BIOGRAPHICAL SKETCH

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NAME: Bozena B. Michniak-Kohn

eRA COMMONS USER NAME (credential, e.g., agency login): bmichniak

POSITION TITLE: Professor of Pharmacy/Pharmaceutics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Leicester Polytechnic, Leicester, U.K.	B.Sc. (Hons)	06/1977	Pharmacy
Leicester Polytechnic, Leicester, U.K.	Ph.D.	06/1980	Pharmacy/Pharmacology
University of Florida, Gainesville FL	Post Doc	01/1983	Pharmaceutics
University of Bradford, Bradford, U.K.	Post Doc	02/1986	Pharmaceutics

A. Personal Statement: The focus of my research for the past 40 years lies in the area of topical, transdermal & transmucosal (buccal) drug delivery. I have a broad background in pharmaceutics and the physical chemistry of pharmaceutical dosage forms and in particular the drug delivery into and across skin and mucosal membranes. As P.I. and Co-P.I. on several federal, university and industrial projects, I have been involved with the design and optimization of formulations applied to the skin, evaluating the mechanism of action of both known and novel dermal penetration enhancers and designing new skin models for evaluation drug transport across the skin. I have contributed significantly to the literature on novel dermal penetration enhancers and retardants. Human full thickness skin alternatives have been developed containing both natural and synthetic biocompatible polymers leading to tissue engineered human skin models that show similar morphology and drug permeability trends to human skin. We are also designing novel drug carrier formulations (nanospheres) and designing & optimizing dermal formulations. I founded and direct the Center for Dermal Research at Rutgers which collaborates directly with a large group of pharmaceutical and personal care companies U.S. and worldwide. I have supervised many graduate and post graduate scholars over my many years in academia and have been recognized several times by the AAPS, CRS and Rutgers University for my support of students through mentoring.

B. Positions and Honors

Positions and Employment

1981-1983	Postdoctoral Fellow, Pharmacy, University of Florida, Gainesville, FL.
1984-1986	Postdoctoral Fellow, Pharmaceutical Technology, University of Bradford, U.K.
1986–1993	Assistant Professor, Pharmacy, University of South Carolina, Columbia, SC.
1993–1998	Associate Professor (tenured), Pharmacy, University of South Carolina, Columbia.
1998–2000	Professor (tenured), Pharmacy, University of South Carolina, Columbia.
2000–2005	Associate Professor, Physiology and Pharmacology, UMDNJ- NJ Medical School, Newark, NJ.
2005–2009	Associate Professor (tenured), Pharmacy, Rutgers University.
2010–present	Director, Center for Dermal Delivery,Rutgers University.
2009–present	Professor (tenured), Pharmacy, Rutgers University.

Honors

1981	Best Publication Prize in the Int. J. Cosm. Sci. for the paper "Studies on the mechanism of topical anhidrosis due to polyvalent cations" 3(1), 29-36. First Author: B. Michniak.

