Informing and Refining the Prescription Drug Promotion Research Agenda

November 19, 2021







Webinar

Welcome and Overview

Mark McClellan

Director, Duke-Margolis Center for Health Policy



Statement of Independence

The Robert J. Margolis, MD, Center for Health Policy is part of Duke University, and as such it honors the tradition of academic independence on the part of its faculty and scholars. Neither Duke nor the Margolis Center take partisan positions, but the individual members are free to speak their minds and express their opinions regarding important issues.

For more details on relevant institutional policies, please refer to the Duke <u>Faculty</u> <u>Handbook</u>, including the <u>Code of Conduct</u> and other <u>policies and procedures</u>. In addition, regarding positions on legislation and advocacy, Duke University policies are available at <u>http://publicaffairs.duke.edu/government</u>.



Remote Participation Instructions

Mute & Slides

- You have been placed on mute; speakers can mute/unmute throughout
- We will advance the slide deck, please prompt us to advance

Questions

• Please feel free to type your question into the Q&A box and we will use your questions to inform the open discussion portion of the event

Zoom Issues? Please Zoom message Rasheed Willis or email rwillis@newmediamill.com



Meeting Agenda

1:00 pm	Welcome and Overview
1:10 pm	Opening Remarks from FDA
1:20 pm	FDA Presentation: The Current Prescription Drug Promotion Landscape
1:35 pm	Session 1: Prescription Drug Promotion in the Digital Space
2:45 pm	Break
3:00 pm	Session 2: Future Directions and Considerations for the Prescription Drug Promotion Research Agenda
4:15 pm	Closing Remarks and Adjournment

All times listed in EST



FDA Opening Remarks

M. Khair ElZarrad

U.S. Food and Drug Administration



The Current Prescription Drug Promotion Landscape

Kathryn Aikin

U.S. Food and Drug Administration





The Current Prescription Drug Promotion Landscape

Kathryn J. Aikin, Ph.D. CDER/OMP/OPDP/APPS

Informing and Refining the Prescription Drug Promotion Research Agenda Virtual Public Workshop November 19, 2021

What does FDA do?



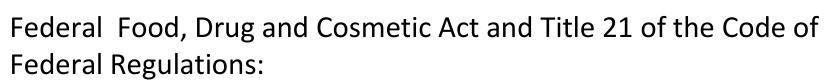
FDA is responsible for:

- Protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation.
- Regulating tobacco products.
- Advancing the public health by helping to speed product innovations.
- Helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

Office of Prescription Drug Promotion (OPDP)

- Protect the public health by helping to ensure that prescription drug information is truthful, balanced, and accurately communicated.
- Guard against false or misleading advertising and promotion through comprehensive surveillance, compliance, and educational programs.
- Foster better communication of information to help patients and healthcare providers make informed decisions about treatment options.

Regulatory Authority



- Prescription drug promotion **must**...
 - Not be false or misleading.
 - Have fair balance.
 - Reveal material facts about the drug including facts about consequences that may result from use of the drug.

FD/



Regulatory Authority, con't.

Post-Approval Regulations located in 21 CFR 314.81(b)(3):

- Require the submission of all promotional materials at the time of <u>initial dissemination</u> or publication.
- Must include Form FDA-2253 and current prescribing information (PI).

OPDP does NOT "approve" promotional materials.



ADVERTISING AND PROMOTION



Myths and Misconceptions

- FDA "legalized" Direct to consumer (DTC) advertising in the late 1990s.
- Industry spends most of its advertising budget on DTC advertising.
- FDA has the authority to ban DTC advertising.
- FDA approves ads.
- FDA regulates "good taste."



What does OPDP regulate?

Prescription drug promotional communications made by or on behalf of the drug's manufacturer, packer, or distributor, including, for example:

- TV and radio commercials.
- Sales aids, journal ads, and patient brochures.
- Drug websites, e-details, webinars, and email alerts.



Categories of Promotional Communications

 $\langle \neg \rangle$



Institutional

Reminder

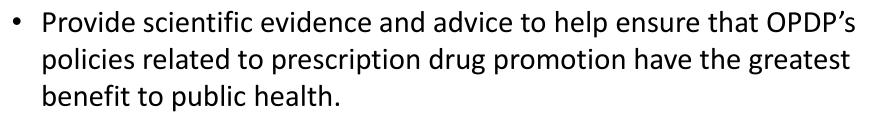
Product Claim

Do not make any representations about a specific product



OPDP RESEARCH

Role of the OPDP Research Team What We Do



- Investigate issues relevant to healthcare provider and patient/consumer usage of medical product information.
- Consider the audience's perception and comprehension of medical product information.
- Assess the accuracy and effectiveness of the information and how it is conveyed.

FD/



Focus of OPDP's Research Studies

Advertising Features:

- How do the features of the promotion impact the communication and understanding of prescription drug product risks and benefits?
- Examples include:
 - Quantitative Information.
 - Promotion and message elements.
 - Description of disease characteristics.
 - Product characteristics.
 - Other elements.

Focus of OPDP's Research Studies, cont.



Target Population:

- How does understanding of prescription drug product risks and benefits vary as a function of audience?
- Variables include:
 - Literacy.
 - Education.
 - Age.

Focus of OPDP's Research Studies, con't.



Research Quality Improvement:

- How can the quality of our research data be maximized to help ensure the best possible return on investment for FDA?
- Variables include:
 - Analytical methodology development.
 - Sampling and response issues.



