Damage and Eye Irritation.
Co-speaker with Dr. Els Adriaens
Webinar series sponsored by Chemical Watch and PETA, February 15, 2018.

Using Non-animal Test Methods to Meet Regulatory and Product Formulation Needs
Sole speaker
Cosmetics Design Europe Virtual Meeting, October 7, 2015

Serious Eye Damage and Eye Irritation
Co-speaker with Joao Barroso
Webinar series on Alternative Testing sponsored by Chemical Watch, December 4, 2014

The NociOcular Assay: A Novel Method Examining TRPV1 Channel Activity for Eye Sting Prediction
Co-speaker with Anna Forsby and Neena Tierney
IIVS Webinar Series, March 13, 2014

Integrated Testing Strategies (ITS) for Skin Sensitization
Co-speaker with Susanne Kolle, and Andreas Natsch
IIVS Webinar Series, November 14, 2013

KeratinoSens Assay: Inter-laboratory Investigations
Co-speaker with David Basketeer
IIVS Webinar Series, September 28, 2011

BOOK CHAPTERS

Use of In Vitro Methods in Pre-clinical Safety Assessment of Skin Care Products.
Gertrude-E. Costin and Kimberly G. Norman
Textbook of Aging Skin- Second Edition; Editors M.A. Farange, K.W. Miller and H.I. Maibach.
Springer-Verlag, 2017

DNA Biomarkers of Aging Skin.
Kimberly G. Norman, Alex Eshaghian and James E. Sligh
Textbook of Aging Skin; Editors M.A. Farange, K.W. Miller and H.I. Maibach.
Springer-Verlag, 2010

MAGAZINE ARTICLE/POSITION PAPER

Cosmetic safety assessments in the 21st century: ***Dr Kimberly Norman of the Institute for In Vitro Sciences looks at how CROs are increasingly specialising in animal-free toxicology.***
Speciality Chemicals Magazine. March 2014 Issue

GRANTS AND AWARDS

Co-Principal Investigator: **"The use of a novel non-animal platform to characterize respiratory effects of fragrance materials."**
Grant received from the Research Institute of Fragrance Materials (RIFM) in 2015.

LUSH Prize 2016 Young Researcher North Americas: Awarded a $15,000 bursary to support replacement research efforts. Laboratory-based proposal on identification and discrimination of respiratory sensitizers using the Direct Peptide Reactivity Assay (DPRA).

RESEARCH ARTICLES

Intra- and inter-laboratory reproducibility and accuracy of the LuSens assay: a reporter gene-cell line to detect keratinocyte activation by skin sensitizers.
Tzutzuy Ramirez, Nadine Stein, Alexandra Aumann, Tina Remus, Amber Edwards, Kimberly G. Norman, Cindy Ryan, Jackie E. Bader, Markus Fehr, Florence Burleson, Leslie Foertsch, Xiaohong Wang, Frank Gerberick, Paul Beilstein, Sebastian Hoffmann, Annette Mehling, Bennard van Ravenzwaay and Robert Landsiedel
Toxicology In Vitro 2016 Apr; 32:278-86.

Using Novel In Vitro NociOcular Assay Based on TRPV1 Channel Activation for Prediction of Eye Sting Potential of Baby Shampoos.
Anna Forsby, Kimberly G. Norman, Johanna El Andaloussi-Lilja, Jessica Lundqvist, Vincent Walczak, Rodger Curren, Katharine Martin, Neena K Tierney
Toxicological Sciences 06/2012; 129(2):325-31.

Somatic alterations in mitochondrial DNA produce changes in cell growth and metabolism supporting a tumorigenic phenotype
Jana Jandova, Mingjian Shi, Kimberly G. Norman, George P. Stricklin, James E. Sligh
Biochimica et Biophysica Acta 11/2011; 1822(2):293-300.

The bovine corneal opacity and permeability test in routine ocular irritation testing and its improvement within the limits of OECD Test Guideline 437
Arnhild Schrage, Susanne N. Kolle, Maria C. R. Moreno, Kimberly Norman, Hans Raabe, Rodger Curren, Bennard van Ravenzwaay, Robert Landsiedel·
Alternatives to laboratory animals: ATLA 03/2011; 39(1):37-53.

