The Noah Worcester Dermatological Society

U.S. FOOD & DRUG ADMINISTRATION

History of Dermatology and Dermatologists at the U.S. Food and Drug Administration

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Disclaimers

This presentation reflects the views of the presenter and should not be construed to represent FDA's official views or policies.

Any representation of brand name drugs in this talk are for purposes of scientific discussion and specific comparison.

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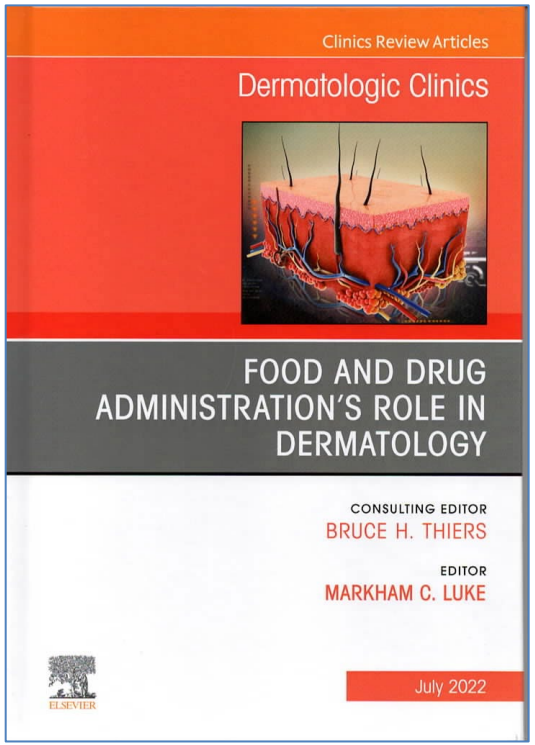

Insightful articles on:

- The History of Dermatology at FDA
- FDA and Dermatologic Drug Development
- Postmarket Assessment for Dermatology Drugs and Cutaneous Adverse Reactions
- How does FDA Approve Generic Drugs
- Dermatology Drugs for Children
- Regulation of Medical Devices for Dermatology
- Regulation of Cosmetics in the United States
- Cutaneous Pharmacokinetic Approaches
- Measuring What Matters to Patients in Dermatology Drugs

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- Collaborative project with FDA's History Office (Vanessa L. Burrows, PhD)
- We wanted to explore some of the early to recent history of FDA, its regulation of dermatology relevant products and its public health minded dermatologists

FDA Centers

Dermatology Relevant:

- **Center for Drug Evaluation and Research (CDER)**
  - Office of New Drugs (OND)
    - Division of Dermatology and Dental Drug Products
  - Office of Generic Drugs (OGD)
- **Center for Devices and Radiological Health (CDRH)**
- **Center for Biologics Evaluation and Research (CBER)**

- Office of Cosmetics and Colors (now in Office of Chief Scientist) – 2024 reorganization of Foods

Table 1
Major legislative milestones that impacted the regulation of dermatology therapy

Law	Year	Regulatory Impact
Biologics Control Act	1902	Required federal licensure of biologics manufacturers and products
Federal Food and Drugs Act (aka, Pure Food and Drugs Act)	1906	Banned marketing of adulterated or misbranded food or drugs; required adherence to drug standards
Federal Food, Drug, and Cosmetic Act	1938	Mandated evidence of safety before marketing drugs; brought cosmetics and medical devices under FDA's authority; created the color certification program
Durham-Humphrey Amendments	1951	Required prescription from medical professional for certain dangerous or habit-forming drugs
1962 Drug Amendments (aka, Kefauver-Harris Amendments)	1962	In addition to safety, required drugs provide substantial evidence of efficacy from sound clinical studies before marketing
Medical Device Amendments	1976	Created risk-based classification system for medical devices, requiring premarket approval for riskiest (Class III) devices and development of performance standards for less risky products
Drug Price Competition and Patent Term Restoration Act (aka., Hatch-Waxman Amendments)	1984	Incentivized development of generic drugs by allowing the use of Abbreviated New Drug Applications relying on evidence of bioequivalence to pioneer products; authorized exclusivity and patent term extension for pioneer products
Prescription Drug User Fee Act	1992	Authorized the collection of user fees to review New Drug Applications
Medical Device User Fee Amendments	2002	Authorized the collection of user fees to review medical device applications, register establishments, or list marketed products
Generic Drug User Fee Amendments	2012	Authorized the collection of user fees to review Abbreviated New Drug Applications