EMERGING TRENDS IN PROMOTION



Changes in the Promotional Landscape

- More internet-based promotion.
- Use of Artificial Intelligence and algorithm-driven promotion.
- Pandemic driven changes.

Audience-specific Changes

HCP

- More remote interactions between sales reps and prescribers
- Algorithm and AI integration with existing legacy marketing channels (e.g., email)
- Proliferation of private chat and video conferencing applications targeting prescribers

DTC

• Algorithm-driven social media is moving to eclipse TV ads in terms of reach

Sources of Information

Among respondents who indicated a DTC ad had ever caused them to look for more health information

	1999 ¹	2002 ¹	2017 ²
Own Doctor	83 %	89 %	65%
Pharmacist	50 %	51%	38%
Reference Book	38 %	40 %	7%
Nurse	33 %	40%	16%
Friend, Relative, Neighbor	31 %	38%	27%
Other Doctor	24 %	25 %	16%
1-800 number	19 %	15 %	5%
Internet	18 %	38 %	68%
Magazine	17 %	18 %	4%*
Newspaper	8 %	7 %	

*magazine or newspaper combined ¹Aikin, Swasy & Braman (2004).

²Aikin, Sullivan, Berktold, Stein, & Hoverman (2021).

FDA

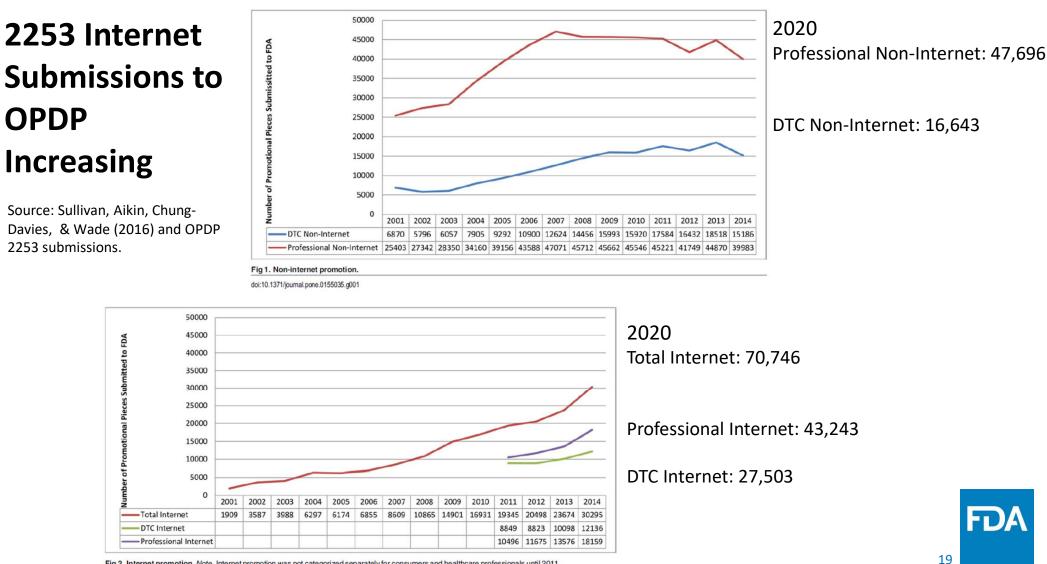


Fig 2. Internet promotion. Note. Internet promotion was not categorized separately for consumers and healthcare professionals until 2011

doi:10.1371/journal.pone.0155035.g002



Rigorous Research in Service of Public Health

- We continue to develop evidence to inform our thinking.
- We evaluate the results from our studies within the broader context of research and findings from other scientific sources.
- Multiple converging results increases confidence in the robust nature of the findings.

This body of knowledge collectively informs our policies as well as our research program.



This Workshop

- The new and different looking beyond traditional media.
- What's coming next in the promotion space where are we headed?
- The future of marketing and regulation from your perspective.

We look forward to a great discussion!

DA U.S. FOOD & DRUG ADMINISTRATION

22

Session 1: Prescription Drug Promotion in the Digital Space

1:35 pm – 2:45 pm



DTC Rx Promotion in the Digital Space:

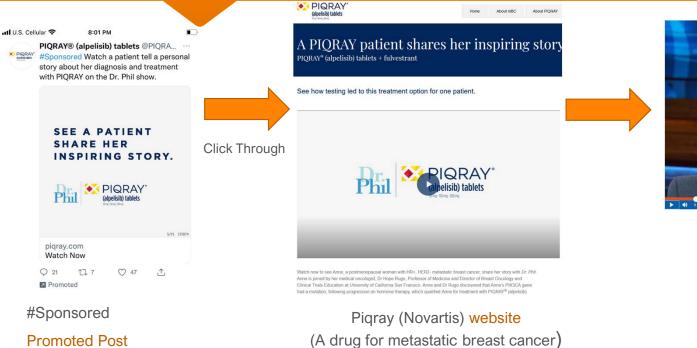
Native Advertising, TikTok & Gen Z as a Vulnerable Audience

Mariea Grubbs Hoy, Ph.D. School of Advertising & Public Relations

mhoy@utk.edu



Marketing Strategy for Piqray: Native Advertising





Native Advertising (seamlessly integrated with "entertainment" content)

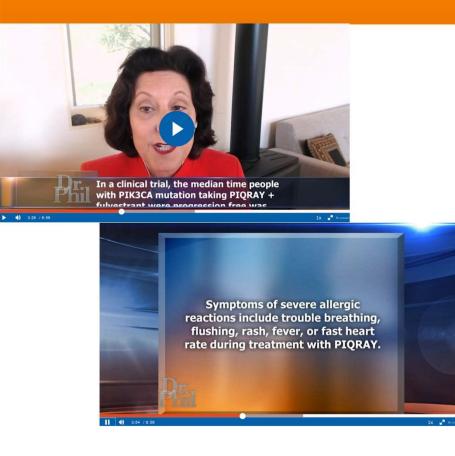
Trusted host, influencer, "Dr."