2000-2005	Chair, NIH Multidisciplinary Special Emphasis Panel: Study Section on Small Business Innovation Research and S. B. Technology Transfer
2002-present	U.S.-Editor of The Controlled Release Society Newsletter
2003-2005	Chair & Vice Chair of Pharmaceutics and Drug Delivery Section, American Association of Pharmaceutical Scientists
2003	Member NIH Study section on Alcohol Abuse and Alcoholism Special Emphasis Panel ZAA1 DD (23)
2005	Ad hoc member NIH Study Section Cancer Drug Development and Therapeutics, ZRG1 ONC-T 10B
2005	Most Cited Paper Award in European Journal of Pharmaceutics and Biopharmaceutics for Wang, Y., Thakur, R., Fan, Q., Michniak, B. Transdermal iontophoresis: combination strategies to improve transdermal iontophoretic drug delivery, Vol. 60, Issue 2 (2005), 179-191.
2005-2009	Permanent Member of NIH Study Section "Gene and Drug Delivery" ZRG1 BST-Z 10B (2005-2009).
2007-2009	Member of Steering Committee of the Nanotechnology Focus Group of AAPS
2007-present	Member of Steering Committee of the Dermatopharmaceutics Focus Group of AAPS & now the new Topical/Transdermal Community Group.
2007	South Wales (Australia) Cancer Institute's Premier Award for Outstanding Cancer Research for five year grant submitted by Khachigian, L. et al. entitled "Novel Gene-Targeted Therapies for Basal Cell Carcinoma".
2007	Meggers Award from the Society for Applied Spectroscopy for paper entitled "Infrared Kinetic/Structural Studies of Barrier Reformation in Intact Stratum Corneum Following Thermal Perturbation" *Applied Spectroscopy*, 2007, 60 (12), 1399-1404. Co-authors: Pensack, Moore and Mendelsohn.
2007	Member of Scientific Advisory Board of the International Pharmaceutical Excipients Council of the Americas Foundation (IPEC)
2008-present	Member of the AAPS Formulation and Drug Development (FDD) Fellows Committee
2008	Fellow of the American Association of Pharmaceutical Scientists
2010	Ad hoc member of NIH Nanotechnology Study Section 2010/05 NANO, (2010).
2010	Induction to the College of NIH CSR reviewers
2011	Rutgers University Aresty Research Center for Undergraduates Faculty Research Mentor of the Year
2015	Elected to The Kosciuszko Foundation Collegium of Eminent Scientists as a Distinguished Fellow of the Collegium for Outstanding Achievements and Contributions to the Polish Scientific Community
2015	Elected to Board of Trustees TRI Princeton, NJ
2018	Scientific Advisory Board of Westchester Biotechnology Project

Other Experience and Professional Memberships

1981-present	Member, Royal Pharmaceutical Society of Great Britain. License #73637.
2008–present	Editorial Board "The Open Nanotechnology & Nanomedicine Journal"
2009-2011	Editorial Board "Transdermal Journal"
2010–present	Editorial Board "Drug Delivery"
2011–present	Editorial Board "Journal of Pharmaceutics and Drug Delivery"
2012–present	Editorial Board "Journal of Outlook on Emerging Drugs"
2013–2014	Invited Guest Editor of Special Issue of Pharmaceutics Journal "Advanced Transdermal Drug Delivery" (ISSN 1999-4923; CODEN: PHARK5)
2014–present	Editorial Board "Journal of Drug Research & Development"
2015-present	Editorial Board "Research & Reports in Transdermal Drug Delivery"
2018-present	Editorial Board "Clinical Dermatology Research Journal"
2019-present	Editorial Board "Pharmaceutics" Impact factor 4.773

C. Contributions to Science

1st Contribution: Chemical and Physical Methods of Drug Permeation Enhancement through Skin

The barrier function of skin can be attributed mostly to the stratum corneum SC layer of the epidermis, and this skin barrier also regulates the transport of compounds into the skin. Passive and active skin penetration enhancement methods have been successfully used to improve the efficiency of either the topical delivery (the drugs/active compounds are delivered into skin strata), or transdermal delivery (drugs/active compounds are delivered into subcutaneous tissues and are taken up systemically into the body). One of the most promising and most widely investigated techniques to facilitate drug permeation through the skin is the use of chemical enhancers. An ideal enhancer would have the following properties: be pharmacologically inert, chemically stable, non-toxic, non-irritant, non allergic and without irreversible effects on the skin. Possible explanations for enhancement of permeation of compounds through the SC: a) disorganization of SC structure due to the interaction of the chemical enhancer with SC intercellular lipids resulting in the fluidization of the lipid environment; b) interaction with intracellular proteins contained within the corneocytes; and c) increasing partitioning and solubility of the drug in the SC. Studies on structure activity relationships of several enhancers revealed that the presence of a cyclic structure plays a significant role in the penetration enhancement activity. I have been instrumental in discovering over 150 new chemical enhancer structures and evaluating their efficacy and mechanisms of action. As an example, we investigated the skin penetration enhancement efficacy of a novel group of aromatic iminosulfuranes. These classes of iminosulfuranes are isoelectronic with dimethylsulfoxide and possess at least one aromatic ring in their structure. Thus, they were expected to show high potency in transporting drugs through the skin while causing minimum or no skin irritation. From all three classes of iminosulfuranes, bromo-iminosulfurane was found to be of note with respect to its high enhancement effects and its high interaction with the lipid bilayers in the SC. The mechanism of enhancement was investigated and this non-toxic and potent enhancer was found to be activated by its own metabolism in skin tissue and the metabolite 4-bromobenzamide played a major role in generating the high penetration enhancement effect. As a result of these studies I have been credited for the introduction of the “pro-enhancer” in dermatopharmacology. In addition, my group was one of two (the other was that of J. Hadgraft in the U.K.) to report the existence of “dermal penetration retardants”.