The intra- and inter-laboratory reproducibility and predictivity of the KeratinoSens assay to predict skin sensitizers in vitro: Results of a ring-study in five laboratories
Andreas Natsch , Caroline Bauch , Leslie Foertsch , Frank Gerberick , Kimberly Norman, Allison Hilberer, Heather Inglis, Robert Landsiedel, Stefan Onken, Hendrik Reuter, Andreas Schepky, Roger Emter
Toxicology in Vitro 12/2010; 25(3):733-44.

Cyclosporine A suppresses keratinocyte cell death through MPTP inhibition in a model for skin cancer in organ transplant recipients
Kimberly G. Norman, Jeffrey A Canter, Mingjian Shi, Ginger L. Milne, Jason D. Morrow, James E. Sligh
Mitochondrion 10/2009; 10(2):94-101

SELECT ABSTRACTS/POSTER PRESENTATIONS

Combining *in silico* and *in vitro* Methods to Improve the Accuracy of Skin Sensitization Prediction for Chemicals.
M. Lamm, N. Hilger, K. Norman
SOT Annual Meeting 2016, Poster Session

Practical considerations for Routine Screening of Skin Sensitizers Using the KeratinoSens Assay
N. Sadowski, E. Willier, K. Norman
ASCCT Annual Meeting 2015, Poster Session

Investigation of Novel *In Vitro* Methods for Predicting the Dermal Sensitization Potential of Synthetic Process Intermediates
Uma S. Bruen, Kimberly Norman, Bruce D. Naumann, SOT Annual Meeting 2015, Poster Session: Alternatives to Mammalian Models II—Skin, Eye, Liver

Evaluation of TRPV1 activity to Assess the Eye Stinging Potential of Cosmetic Formulations A. Gill, W. Chen, K. Norman, L. Krawiec, A. Dang, C. Gomez
SOT Annual Meeting 2015, Poster Session: Late Breaking

Using the Novel NociOcular Assay to Predict the Eye Sting Potential of Shampoos and Sunscreen Products
K. Norman, L. Krawiec, E. Sly, V. Diersen, A. Forsby
Poster Session: Alternatives to Mammalian Models II—Skin, Eye, Liver

Predicting Eye Stinging Using the Novel NociOcular Assay.
V. Diersen, L.Krawiec, E.A. Sly, K. Norman
ASCCT Annual Meeting 2014, Poster Session

Investigations on Reducing Ocular Irritation Associated with Harsh Ingredients by Altering Physicochemical Properties of the Formulation.
K.N. Boyd, E.A. Sly, K. Norman,
SOT Annual Meeting 2014, Poster Session

Surfactant Responses in the Bovine Corneal Opacity and Permeability Assay: Points to Consider for In vitro Eye Irritation Testing.
J.E. Bader, G. Costin, A. Hilberer, G. Mun, J.R. Nash, K. Norman, N. Wilt, H. Raabe
SOT Annual Meeting 2013, Poster Session: Alternative Model- Eye and Skin

In Vitro Ocular Irritation Testing Strategy for Prototype Cleaning Products.
M. Bauman, K. Norman, G. Mun, H. Raabe.
SOT Annual Meeting 2013, Poster Session: Alternative Model- Eye and Skin

Application of a Modified KeratinoSens Assay to Predict the Skin Sensitization Hazard for Botanical Extracts.
D. Gan, K. Norman, N. Barnes, H. Raabe, C. Gomez, J.W. Harbell
SOT Annual Meeting 2013, Poster Session: Alternative Model- Eye and Skin

Inter-laboratory Study of the Reproducibility of the Bovine Corneal Opacity and Permeability Assay: Investigations of Solid Test Substances.

K. Norman, A. Schrage, S.N. Kolle, M.C. Moreno, B. van Ravenzwaay, R. Landsiedel, H. Raabe
SOT Annual Meeting 2012, Poster Session: Alternatives to Mammalian Models for Ocular Toxicity Testing

Considerations for Demonstrating the Inter-laboratory Reliability of the Bovine Corneal Opacity and Permeability Assay (BCOP) and Chorioallantoic Membrane Vascular Assay (CAMVA).

G. Mun, N. Wilt, D.A. Donahue, J. Avalos, K. Norman, A. Hillberer. F. Simion, H.Raabe
SOT Annual Meeting 2012, Poster Session: Alternatives to Mammalian Models for Ocular Toxicity Testing

Development of an *In Vitro* Model to Assess the Efficacy of Topical Antioxidants.

M. Krcha, L. Krawiec, K. Norman
SOT Annual Meeting 2012, Poster Session: Alternatives to Mammalian Models for Dermal Toxicity