Marketing Strategy for Piqray: Native Advertising



- Within the context of native advertising, we hear Anne's story (typical consumer endorser) and Anne's doctor (expert endorser) discuss her case and the benefits of Piqray.
- Dr. Phil gives an audio disclosure prior to the interview that the doctor is there at the request of Novartis, the segment sponsor. She is not being compensated for this engagement.

Marketing Strategy for Piqray: Native Advertising



- Risks are given during the segment – but competing audio & text disclosures.
- Viewers (patients, loved ones, caregivers) become vulnerable audience segments who are likely to respond differently to the use of these tactics compared to other product usage scenarios.
- How might Dr. Phil's audience (and the target market for a breast cancer drug) respond to all the components of this marketing strategy?

Marketing Strategy: Native Advertising



Yahoo 🤣 @Yahoo

Seniors: It's Not Normal To Constantly Feel Sleepy During the Day. These Medication For Excessive Sleepiness Could Help.

yhoo.it/3qfJ7ml



193 🔿

Promoted

This looks like a Yahoo story and appears as a promoted post in my feed.

Search results on Yahoo

SUNOSI Can Help You Stay Awake For Amazing Things If you have obstructive sleep apnea or narcolepsy and are often tired during the day, ask your doctor if once-daily SUNOSI may be right for you.

https://www.sunosi.com/

livingwithih.com

Take Control Of Hypersomnia - Get Help With A Sleep Do... Find A Local Sleep Specialist To Better Understand & Manage Your Idiopathic Hypersomnia. Sign Up For Updates That Could Benefit You or a Loved One That May Be Struggling With IH.

Take The Sleepiness Quiz Use The EDS Screening Tool To Learn More About Your Sleep Habits.

What Is IH Really Like? Learn About The Real Impacts Of Living With Idiopathic Hypersomnia.

Find A Sleep Specialist Get The Conversation Started By Finding Sleep Doctors Who Can Help.

Hypersomnia Resources Discover Tools That Can Help You Track & Monitor Your IH Symptoms. Sign Up for Email Updates

Learn About Managing Your Symptoms

IH Management Info

for Idiopathic Hypersomnia.

Stay Connected & Up to Date on the Latest With Idiopathic Hypersomnia.

www.tiredwithsleepapnea.com

Excessive Daytime Sleepiness - Treatment Option Available Learn More About A Treatment For Excessive Daytime Sleepiness in Obstructive Sleep Apnea. Rate Your Excessive Daytime Sleepiness And Talk To Your Doctor Today.

Rate Your Sleepiness Daytime Sleepiness EDS In Sleep Apnea Patient Care Program EDS In Narcolepsy Savings Card Available

www.idiopathic-hypersomnia-treatment.com

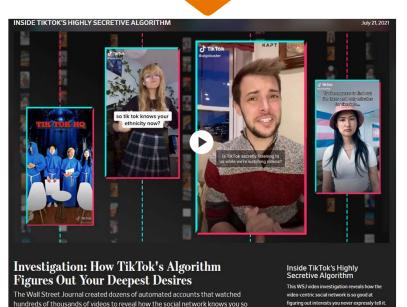
Getting Hypersomnia Treatment - Official Patient Site

Ask Your Doctor How Your Treatment Plan Addresses Your Idiopathic Hypersonnia. Learn More. Stay Connected Through Your IH Journey, Register Now to Stay Up to Date on Resources. IH Treatment - Potential Savings Options - Unlock Support - Explore Patient Resources

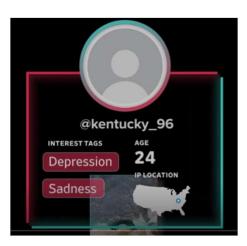
www.InsomniaTreatmentInfo.com

Physicians Treating Insomnia - See a Prescription Sleep Aid View Efficacy and Safety Information for an Insomnia Prescription Treatment Option. Sign Up and Access Physician Resources Including Prescribing Information and More. Free Trial Offer - Safety and Efficacy Info - Safety - Prescribing Information - Patient Brochure

Social Media Platforms (and the use of algorithms to serve targeted ads)



- WSJ created a bot
- 15th video Bot pauses on a 35-sec video that signals sadness and depression and watches it twice
- TikTok is cued that perhaps the viewer is feeling down (by descriptors of content producer).



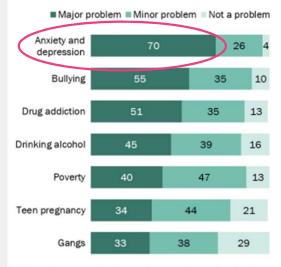


Vulnerable Audience: Gen Z (Ages 9-24)

- TikTok is now the most used app by teens & preteens in the US
- One-third of US users may be 14 or under
- 1 in 6 US youth aged 6-17 experience a mental health disorder each year
- 50% of all lifetime mental illness begins by age 14, and 75% by age 24.

