

# **GDUFA Science and Research Program**

## *Getting Involved in Research*

*Society for Investigative Dermatology Annual Meeting, 2022*

FDA Session: Advances in Topical Dosage Form Characterization and Measuring Drug Concentrations in the Skin

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CDER | U.S. FDA

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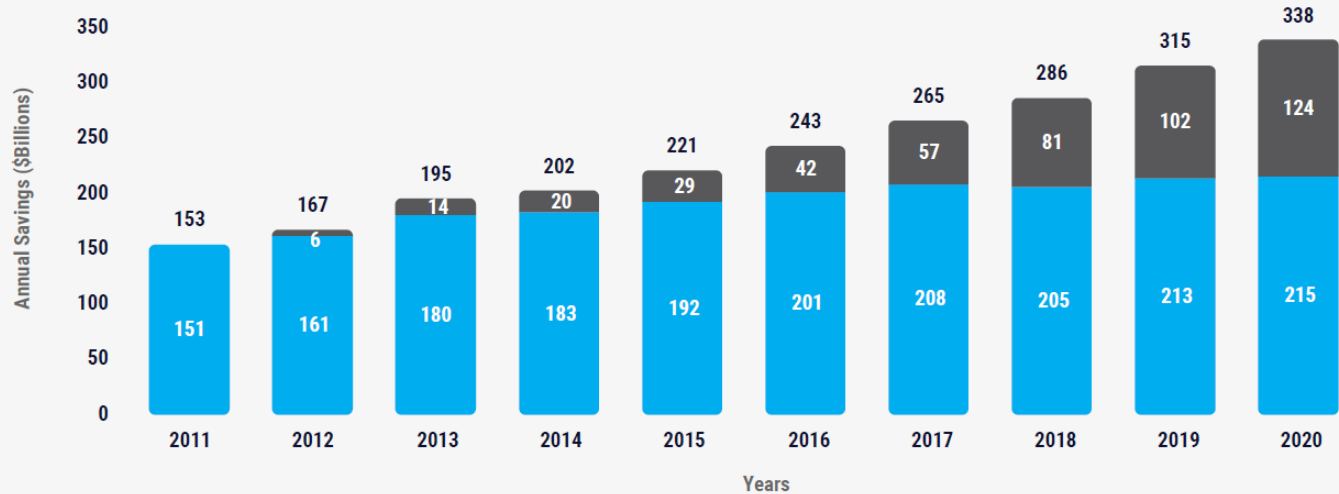
# Disclaimer