Table 2
Board-certified dermatologists who were managers at FDA

Name	Managerial Roles	Years
Dr Clarence Carnot Evans	Dermatology Branch Chief	1987–1992?
Dr Jonathan K. Wilkin	Division Director, DDDDP	1994–2005
Dr Susan Walker	Dermatology Team Leader, DDDDP	1997–2002
	Division Director, Nutritional Supplements	2003–2007
	Division Director, DDDDP	2007–2011
Dr Martin Okun	Dermatology Team Leader, DDDDP	1998–2000
Dr Markham C. Luke	Dermatology Team Leader, DDDDP	2001–2008
	Deputy Office Director, ODE, CDRH	2008–2016
	Acting Director, Cosmetics	2012–2013
	Division Director, Therapeutic Performance of Generic Drugs	2016-present
Dr Jill Lindstrom	Dermatology Team Leader, DDDDP	2004–2010
	Deputy Division Director, DDDDP	2010–2019
RADM Dr Boris Lushniak	Assistant Commissioner, Director, Emergency Preparedness (subsequently became Acting Surgeon General for the United States)	2005–2010
Dr Elektra J. Papadopoulos	Associate Office Director, New Drugs and Deputy Director, Clinical Outcomes Assessments	2009-2021

Fig. 6. Clarence Carnot Evans. *Courtesy of* FDA History Office Still Image Collections.

Fig. 7. Drs. Jonathan Wilkin, Mohamed Al'Osh and Markham Luke.

Table 3
Dermatologists who have worked full-time at FDA

Name	FDA Center(s)	Years
Dr Lawrence B. McCaleb	Division of Drugs	1939–1942
Dr Clarence Carnot Evans	Bureau of Medicine CDER	1963–1992?
Dr Phyllis Huene	Bureau of Medicine CDER	1964–2005
Herbert Golomb	Bureau of Medicine	1963-?
Donald Mitchell	Bureau of Medicine	1963-?
Walter Edmundson	Bureau of Medicine	1963-?
Glenn Hays	Bureau of Medicine	c. Late-1960s
Wilson Powell	Bureau of Medicine	c. Late-1960s
John B. Sanders	Bureau of Medicine	c. Late-1960s
Leonard Trilling	Bureau of Medicine	c. Late-1960s
Dr Ramsey Labib	CDER	1990–2002
Dr Ella Toombs	CDER	1989–2002
Dr Brenda Vaughan	CDER	1993–2011
Dr Lois LaGrenade	CDER	1997–2019
Dr Denise Cook	CDER	1995–2022
Dr Jonathan K. Wilkin	CDER	1994–2005
Dr Susan Walker	CDER, CFSAN	1996–2011
Dr Kathy A. O'Connell	CDER, CBER	1996–2014
Dr Martin Okun	CDER	1997–2001
Dr Markham C. Luke	CDER, CDRH, CFSAN	1998-present
Dr Brenda Carr	CDER	2000-present
Dr Elektra Papadopoulos	CBER, CDER	2001-2021
Dr Jill Lindstrom	CDER	2002–2019
Dr Patricia Brown	CDER	2005-present
Dr Jane Leidtka	CDER	2006–2020
Dr Boris Lushniak	OC	2004–2010
Dr Kenneth Katz	CDER	2006–2007
Dr Melinda McCord	CDER	2009-present
Dr Laura Marquart	CDRH	2013-present
Dr Schlomit Halachmi	CDRH	2013-present
Dr Roslyn E. Epps	CDER	2015-present
Dr Melissa Reyes	CDER	2016-present
Dr Felisa Lewis	CDER	2020-present
Dr Mary Kim	CDER	2021-present