Anxiety and depression top list of problems teens see among their peers

% of teens saying each of the following is a _____ among people their age in the community where they live



Note: Share of respondents who didn't offer an answer not shown. Source: Survey of U.S. teens ages 13 to 17 conducted Sept. 17-Nov. 25, 2018.

"Most U.S. Teens See Anxiety and Depression as a Major Problem Among Their Peers"

PEW RESEARCH CENTER



Congress demands TikTok share information about its 'dangerous' algorithm after oversight committee finds the platform is serving harmful content to underage users

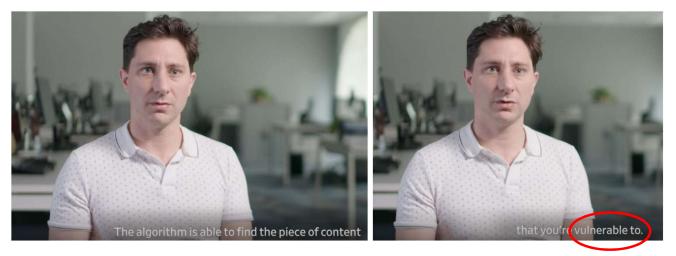
Nov. 10, 2021



- Children as young as 9 are able to easily create an account
- TikTok is not adequately policing
- Sex and drug-related videos and those with COVID-19 misinformation shown to underage users
- Requiring research, documents, policies & communication due to Congress by Nov. 23.

Social Media Platforms

(and the use of algorithms to serve targeted (Rx ads) to a vulnerable audience)



What are the implications for DTC Rx – especially given the demographic that watches TikTok?

Thank You !



Informing and Refining the Prescription Drug Promotion Research Agenda

- 1. The Perils of Direct-to-Consumer Ads of Prescription Drugs on Social media
- 2. Patient Influencers on Instagram
- 3. Telehealth Virtual Waiting Room as an Advertising Medium

Hyosun Kim, Ph.D., Indiana State University

The Perils of Prescription Drug Ads:

Examining the Issues Misleading Advertising on Social Media through FDA Warning Letters

- 1) The peril of first-person point of view testimonials from patient spokespeople
- 2) The peril of promotions of non-FDA-approved prescription drugs
- 3) The peril of risk information presentation



Superimposition normally used in a screenplay as "**Superimpose**" or "Super" is when letters are placed over the film.





Paid partnership with celgene Los Angeles, California

louiseroe #Ad I recently had a blast swapping worlds for a day with Alycia, a financial analyst who also lives with psoriasis. I learned a ton from her, and I hope she feels the same. Www.psoperspective.com for more! xoxo Otezla® (apremilast) ^{30mg} tablets

#psoriasis #psoriasiswarrior #dermatological	ogy
claujane4 #coatgoals ₩	\bigcirc
mka2.0 It's the stress Louise be cool	\bigcirc
kami.frances Love this look so much.♥♥	\bigcirc
noura.frj 💞	\bigcirc
femme_de_lune 🙂 🙌	\bigcirc
anka_roj Love your coat 💗	\bigcirc
\heartsuit Q 1	\Box
3,119 likes	
NOVEMBER 28, 2018	

...

Add a comment...





View More on Instagram

♥ Q ↓ 11,863 likes jtm_fit

// Gratitude //

We live in an amazing era where technology can immensely improve quality of life. Of course having type 1 diabetes sucks at times but with the technology available to us it makes having this disease a whole lot easier -

I recently got a new medical device called a continuous glucose monitor. That's the gray thing that's always attached to my side. The NEW @Dexcom G6 tests my blood sugar automatically every 5 minutes so that I barely have to prick my fingers anymore. It's such a game changer! It's really accurate too.

It also has an app so I can view and control everything from my phone. On top of that, it has a built in alarm system so that anytime my blood sugar is going dangerously high or low, it alerts me so that I can take action as needed

I've had type 1 diabetes for a little over 5 years and never tried a CGM until now. Wish I had gotten one a little sooner!

@dexcom #type1diabetes #type1warrior #sponsored #dexcomg6 #dexcomwarrior

0

view all 245 comments

Add a comment...

Dexcom, a medical device manufacturer for Type 1 diabetes, earned the best Social Media Campaign award by PR daily in 2018 by partnering with patient influencers on Instagram (PR Daily 2018)

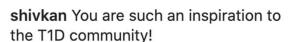


paollafndz My dad have diabets Too! You are a exemple of person!!!! I will show ur profile for him

