

Bozena B. Michniak-Kohn, Ph.D., Director of the Center for Dermal Research (CDR)

about her work and the growing demand of biological effective products

Editors Note:

We encourage our readers to “study” this interview since Dr Michniak-Kohn’s answers include in-depth scientific knowledge that will expand your horizons and point to expanding opportunities for cross fertilization of cosmetic and pharma science and technology.



Bozena B. Michniak-Kohn, Ph.D.,

EURO COSMETICS: *Dr. Michniak-Kohn, can you please tell us briefly about your professional/educational background?*

Dr. Bozena B. Michniak-Kohn: Currently I am a Professor of Pharmaceutics at the Ernest Mario School of Pharmacy, and Founder/Director of the Center for Dermal Research CDR at Rutgers-The State University of New Jersey, Piscataway, NJ, USA. I am also a Professor at Rutgers University in the Pharmaceutical Sciences, Biomedical Engineering, Chemical and Biochemical Engineering, Chemistry and Chemical Biology as well as the RWJ Graduate School of Biomedical Sciences and received my B. Sc. (Honors) in Pharmacy and Ph.D. in Pharmacology from the U.K.

My main research focus is topical and transdermal delivery of active compounds. I have 40 years experience in design & optimization of topically applied formulations as well as transdermal patches. I hold several patents for novel drug carrier approaches for dermatologicals.

I have directed over 50 Ph.D. and Masters students and the work resulted in over 135 peer-reviewed manuscripts, over 425 abstracts, 2 books, and 35 book chapters. I am a member of 10 journal editorial boards, several scientific advisory boards, member of Board of Trustees at TRI, Princeton and a reviewer for about 44 cosmetic, pharmaceutical and drug delivery journals. For this work I have been awarded Fellow status of the American Association of Pharmaceutical Scientists (AAPS) in 2008. Further information can be found on my websites: www.centerfordermalresearch.org, www.derm.rutgers.edu and www.michniaklab.org.

EURO COSMETICS: *You are the Founder and Director of the Center for Dermal Research CDR at Rutgers University, Piscataway, New Jersey, USA. Can you tell us what this Center is known for?*

Dr. Bozena B. Michniak-Kohn: I founded the CDR in March 2011 so this year is our 5th anniversary. The CDR is a premier dermatopharmaceutics research center in NJ conducting studies on topical and transdermal compound delivery, formulations, skin biology, and skin tissue engineering. The Center provides research opportuni-

ties for the pharmaceutical, personal care, cosmetic and excipient companies to conduct independent research/contract studies.

In addition, the CDR offers educational outreach, training and networking with monthly seminars, workshops, training events, skin courses and our annual conference “Innovations in Dermatological Sciences”.

Many companies work with us in a variety of areas critical to cosmetic and pharma ingredients and formulations. Some of the research and testing services we provide include, but are not limited to: conducting skin permeability studies of actives, location of the delivery of actives, optimization of formulations and evaluation of enhancing or retarding penetration of actives (depending on their target of action).

We also provide research and testing for semi-solid formulation dissolution testing/actives release from formulations, design of novel skin formulations (semisolids, polymer films, face masks, etc.), genomics/protein extraction, skin pH changes, tissue engineered skin models, skin cell lines and skin irritation testing.

Partnerships have been established between the CDR and TRI Princeton, NJ, Columbia University Department of Dermatology, New York (Dr. Angela Christiano) as well as Basic and Applied Dermatology Forum (BADF) headed by



Dr. Otto Mills. TRI Princeton provides the CDR with specialized spectroscopic visualization techniques for skin and hair, Dr. Christiano has excellent dermatological facilities at Columbia University and Dr. Mills provides additional seminar speakers as part of the BADF series.

EURO COSMETICS: *What type of research do you do with your laboratory group?*

Dr. Bozena B. Michniak-Kohn: The skin is a complex membrane that performs many physiological functions such as metabolism, synthesis, temperature regulation, and excretion. Its upper layer, the stratum corneum, is considered to be the main barrier to the percutaneous penetration of exogenous materials. This barrier is also important in the maintenance of water within the body as well as in the absorption of pharmaceutical, cosmetic and personal care actives and other agents.