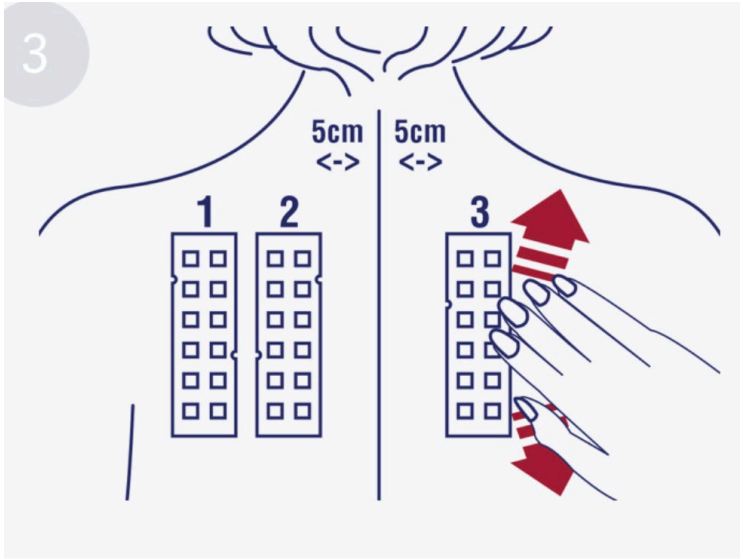
Fig. 8. Drs. Brenda Vaughan, Elektra Papadopoulos and Jill Lindstrom.

Pictorial History: Problem Products

Fig. 1. LashLure and Electreat. *Courtesy of* FDA History Office, Legacy Artifact Collection.

Pictorial history: Irritant and Contact Dermatology

Fig. 3. Draize test. *Courtesy of* FDA History Office, Photograph Collection.



Pictorial history: Corticosteroids and Retinoids

Fig. 4. Terra-Cotril hydrocortisone ointment. *Courtesy of* National Museum of American History, Smithsonian Institution.

Fig. 5. Accutane warning. *Courtesy of* FDA History Office Still Image Collections.

Some Dermatology-relevant FDA Milestones

20 years since Biologic Drugs Migration

- In 2003-4, biologic drugs were migrated from CBER to CDER. This includes drugs like botulinum toxin.
- Since then, great strides have been made in the regulation of biologic drugs, including the advent of biosimilars.
- Biosimilars, under user fee provisions have advanced with regard to their own regulatory science and research program.

10th Anniversary for Indoor Tanning Bed Reclassification

- Indoor tanning beds/booths are regulated by CDRH.
- Regulated as Class 1 – low risk - devices until June 2014, when they were reclassified to Class 2 – higher risk.
- As part of the reclassification, indoor tanning beds have a boxed warning regarding safety and recommendations not to used by children.
- Notable reduction in the use of UV indoor tanning, in favor of spray tanning booths.

Over 12 years with GDUFA

- The Generic Drug User Fee Amendments (GDUFA) was signed into law in July 2012, as part of the Food and Drug Administration Safety and Innovation Act (FDASIA)
- One out of numerous User Fee Programs that help the FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry
- GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and improve upon the predictability of the review process
- One unique feature of GDUFA is the Regulatory Science and Research Program ~ $20 million annually
- GDUFA must be reauthorized every 5 years (currently in GDUFA III)

https://www.fda.gov/industry/fda-user-fee-programs
https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments

Advances in Dermatopharmacokinetics

- Vasoconstrictor or skin blanching assay for corticosteroid strength/penetration (McKenzie & Stoughton)
- Systemic PK correlation with local action
- Tape Stripping
- In Vitro techniques – in vitro release testing (IVRT) and in vitro permeation testing (IVPT)
- In vivo Microdialysis and Dermal Open-Flow Microperfusion (dOFM)
- Confocal Raman Spectroscopy techniques – stimulated Raman scattering microscopy (Conor Evans, Richard Guy, RiverD, others)
- Future techniques including in vivo, in situ , real-time microbiosensors

Summative Conclusion

- The history of dermatology and the tools used for treatment and diagnosis by dermatologists are intertwined with the history of product regulation at the FDA
- Many dermatologists at FDA have played an important role in shaping the landscape of treatments and diagnostics over the years
- FDA regulation of dermatologic products involves a mix of legal, scientific, and risk comprehension

Thank You

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