142w Reply

reyvox Bro you're an inspiration





102w Reply



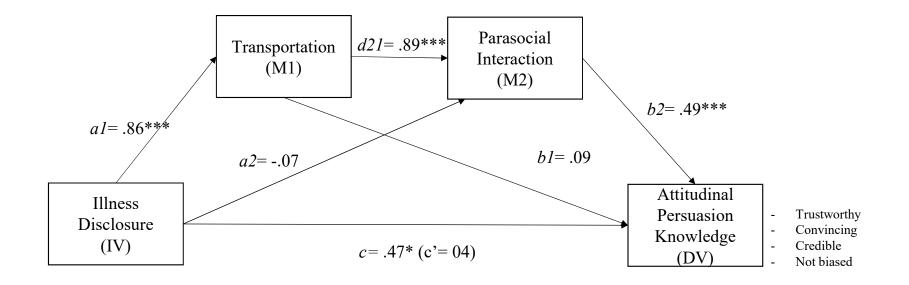




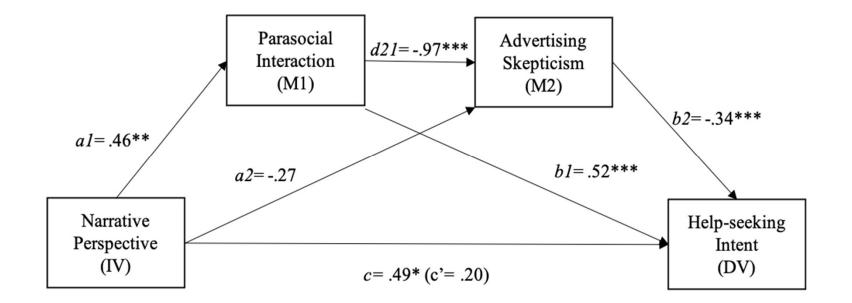
Patient Influencers on Instagram

- When patient influencers' illness disclosures go public, consumers are likely to become immersed in the story, which then helps them develop strong parasocial relationships with the influencers.
- More importantly, this transportation to the narrative world and strong pararsocian interaction then causes consumers to feel less negative about the sponsored ad posts featuring prescription drugs.

Effects of illness disclosure on Ad attitudes



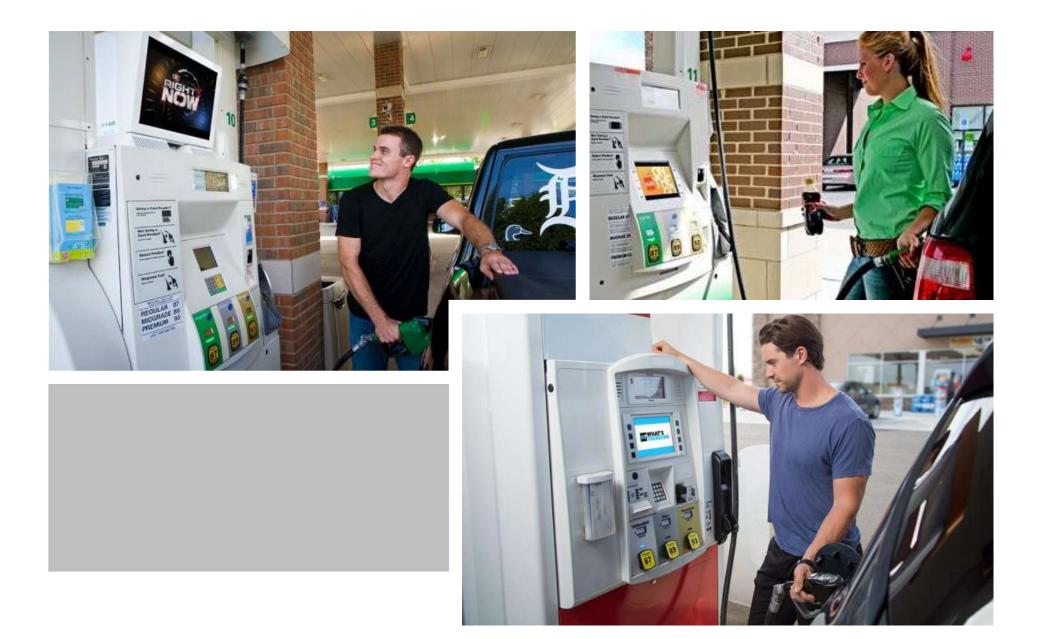
Effects of 1st person-perspective on help-seeking



Disclaimer: The view and opinions expressed in the ad are those of the presenter. <u>Result of the drug may vary depending on</u> the patient's condition.

Telehealth Virtual Waiting Room

- Personalized, tailored ad
 - Undivided attention
- Patients are highly motivated to process information





Duke Margolis Center Virtual Public Workshop

Four Topics to Inform the Future of Prescription Drug Promotion Research

Duke MARGOLIS CENTER for Health Policy UC San Diego

Tim Mackey, MAS, PhD Professor, UCSD \bigcirc

Topic 1: Social Media Targeted Ads

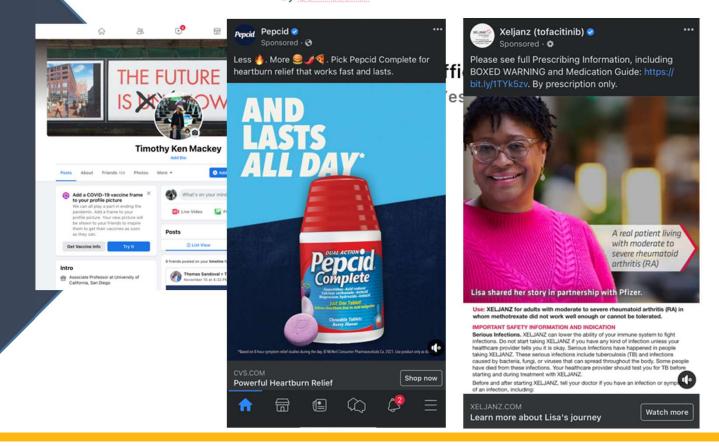
- Transparency about DTCA
 digital targeting
- Role of cookies files (users visiting health sites, etc.)
- Examples: Targeting metadata for off-label use and prescribing; targeting based on "interest" or "awareness" categories/metadata and

user forums (e.g., healthrelated metadata); other proxy behavioral and demographic data

The Markup

Citizen Browser How Big Pharma Finds Sick Users on Facebook

We found drug ads targeted at users interested in everything from bourbon to therapy By Colin Lecher





Topic 2: Patient Education, Assistance, **Coaching Portals**

- Use of patient education, • assistance, and coaching portals to engage directly with patients (including direct and through third parties)
- Possibility of direct marketing and influence
- Generation of CHI vs. PHI in portals?