There are several categories of cosmetic/pharmaceutical products which are targeted to the skin, or utilize the skin as a port of entry into the body. These include transdermal actives delivery systems (patches), gels, creams, ointments, lotions, as well as subcutaneous implants and dermal vaccinations. In contrast to the traditional oral route, the use of transdermal drug delivery by-passes the first pass metabolism of the liver, the acidic environment of the gastrointestinal tract, and

problems of absorption in the stomach which often contains food resulting in erratic and pulsed delivery of drugs into the intestine and variability in plasma concentration-time profiles.

As with other routes of delivery, transport across, and into the skin is also associated with several disadvantages, the main drawback being that not all actives are suitable candidates. A number of physicochemical parameters have been identified (such as molecular weight, partition coefficients) that influence the diffusion process, and variations in permeation rates can occur between different skin models, patients, different races, and between young and old. The major challenge is overcoming the resistance of the skin to permeation in a reversible and non-damaging manner as well as the design of therapeutically effective topical and transdermal formulations.

The main focus of our research group is in the area of topical and transdermal drug delivery. Part of the work is devoted to the tissue engineering of skin. We have developed a human skin co-culture of fibroblasts and keratinocytes using collagen as a dermal matrix. It has been shown importantly, to possess similar drug permeability to human skin. Our intention is to develop this bioengineered human skin as a screen for examining skin barrier prop-

erties, as well generating a useful model for inflammatory and cytotoxicity testing. Projects include evaluation of correlations between the drug permeability, stratum corneum lipid composition/organization, growth media composition, immunohistochemistry, and morphology and gross structure of the bioengineered skin.

Other major projects in the laboratory include optimization of formulations for topical and transdermal delivery, such as topically applied gels, drug targeting, nanosphere formulations, as well as liposomal creams. Drug permeability pathways and effect of agents as well as iontophoresis on skin membranes are being investigated using confocal microscopy as well as SEM, TEM, Raman spectroscopy and FTIR (Fourier-Transform Infra red spectrometer).

Structure-activity relationships have been investigated for over 250 newly synthesized compounds with both dermal enhancing and retarding properties. The work includes chemical modeling of both the enhancer/retardant compounds as well as the modeling of lipid layers of the stratum corneum. The potential uses for retardant compounds include sunscreens and other cosmetic formulations, as well as insecticides. Chemical enhancers may be used in transdermal drug delivery systems to allow increased active compound permeation into and across the skin thereby

decreasing the amount of drug needed in the formulation as well as side-effects ex. topical steroids. Part of the work includes in vivo pharmacokinetics in rodents and pigs and metabolic studies with drugs administered by several routes (topical, intravenous-infusion, bolus, and oral).

EURO COSMETICS: *How do you interact with the cosmetic and personal care industry?*

Dr. Bozena B. Michniak-Kohn: We have interactions with the personal care and cosmetic industries from networking sources, website connections as well as word-of-mouth. We provide opportunities for conducting studies in our laboratory as well as access to equipment located at Rutgers University such as electron microscope facilities, DCSs, FTIRs, etc. In addition, we provide training (for example, in permeability studies, conducting validated assays, etc.) for new company employees, and act as a resource for company recruitment from our pool of graduates and post doctoral students. We offer different skin courses covering all levels and topics from basic skin physiology to the challenges of selection of actives, claim substantiation and formulation optimization.

EURO COSMETICS: *CDR conducts research in the cosmetic and personal care area. Can you illustrate what types of studies are performed?*

Dr. Bozena B. Michniak-Kohn: We have many projects in our laboratory from the cosmetic and personal care industries. Many studies involve examining the transport of molecules into the skin and the localization of where the compounds reside within the skin layers. We perform skin irritation, genotoxicity and phototoxicity studies using fibroblasts and keratinocytes and three dimensional skin models. We provide microtoming and histological evaluations of treated and non-treated skin samples. Visualization of skin samples post treatment as well as more in depth examination using Raman and FTIR spectroscopy together with our partners TRI Princeton, NJ.