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

# Impact of Generics on Savings

**ANNUAL SAVINGS FROM GENERICS AND BIOSIMILARS (\$BILLIONS)**

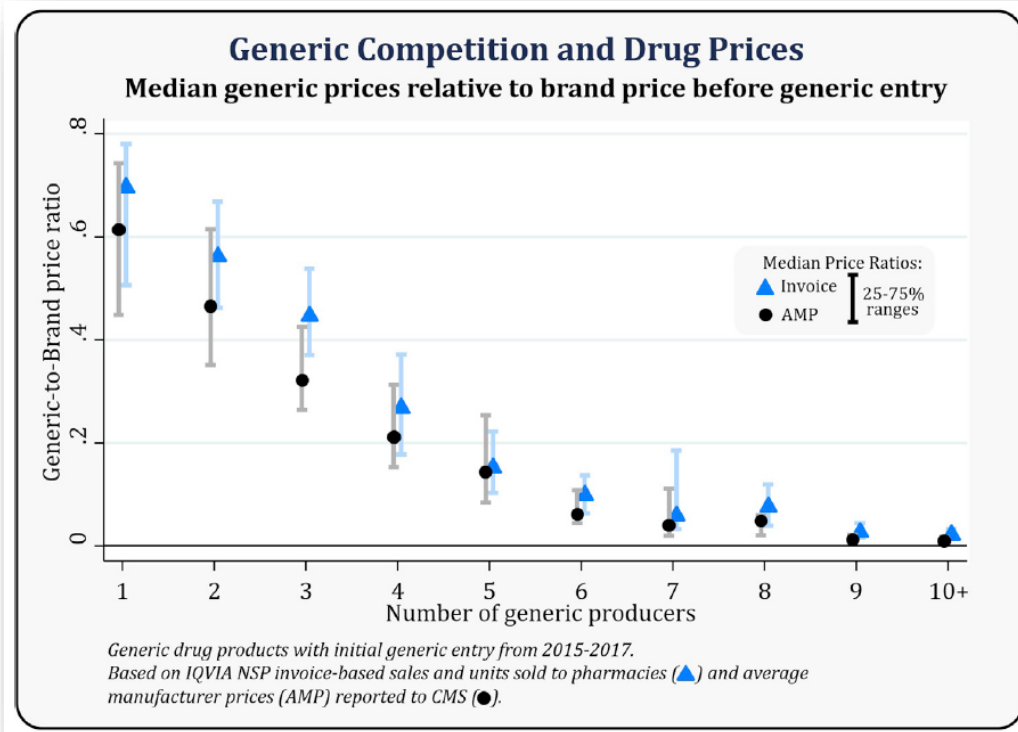


Source: IQVIA, National Sales Perspectives, Dec 2020

● Older Generics ● Newer Generics

2021 AAM U.S. Generic & Biosimilar Medicines Savings Report. Available at:  
<https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf>

# Impact of Generics on Pricing



US Food and Drug Administration. New evidence linking greater generic competition and lower generic drug prices. Available at: <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices>.

# Patient Access to Topical Products

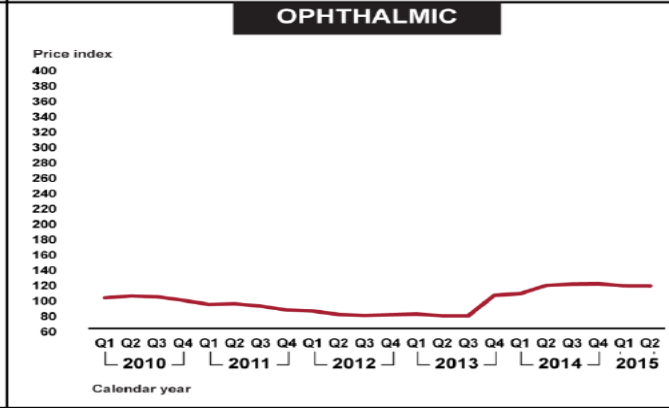
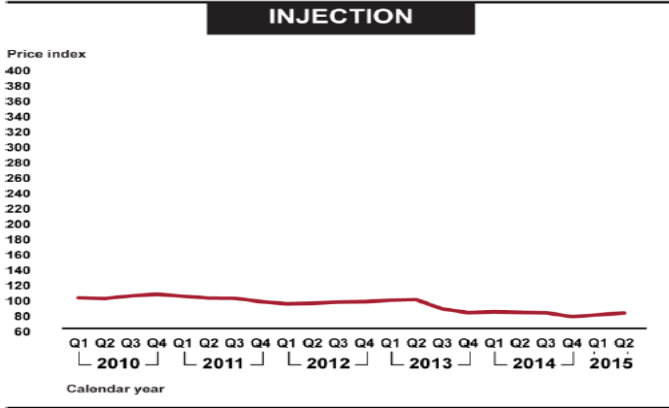
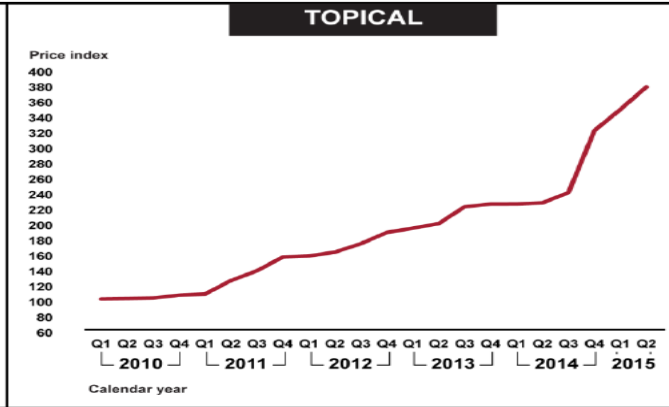
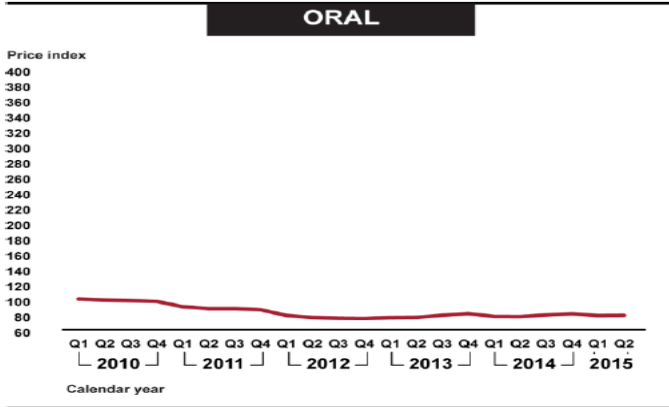
- The majority of topical dermatological drug products have fewer than three generic competitors; for many products no generics are available at all.
- This may have been attributable to the historical barriers to the development of topical dermatological drug products, possibly including:
  - Difficulty/issues with comparative clinical endpoint bioequivalence (BE) studies
  - The complex nature of topical formulations