ResMed

ResMed Cares for Your Sleep

We aim to provide you with convenient, compassionate and quality care possible at the comfort of your home.

If you are looking for solutions for any of your sleep concerns, book consultation with our sleep coaches

We continue to support you during this period of COVID-19 with telesleep consultations with our sleep coaches.

Although we strive to answer as many questions on our website, we might not have covered them all. If you have any question around COVID-19, click here or for a general question, please visit here

Share your challenges and ask any questions you might have about your sleep. Call at 1800 103 3969 (Monday to Friday, 10 AM to 6PM) to speak to sleep coach.

Request Sleep Coach Consultation First name Your Email* Phone Numbe

CMAJ

Patient engagement or social media marketing?

he rising use of social media creates an obvious opportunity for certain parties, such as pharmaceutical companies, to engage with the public in new ways.

Advocates of pharmaceutical companies reaching out to potential customers online suggest the industry has been too reluctant to invest heavily in social media strategies, mainly because of a vague regulatory environment. But skeptics of the practice say the pharmaceutical industry is already gung ho about social media, which some companies appear to be using to circumvent restrictions on direct-to-consu advertising, a practice legal in only the United States and New Zealand. In a recent report called "Engaging

> events received through social media and how to measure return on investment. New strategies would also be required to respond much more quickly to consumer concerns. A slow response can escalate into a public-relations nightmare with tweets, Tumblr and Facebook comments going viral in hours.

"Users of social media now expect to be able to have a conversation with pharmaceutical companies when they face uncertainties," states the report, "If there is no conversation, or only a standardized answer, it could lead to frusal industry has tration and be of little overall benefit to social media, both involved parties."

But what does engaging patients their paper. really mean in this context? "When you talk about engagement, it is really about global and connected online, a profile direct marketing to the consumer," says that precisely fits the patient/con Timothy Mackey, an investigator for the of eDTCA 2.0," the paper states. "Pub-San Diego Center for Patient Safety at the University of California San Diego. lic health policy must take into accoun this new consumer and the rapidly In a 2011 paper entitled "Prevadeveloping digital environment lence and global health implications

Some websites set up by drug comof social media in direct-to-consumer panies (and medical-device manufacdrug advertising," Mackey and colturers) to create communities of potenleagues looked at the social media tial consumers have scant corporate

CMAJ, May 13, 2014, 186(8) E237

presence of the 10 largest global phar

maceutical corporations. All were

active on Facebook, Twitter, spon

sored blogs and other social media

platforms, and 80% had YouTube

channels. Many individual drugs also

had dedicated Facebook pages and

This has led to a new form of direct

to-consumer advertising, developed for

interactive social media, which the

researchers have dubbed eDTCA 2.0

they are intended solely for US resi-

dents, the Internet transcends borders

These websites don't appear to restrict

access to web users from outside the

US, Mackey and colleagues note in

"The new consumer is one that is

Though some of these websites state

Twitter feeds.

patients through social media," the IMS Institute for Healthcare Informatics states that "the strategies that pharma ceutical companies use to engage with social media could be categorized as Other concerns include how - or whether --- to handle claims of adverse low-risk and less innovative than those employed in other industries." at use of social alts has grown % by 2013, and irth most popurmation in the se numbers are ort suggests, as - those as nd tweeting as athing - grow me more con-

te, a company

guidance from

the US, Canada

using social

n the promotion

Some compa-

should strict

sciation or its licensor

invest heavily

legy for fear of

rece.

nple, the only

necticut. One





NEWS

MAYO CLINIC PROCEEDINGS

Topic 3: EHRs, DTCA, and off-label promotion?

- Concern about data service provider companies imbedding off-label prescribing information in commercial EHR
- Possibility of other commercial agreements to imbed or prioritize certain off-label information in EHR indications module and clinical decision-making software

agencies, clinicians, medical professional organizations, and patient advocacy groups should readily endorse and demand.

Charles B. Porter, MD University of Kansas Medical Center and Hospital Kansas City, KS

 Mackey TK, Liang BA, After Amorin v FDA: What will the future hold for off-label promotion regulation? Mayo Clin Proc. 2016;91(6): 701-706.

 Yancy CW, Jessup M, Bodurt B, et al. 2013 ACCF/ AHA guideline for the management of heart failure a report of the American College of Cardology Foundation/American Heart Association Takk force on Practice Guidelines. J Am Call Cardol. 2013;82(16):e147-e239.
 Eguide T, Budening DL, Verma A, et al. Association of

off-label drug use and adverse drug events in an adult population. JAMA Intern Med. 2016;176(1):55-63.

http://dx.doi.org/10.1016/j.mayocp.2017.02.001

In Reply—Electronic Health Records and Drugs of Prescribed for Off-label Indications

We thank Dr Porter for his letter to the editor that highlights an emerging yet underrecognized form of off-label promotion that could undermine clinical care and population health outcomes Dr Porter describes the presence of off-label prescribing information embedded in the commercial electronic health record (EHR) systems at his institution, a phenomenon that is likely pervasive across medical facilities throughout the country and a practice that may be influencing the prescribing habits of tens of thousands of physicians every day.