EURO COSMETICS: *Locating actives in skin*

layers is important for cosmetic product claims. What kind of work do you do to address this challenge?

Dr. Bozena B. Michniak-Kohn: We can “strip” the stratum corneum (SC) from the skin using adhesive tape and analyze the concentration of the active in each strip. This allows one to plot active compound concentration gradients across the SC. In addition, we can check what remains unabsorbed on the surface of the skin and perform so-called “mass balance studies”.

We can also microtome (section) the skin samples post treatment and analyze/visualize each skin section for presence of actives. By this means we can separate the epidermis and dermis and analyze for actives in each main skin layer—all will depend on the specific requirements of a project protocol. We have a license to use radioactively labeled compounds which also allow detailed examination of the skin localization of the active. Even though it may not be apparently “relevant” we also always check transdermal skin permeation of actives—hoping to see little or none at all for cosmetic/personal care actives and ingredients. It is especially important to cosmetic ingredient developers to show that the active/ingredient does not pass across the skin and that systemic uptake is not an issue.

EURO COSMETICS: *And where are the biggest challenges for the cosmetics industry in the near future?*

Dr. Bozena B. Michniak-Kohn: The biggest challenge will be the increasing demand from customers for products that show effective biological activity and yet remain outside the „pharmaceutical“ realm ... we are already facing some of these issues today with claim substantiation, etc. It will be interesting to see how the FDA will handle these new and challenging products in the future.

EURO COSMETICS: *In what areas do you see the greatest need for cosmetics manufacturers?*

Dr. Bozena B. Michniak-Kohn: I see a surging interest and need for locating actives in

various skin layers and formulating expertise as the two main areas in demand.

Generally, for cosmetic manufacturers, the challenge is in sourcing of new ingredients & materials- natural or synthetic. Today's clients and regulators demand new and effective products based on strong science. The industry is, and will be coming up with new actives (results of skin genotyping and proteomics research) but with the restriction of not crossing over to the pharmaceutical/FDA side ... This is going to pose a significant challenge ... and may lead to changes on how we treat such products from a regulatory perspective.

EURO COSMETICS: *What trends do you observe?*

Dr. Bozena B. Michniak-Kohn: The trends will all mostly come from advances in skin biology and in particular the proteomics and genomics science sectors. We already know many of the the skin genes that are related to inflammation, ageing, pigmentation, action on microbes, sensitivity to UV radiation and certain drugs, transcription, calcium ion transport, etc. So we have the targets and the search in on to find the active compounds that can selectively up- or down-regulate these cell pathways.



The second trend will be in more “personalized” cosmetics following analysis of buccal swabs or saliva, hair samples, etc.





The third trend will be in creating a barrier against "pollutants" from the air. Many customers believe that their skin is affected in some (usually deleterious manner) by pollution, dirt and chemicals from emissions (car, factory, etc). Fourthly, there is a trend to combine nutritional aspects with cosmetic product development.

EURO COSMETICS: *You have an annual symposium each year. What is this about and on what subjects was it this year?*

Dr. Bozena B. Michniak-Kohn: This year's two day symposium „Innovations in Dermatological Sciences“ took place on September 29th & 30th and was focused on „Delivery of Actives to Skin“. In addition, we also celebrated the 5th anniversary of the CDR with a champagne reception and a retrospective on the past five years of CDR events and Center supporters. The conference attracted over 175 attendees and took place at the Marriott Renaissance Hotel in Woodbridge, NJ.

The first day agenda was focused on the challenges of transporting compounds into skin layers. The plenary session was given by Prof. Samir Mitrogotri from USC-SB California on „Ionic liquids for skin absorption“.

The second day focused more on solutions to the challenges of delivery of actives to skin and the plenary speaker was Dr. Gary Cleary of the nicotine, scopolamine and nitroglycerin transdermal patch fame, inventor and entrepreneur currently at Cape Therapeutics, CA speaking on „From the jungle, Yucca plants and yams to transdermal patches“.

We were able to connect with many in vitro scientists from academia and industry. We look forward to next year.

EURO COSMETICS: *Thank you for the conversation.* ■



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