1) Zhang, J., Michniak-Kohn, B.B. Investigation of microemulsion and microemulsion gel formulations for dermal delivery of clotrimazole. . International Journal of Pharmaceutics, 2018, Jan 30; 536 (1), 345-352. https://doi.org/10.1016/j.ijpharm.2017.11.041. PMID 29170117.
2) Haq, A. Goodyear, B., Ameen, D., Joshi, V., Michniak-Kohn B. Strat-M synthetic membrane: Permeability comparison to human cadaver skin Int. J. Pharmaceutics, 2018, Aug 25; 547 (1-2); 432-437 doi: 10.1016/j.ijpharm.2018.06.012. Epub. 2018 June 14. PMID 29890259.
3) Ameen, D., **Michniak-Kohn, B.** Development and in vitro evaluation of pressure sensitive adhesive patch for the transdermal delivery of galantamine: Effect of penetration enhancers and crystallization inhibition. European Journal of Pharmaceutics and Biopharmaceutics, 2018, 139, 262-271. Doi:10.1016/j.ejpb 2019.04.008. PMID 30981946.
4) Haq, A., Michniak-Kohn, B. Effects of solvents and penetration enhancers on transdermal delivery of thymoquinone: permeability and skin deposition study. Drug Delivery, 2018, 25 (1), 1943-1949; doi:10:1080/10717544.2018.1523256. PMID 30463442.
5) Haq, A., Chandler, M., Michniak-Kohn, B. Solubility-Physicochemical-Thermodynamic theory of penetration enhancer mechanism of action. Int. J. Pharm. (2019) Dec 18; 575:118920. Doi: 10:1016/j.ipharm.2019.118920. (Epub ahead of print). PMID 31863880 .

2nd Contribution: Novel Drug Carriers for Topically Applied Formulations

Polymeric nanoparticles are nano-sized drug carriers that provide controlled and improved loading, protection, tunable release, and targeted delivery of drugs. Tyrosine-derived nanospheres (TyroSpheres™), proven as a versatile drug carrier for lipophilic compounds and offering a controlled drug release pattern, were developed and patented by the group at the New Jersey Center for Biomaterials (Rutgers-The State University of New Jersey). The medical applications of this new technology have been explored, focusing on topical route of administration. The broad scope and the depth in detail of the research conducted over the past decade demonstrated the potential of TyroSpheres™ for the pharmaceutical, personal care and cosmetic industries. By changing the molecular weight of PEG and the pendent group of the dipeptide derivatives, the size of the TyroSpheres™ can be regulated within a range of 36 to 122 nm. The size distribution is narrow as the