Dr Porter describes several real-life instances of questionable off-label indications (those not approved by the US Food and Drug Administration [FDA]) embedded in the indications module content of an EHR system at a major academic medical center. He also details 3 key risk factors for patient safety:

(1) inclusion of off-label uses that are not approved by the FDA and that lack sufficient evidence, (2) possible exclusion of some FDA-approved indications, and (3) lack of differentiation between listed indications that are FDA approved vs those that are off-label. This raises a critical question: Who decides what is included in an EHR drug information module, and how are those decisions made?

It turns out that inclusion of off-label prescribing information in EHRs-health information technology systems that are now becoming the new norm in clinical decision making and directly enabling electronic prescribing-is an area that lacks sufficient transparency, regulation, and oversight. Critical decisions about off-label prescribing-ie, decisions that could adversely impact clinical care, result in a higher number of adverse events, and lead to waste and poor utilization of drugs-appear to be in the exclusive purview of drug data vendors themselves. These vendors, in turn, make decisions on inclusion using internal staff and editorial review boards and use these proprietary modules to compete for business. They also appear to unfairly rely on astute clinicians, like Dr Porter, to correct and remove unsubstantiated indications, a process that is inefficient and begs for greater quality processes and rigor on the part of drug knowledge base vendors and contractors that populate EHRs with drug prescribing information

Importantly, the problem identified by Dr Porter is emblematic of a larger battle in our medical legal and regulatory environment. As detailed in our June commentary in this journal on the court decision Amarin v FDA¹ and as discussed in subsequent commentaries in journals such as the New England Journal of Medicine² and JAMA Internal Medicine.³ recent court

decisions have consistently eroded the FDA's regulatory authority over off-label promotion activities. This is happening despite hundreds of millions of dollars in off-label fraud and abuse settlements successfully prosecuted by the US Department of Justice, many of which involved egregious off-label marketing that has directly endangered patients (such as promoting a drug for an indication or patient population with a "black box" warning)."

At the heart of this debate is a simple question: Should the FDA evaluate and oversee the truthfulness and veracity of drug product claims or should this be left to decisions by the courts and/or self-regulation by manufacturers? This question now extends to EHRs, with court decisions like Amarin stripping away the FDA's ability to vigorously regulate how commercial entities like EHR data vendors market and disseminate off-label information. It also raises a more fundamental issue: should commercial free speech be constitutionally protected, even when it potentially endangers public health?

Collectively, we argue that leaving important scientific and clinical decisions about off-label promotion in the hands of commercially driven entities endangers the checks and balances of the FDA's drug approval processes that emphasize safety and efficacy. It also compromises the important role of clinicians as the learned intermediary because the easing of off-label regulation, the retreat of FDA oversight, and more selective US Department of Justice enforcement will likely lead to the proliferation of poor-quality off-label information that clinicians will have to navigate and interpret.

In the case of EHRs and off-label prescribing data, hospital systems that license and pay for technology solutions of questionable quality and usefulness should be the first to take

> Mayo Clin Proc.
> April 2017,92(4) 680-686 www.mayoclinicproceedings.org

$\bigcirc \bigcirc$

Topic 4: OP-Twitter promoting behavior associated posts

- CMS OP provides industry-physician promotional data (sorted for top 50 in consulting payments)
- Promoting treatment methods
- Link to promotional videos
- Promotion posted by other social media users

```
← Tweet
```

Migraine World SummitTop 15 total consult payment receiver:
\$898k(732 payments) in 2020 []

<u>,</u>↑,

Botox- Not just for beauty? Dr Andrew Blumenfeld explains how Botox can be used to treat chronic migraine: ow.ly/dPxd50wsido



3 Retweets 1 Quote Tweet 6 Likes





Key Questions

- Isn't Botox mainly a beauty treatment?
- What exactly is Botox made of and is it dangerous?
- Are people who are using Botox for chronic migraine also getting cosmetic benefits?
- How strong is the evidence supporting Botox?
- How much does Botox cost?
 Top 15 total consult payment receiver:
 \$507k(501 payment) in 2020 Ⅰ

Joey Braun @joeybraun_ - Jun 18, 2019 ... Episode 16 | In this episode of Mindshape we sat down with the founder of Frost Smiles and the author of the book the Artist Orthodontist, Dr. Stuart Frost. He talks about the power that gratitude has and how it can change your life forever. Top 15 total consult payment receiver:

\$403k(29 payments) in 2020

* 10

MINDSHAPE

Dr. Stuart Frost Founder of Frost Smiles Ruthor

uroliftdrgange.com HIFU Prostate Cancer Treatment & Success Rate Information Learn about high-intensity focused ultrasound (HIFU) treatment, a safe alternative treatment for prostate cancer. Contact Dr. Gange for more ...