# The GAO Report (GAO-16-706)



- The U.S. Government Accountability Office (GAO) Report in Aug 2016 analyzed a period spanning Quarter 1 of 2010 through Quarter 2 of 2015
- **57%** of the topical drug products experienced an extraordinary price increase in that period
- The average price of topical generic drugs was **276% higher** by the end of the period analyzed
- Manufacturers and other stakeholders reported that market **competition**, influenced by various factors, drives generic drug prices

# The GAO Report (GAO-16-706)



Source: GAO analysis of Medicare Part D prescription drug event data. | GAO-16-706

# Retail Prices for Dermatologic Drugs



Drug	Type	Price, US \$				Absolute Change, 2009-2015	% Change, 2009-2015
		2009	2011	2014	2015		
Altanax, 15 g	I	92.50	106.18	168.75	196.86	104.36	112.82
Benzaclin, 50 g	A	166.79	205.80	451.29	503.85	337.06	202.08
Carac cream, 30 g	N	159.40	227.16	2939.68	2864.70	2705.30	1697.18
Clobex spray, 4 oz	S	389.57	500.29	827.11	958.01	568.44	145.91
Cloderm cream, 30 g	S	96.47	132.92	220.75	360.02	263.55	273.19
Cutivate lotion 120 mL	S	305.00	493.92	918.63	1067.25	762.25	249.91
Derma-Smoother FS oil, 4 oz	S	45.70	47.23	247.84	322.67	276.97	606.06
Finacea, 50 g	A	124.42	185.42	288.92	284.30	159.88	128.51
Olux-E foam, 100 g	S	307.58	382.79	750.79	841.76	534.18	173.67
Oracea, 40 mg (30 tablets)	A	439.01	416.09	632.80	702.46	263.45	60.01
Oxistat cream, 30 g	I	76.50	119.25	399.00	544.66	468.16	611.97
Oxsoresalen-Ultra, 10 mg (50 capsules)	P	1227.32	2150.49	4568.54	5204.31	3976.99	324.04
Retin-A Micro, 0.1%, 50 g	A	178.05	335.73	791.47	914.52	736.47	413.64
Solaraze gel, 100 g	N	442.89	618.56	1738.91	1883.98	1441.09	325.38
Soriatane, 25 mg (30 capsules)	P	757.75	958.50	1452.50	1595.27	837.52	110.53
Taclonex, 60 g	P	465.99	522.58	848.21	962.90	496.91	106.64
Targretin gel, one 60-g tube	N	1686.78	1787.97	15 708.40	30 320.12	28 633.34	1697.51
Tazorac cream, 0.1%, 60 g	A	266.18	464.96	656.20	722.27	456.09	171.34
Xolegel, 30 g	I	212.50	278.00	389.25	641.96	429.46	202.10

Abbreviations: A, acne and rosacea; I, antiinfective; N, antineoplastic; P, psoriasis; S, corticosteroid.

