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## Preface

# The US Food and Drug Administration's Intersection with Dermatology



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*Editor*

I am writing this opinion piece and one of the forewords to this issue from the confines of my alternate workplace (my home) in the midst of the COVID-19 pandemic. My Food and Drug Administration (FDA) work allows me to do much of it from home currently due to twenty-first-century technology (ie, the Internet, thumb-sized desk-top video cameras, and collaborative work software). My coworkers and my Division have maintained a high level of work throughout and have met our work deadlines despite the pandemic. It is my assessment that this would not have been possible at the start of my career at FDA in 1998. I recall that some medical officers were still dictating their reviews to be transcribed by typists, and it was novel to have an electronic submission for a drug application. I had come to FDA from the National Institutes of Health, where I was previously serving as a Clinical Associate at the National Cancer Institute, seeing patients and conducting research in the laboratory of Dr Kim Yancey. It was a big paradigm shift for me to start as a Medical Officer reviewer for the FDA back then. I had the privilege and fortune of being hired by and working under Dr Jonathan Wilkin, an academician and dermatologist with broad interests, who took to his job as an FDA regulator with utmost enthusiasm. I recall that he was full of ideas and always thought himself fortunate to be able to work at FDA.

The FDA has grown over the years that I have worked here. It currently encompasses Center

programs in foods and cosmetics (Center for Food Safety and Nutrition or CFSAN), drugs (Center for Drug Evaluation and Research or CDER), medical devices (Center for Devices and Radiologic Health or CDRH), biologics (Center for Biologics Evaluation and Research or CBER), veterinary medicine (Center for Veterinary Medicine or CVM), and tobacco (Center for Tobacco Products or CTP). In addition, there are additional centers responsible for field offices and inspections and the National Center for Toxicological Research or NCTR. Together, these entities intersect with the field of dermatology and other medical fields in multiple ways.

I am a dermatologist, board-certified, with a history of advocacy in this field as a resident and as academic faculty. Dermatology is an ideal medical field to discuss interaction with FDA. Dermatologists prescribe and use a myriad of products in the care of our patients. Skin care occurs both with and without health care worker “knowledgeable intermediaries.” Various consumer and personal care products are used by the lay public to care for their skin, hair, and nails, some of which are regulated by FDA. We (my fellow article authors and I) have endeavored in this *Dermatology Clinics* issue to address broadly the various products for human use that are regulated by FDA. We attempt to anticipate some of the questions or knowledge needs about FDA that a practicing dermatologist or skin health care practitioner might have in the articles that constitute this issue.

We hope that you enjoy reading through the various pieces that we have assembled in this issue. For the dermatologist who is starting on her or his career, we encourage them to explore how they might contribute to the global dermatology society by considering working at FDA, perhaps as a reviewer or serving as an advisor and consultant for one of its relevant Advisory Committees should they have the qualifications and lack any conflict of interest. One of the fulfilling parts of working at FDA in my estimation is the ability to be a less conflicted observer/reviewer/gatekeeper and to work at providing consistent expert knowledge with less bias (we all have personal biases) and level-playing-field

advice and decision making. This aspect, I believe, characterizes what sets apart an FDA review.

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