Non-Invasive Cancer Treatment

For early to intermediate risk cancer, HIFU is equal to radical surgery in

terms of cancer control. And it offers a much more favorable side effect

profile. Learn more about this innovative treatment option this #Movember:

HIFU PROSTA

Preserving Quality of

♀ ῒ ♡₂ ῒ

Other Social Media promoting behavior associated post samples

Instagram:

products

products

Promoting service

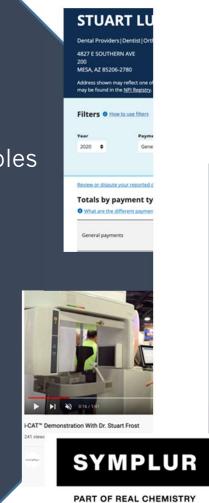
TikTok: Promoting

YouTube: Promoting

•

•

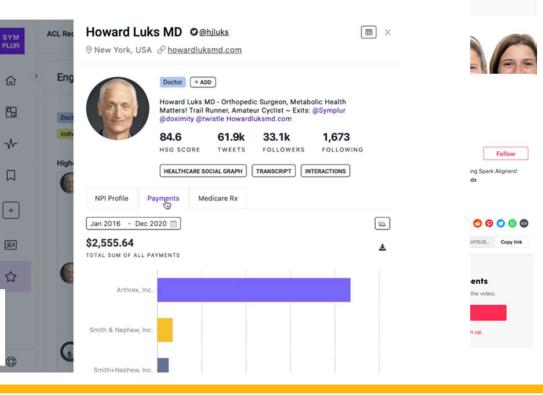
•



Top 15 t \$403k (2

Three updates for you

- Physician payments data is now available in Symplur. We're
 putting social media conversations in the context of industry payments.
- Clinical trials data is here. Principal and co-investigators are now tagged with a new healthcare stakeholder label named "Investigator".
- Social media and scholarly impact scores have a positive relationship. A study looked at the correlation between the Healthcare Social Graph Score and h-index for scientific authors.



ILE VIRTUAL

y Lun...

Policy Proposal: Greater Transparency? Modeling after OP for DTCA

REFLECTION

STA]

It's Time to Shine the Light on Direct-to-Consumer Advertising



Table 1: Proposed Public DTCA Disclosure Categories

DTCA Data Category Description

Expenditure amount	Monetary value (\$USD) for promotion for each marketing medium utilized
Category of DTCA	Product claims ad, reminder ad, help-seeking ad
Marketing medium	TV, radio, print, outdoor, Internet, Internet-social media, prescription drug coupon, etc.
Language	Language(s) utilized in DTCA
Location	Name of country/state DTCA is limited to/disseminated in
Time	Length (in days) of DTCA promotional campaign
Product class	Pharmaceutical, biological, medical device, etc.
Therapeutic category	Therapeutic category of DTCA product
Disease associated	Disease information associated with DTCA
Name of product	Branded or proprietary name of DTCA product

CORRESPONDING AUTHOR Timothy Ken Mackey, MAS, PhD ADOBE Global Health Policy Institute 8950 Villa La Jolla Drive, Suite #A204 La Jolla, CA 92037 tmackey@ucsd.edu

RISE, DECLINE, AND LACK OF TRANSPARENCY OF PHARMACEUTICAL MARKETING

DTCA, a phenomenon legally permissible only in the United States and New Zealand among developed countries,2 experienced rapid growth



ANNALS OF FAMILY MEDICINE . WWW.ANNFAMMED.ORG . VOL. 13, NO. 1 . JANUARY/FEBRUARY 2015 82



Tim K. Mackey (<u>tkmackey@ucsd.edu</u>) Mackey Lab: Alec Calac, BS, Michael Haupt, MA, Raphael Cuomo, PhD, Vidya Purushothaman MBBS, MAS, Cortni Bardier, MA, Matthew Nali BA, Zoe Li, BS, James Maroulis, MAS, JD, Chenna Basavaptna, BS





FDA U.S. FOOD & DRUG





National Institute on Drug Abuse



America's Seed Fun





Session 1: Prescription Drug Promotion in the Digital Space

Session 1 Discussion Questions:

- What current trends in online prescription drug promotion are you paying attention to and why?
- How are prescription drug manufacturers using social media and other digital tools to connect with patients? What are the research implications of prescription drug promotion that occurs in digital spaces such as through social media groups for patients with specific health conditions?
- What are the implications of prescription drug manufacturers engaging with patients in virtual health care settings, such as virtual patient waiting rooms in online telemedicine clinics? What obstacles for research does this cause, and how might those obstacles be overcome? Similarly, what opportunities for research are present in these new frontiers?
- What are the implications of prescription drug manufacturers using digital tools such as EHRs to reach health care providers? What are the implications of promotion to health care providers utilizing digital tools? What obstacles for research does this cause, and how might those obstacles be overcome?
- What methodological gaps exist in this research space? What do you wish you could measure but can't due to methodological limitations?



Break

2:45 pm – 3:00 pm



Session 2: Future Directions and Considerations for the Prescription Drug Promotion Research Agenda

3:00 pm – 4:15 pm



Session 2: Future Directions and Considerations for the Prescription Drug Promotion Research Agenda

Session 2 Discussion Questions:

- What are some emerging trends in prescription drug promotion to patients and health care providers? How might prescription drug promotion evolve in the digital space in the future?
- In what ways has the pandemic accelerated or changed emerging trends in prescription drug promotion?
- In what ways might consumer perceptions of prescription products be impacted by emerging trends in prescription drug promotion?
- What evidence gaps exist in prescription drug promotion research?
- What do you think are the most pressing areas/questions for research on prescription drug promotion?
- What lessons can prescription drug promotion researchers learn from other fields?



Adjournment

Informing and Refining the Prescription Drug Promotion Research Agenda

November 19, 2021



Thank You!

Contact Us



healthpolicy.duke.edu



Subscribe to our monthly newsletter at dukemargolis@duke.edu



1201 Pennsylvania Avenue, NW, Suite 500 Washington, DC 20004



DC office: 202-621-2800 Durham office: 919-419-2504



Duke MARGOLIS CENTER 65