polydispersity index (PDI) is less than 0.25. For the leading polymer, PEG_{5k}-oligo(DTO-SA)-PEG_{5k}, more than ten lipophilic drugs and fluorescent model compounds have been successfully loaded into TyroSpheres™, without changing their size and size distribution. Significant efforts have been devoted to paclitaxel-loaded TyroSpheres™. Up to 8 wt% of paclitaxel can be loaded into TyroSpheres™ with the encapsulation efficiency higher than 70 wt%. Sustained release pattern of paclitaxel from paclitaxel-TyroSpheres™ dispersions was recorded under sink conditions, and the release rates were regulated by the initial loading of the paclitaxel. The potential of TyroSpheres™–based delivery systems in medical applications was explored for the treatment of skin diseases. The TyroSpheres™ provide a platform technology of nano-sized carriers for the loading and delivery of various lipophilic compounds topically. Currently, the TyroSpheres™ are being investigated as delivery vehicles for acne.

1) Batheja, P. Sheihet, L., Kohn, J., Singer, A., Michniak-Kohn, B. Topical drug delivery by a polymeric nanosphere gel: formulation optimization and in vitro and in vivo distribution studies. Journal of Controlled Release (2011) 149, 159-167 and (2010), doi:10.1016/j/jconrel.2010.10.005. PMID 20950659.
2) Kilfoyle, B.E., Sheihet, L., Zheng, Z., Laohoo, M., Kohn, J., Michniak-Kohn, B. Development of paclitaxel-TyroSpheres for topical skin treatment. Journal of Controlled Release (2012), 163, 18-24 and doi:10.1016/j.jconrel.2012.06.021.PMID 22732474.
3) Dorrani,M, Garbuzenko, O., Minko, T., Michniak-Kohn, B Development of edge-activated liposomes for siRNA delivery to human basal epidermis for melanoma therapy. Journal of Controlled Release (2016), 228, 150-158. PMID 26965957.
4) Ameen, D., Michniak-Kohn, B. Development and in vitro evaluation of pressure sensitive adhesive patch for the transdermal delivery of galantamine: Effect of penetration enhancers and crystallization inhibition. European Journal of Pharmaceutics and Biopharmaceutics, 2018, 139, 262-271. Doi:10.1016/j.ejpb 2019.04.008. PMID 30981946.
5) Ramezanli, T., Michniak-Kohn, B, Development and characterization of a topical gel formulation of adapalene-Tyrospheres and its clinical efficacy assessment. Molecular Pharmaceutics, 2018, July 31, doi: 10.1021/acs/molpharmaceut.8b00318 (Epub ahead of print). 2018, Sept 4;15: 38, 3813-3822. PMID 29996653.

3rd Contribution: Novel models of human skin for permeability testing

Human skin equivalents (HSEs) are bioengineered substitutes composed of primary human skin cells (keratinocytes, fibroblasts and/or stem cells) and components of ECM (mainly collagen). In the last three decades, tremendous efforts have been devoted to the research and development of HSEs, resulting in a number of clinical products and skin models for pharmaceutical and cosmetic companies. In general, HSEs are applied in two major categories: (a) as clinical skin replacements and grafts; and (b) as models for drug permeability tests and toxicity screening. The other field of application for HSEs is as models for drug/ingredient permeability testing and toxicity screening. Animal testing of cosmetic ingredients is strictly limited in the European Union; even if no alternative tests are available, the majority of the animal tests are banned. Human cadaver skin and excised animal skin have been traditionally used as topical and transdermal permeation models. Although human cadaver skin replicates *in vivo* permeation performance to some extent, there is a high sample-to-sample variation. Animal skin, though easily procured, is morphologically different to human skin. Therefore, there is a commercial need for better HSEs that serve as a suitable model for various skin tests. I have lead research efforts to optimize both collagen, porcine mesothelial as well as polymer skin models in a effort to increase their drug permeability performance and hence improving the barrier property of the skin models.