Source: Miranda E. Rosenberg, BA and Steven P. Rosenberg, MD (2016) *Changes in Retail Prices of Prescription Dermatologic Drugs From 2009 to 2015*. JAMA Dermatology. 152(2):158-163. doi:10.1001/jamadermatol.2015.3897



# FDA-Funded Science & Research



- Has already supported the development and approval of numerous topical generic products
- Current priorities for dermatological products:
  - Enhance understanding of the role of excipients in topical drug absorption to evaluate in vitro BE methods for non-Q1/Q2\* topical drug products applied to skin or other local areas
  - Improve physiologically based pharmacokinetic (PBPK) and computational fluid dynamics (CFD) models of drug absorption to support alternative BE approaches

\*Products that are not qualitatively (Q1) or quantitatively (Q2) the same as the reference product

# Examples: Recent Research Awards

- **Dermal Drug Product Quality and Bioequivalence Assessment through Advanced Mechanistic Absorption Modeling and PBPK Simulation.**
  - Awarded to Simulations Plus (1U01FD007320)
- **Quantitative Expression and Inter-Individual Variability of Skin Proteins Involved in Drug and Excipient Metabolism and Transporters Using Targeted and Label Free LC MS/MS Proteomics.**
  - Awarded to the University of Manchester (1U01FD007348)
- **Bioequivalence Considerations of Topical Rectal and Vaginal Suppositories.**
  - Awarded to the University of Rhode Island (1U01FD006721)
- **In Vitro and Non-Clinical Evaluation of Locally-Acting Topical Dermal and Ophthalmic Formulation Properties.**
  - Awarded to Absorption Systems LP (75F40119D10024)

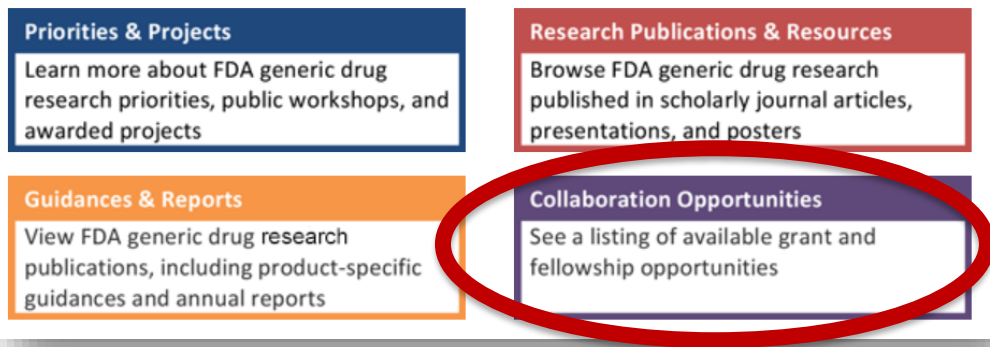
# Examples: Recent Research Awards

- **Bioequivalence of Topical Products: Elucidating the Thermodynamic and Functional Characteristics of Compositionally Different Topical Formulations.**
  - Awarded to the University of South Australia (1U01FD006496)
  - Awarded to the University of Mississippi (1U01FD006507)
- **Formulation Drug Product Quality Attributes in Dermal Physiologically-Based Pharmacokinetic Models for Topical Dermatological Drug Products and Transdermal Delivery Systems.**
  - Awarded to Simulations Plus, Inc. (1U01FD006526)
  - Awarded to the University of Queensland (1U01FD006522)
- **Bioequivalence of Topical Products: Comparing Dermal Pharmacokinetics by Microdialysis or Microperfusion Techniques.**
  - Awarded to Joanneum Research (U01FD005861)
  - Awarded to Long Island University (U01FD005862)

# We Want (to Fund) YOU

<https://www.fda.gov/drugs/generic-drugs/science-research>

- Collaborations
  - Grants
  - Contracts
- Post-Doctoral Fellowships
  - ORISE Fellows Program



The screenshot shows a navigation menu with four items: 'Priorities & Projects' (blue header), 'Research Publications & Resources' (red header), 'Guidances & Reports' (orange header), and 'Collaboration Opportunities' (purple header). The 'Collaboration Opportunities' item is circled in red. The text for each item is as follows:

- Priorities & Projects**: Learn more about FDA generic drug research priorities, public workshops, and awarded projects
- Research Publications & Resources**: Browse FDA generic drug research published in scholarly journal articles, presentations, and posters
- Guidances & Reports**: View FDA generic drug research publications, including product-specific guidances and annual reports
- Collaboration Opportunities**: See a listing of available grant and fellowship opportunities





# Acknowledgements

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# Thank You

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