1) Batheja, P., Song, Y., Wertz, P., Michniak-Kohn, B. Effects of growth conditions on the barrier properties of a human skin equivalent. Pharm. Research (2009), 26 (7), 1689-1700. PMID 19415472.
2) Zheng, Z., Michniak-Kohn, B. Tissue Engineered Human Skin Equivalents. Pharmaceutics ISSN 1999-4923 www.mdpi.com/journal/pharmaceutics doi: 10.3390/pharmaceutics4010026, (2012), 4, 26-41.PubMed PMID: 24300178; PubMed Central PMCID: PMC3834903.

3) Tsai, P.-C., Zhang, Z., Roberts, K., Florek, C, Michniak-Kohn, B. Constructing human skin equivalents on porcine mesothelial acellular peritoneum extracellular matrix for in vitro irritation testing, Tissue Engineering Part A (2016) Jan; 22 (1-2), 111-22; (2015), Sept. 28 [Epub. ahead of print], PMID 26415037.

4) Haq, A., Goodyear, B. Ameen, D., Joshi, V., Michniak-Kohn, B. Strat-M synthetic membrane: Permeability comparison to human cadaver skin. Int. J. Pharmaceutics, 2018, Aug 25; 547 (1-2); 432-437 doi: 10.1016/j.ijpharm.2018.06.012. Epub. 2018 June 14. PMID 29890259.

Link to My Bibilography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1ToZp_65HfEQv/bibliography/48083327/public/?sort=date&direction=ascending.

D. Additional Information: Research Support and/or Scholastic Performance

Research Support Ongoing

1. Industry Support: From pharmaceutical companies to conduct industrially relevant research.
2. Agency: European Commission Research & Innovation HORIZON 2020 Call: H2020-MSCA-RISE-2017 (Marie Sklodowska-Curie Research & Innovation Staff Exchange). Topic MSCA-RISE 2017 Proposal No. 778051 "Open Research Biopharmaceutical Internship Support" 2017-2019 P.I. Janina Lulek, University of Poznan, Poznan, Poland. Rutgers P.I. B. Michniak-Kohn. Funded July 2017.
3. Agency: NIH/FDA Small Business Innovation Research (SBIR) Phase II Grant No. 2R44FD005345-02. Title "A multiscale simulation toolkit for computational pharmacology of trans/intradermally administered compounds in healthy and diseased populations". P.I. Mahadevabharath R. Somayaji, Computational Medicine and Biology Division, CFD Research Corporation, Huntsville AL. Subcontractor B. Michniak-Kohn for total $140,000 for 2 years. Sept. 2019-Sept. 2021.

Completed:

1. Agency: DOD SBIR#HDTRA 1-17-P-0003 "Dermal Medical Countermeasures for Chemical Weapons Exposure", 01/12/17-07/11/17. P.I. Michael Liu (Zymeron Corporation); Subcontractor P.I. B. Michniak-Kohn (Rutgers), $30,001 for Phase I (30% of the total).
2. Agency: NSF Proposal # 0540855 C-SOC Center for Structured Organic Particulate Systems C-SOPS, 06/06/06 – 06/06/16. P.I. Muzzio, F. My roles: Member of the Leadership Team, Leader of Project Area C5. Drug release and dissolution of pharmaceutical dosage forms is being examined and related to processing parameters.
3. Agency: NSF AIR "Industry Academia Research Partnership for Developing and Implementing Non-Destructive Characterization and Assessment of Pharmaceutical Oral Dosages in Continuous Manufacturing Processing" P.I. Cuitino. Co-P.I. B. Michniak-Kohn. 07/01/2012-07/01/2015. From NSF with additional match from Johnson & Johnson.
4. Agency: NIH R01 AR056079-01 "Nanospheres as Delivery Vehicles for Psoriasis Therapeutics," 5/1/08 – 7/1/12. Principal Investigator. Novel tyrosine based nanospheres are used to encapsulate paclitaxel, Vitamin D3 and betamethasone. Post-characterization the delivery of these carriers is being studied into human healthy and psoriatic skin in vitro as well as in vivo in a mouse psoriatic model.