

# US FDA's Experience with Medicines Communication using Social Media

EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting  
Workshop on social media

FDA, CDER Office of Communications, Division of Drug Information

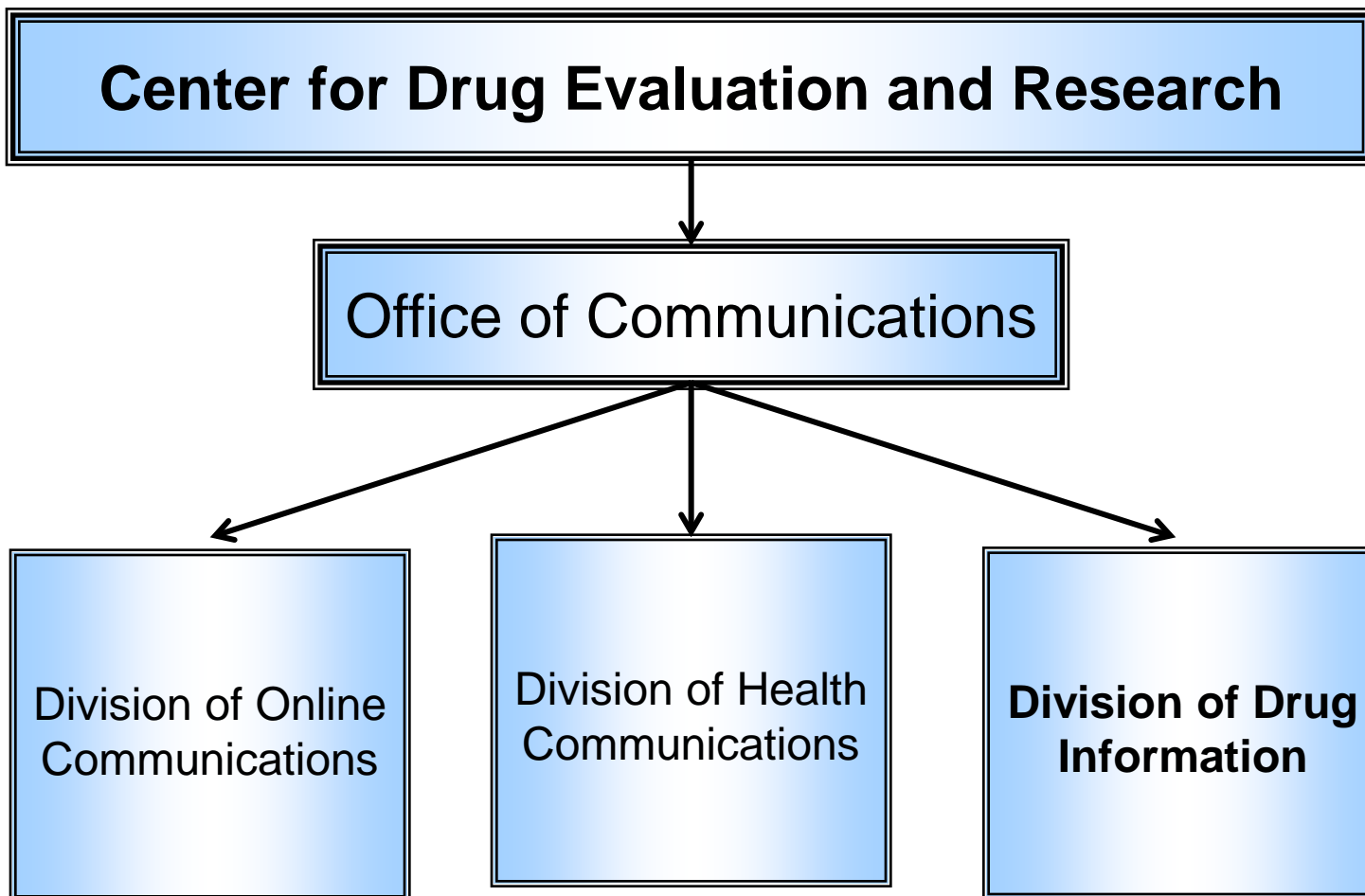
**CAPT Catherine Chew, PharmD**

Deputy Director, Division of Drug Information

**Kimberly Chiu, PharmD**

CDER Social Media Lead, Division of Drug Information

# CDER/Office of Communications



# Know Your Audience

Who is your target audience?



**Patients and  
Consumers**



**Health Care  
Providers**

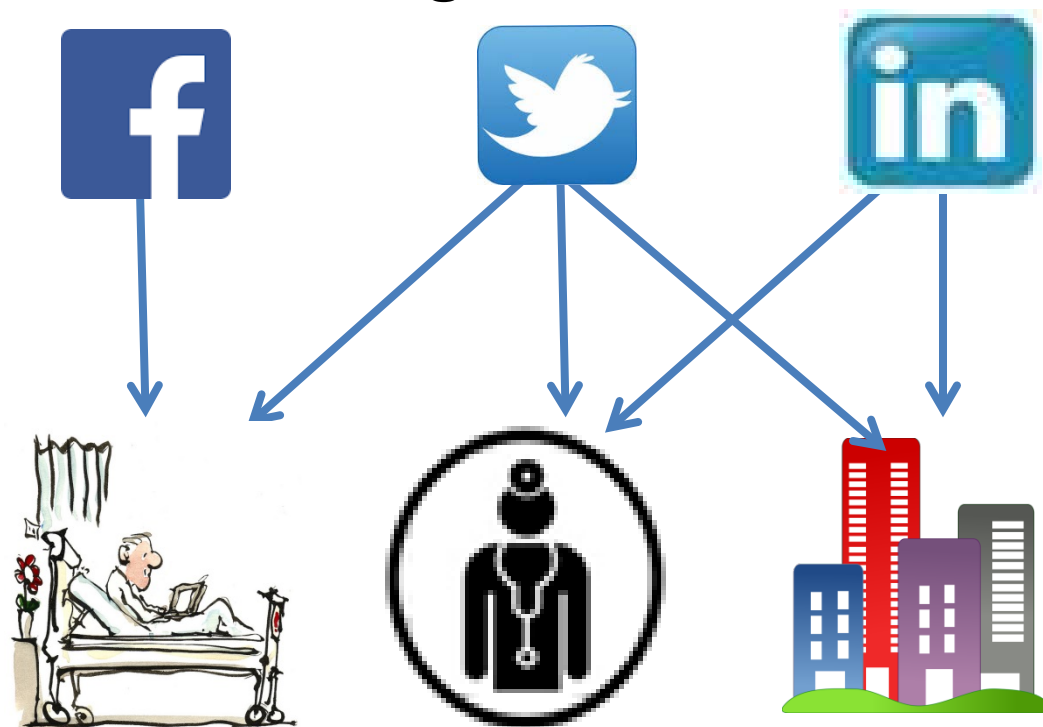


**Regulated  
Industry**

# Know Your Audience

**What platform(s) does your target audience use?**

FDA's Center for Drug Evaluation and Research




# Know Your Audience

**What platform(s) does your target audience use?**

FDA proactively segments twitter audiences

By Product Area (Examples)	By Audience (Examples)	By Programs (Examples)
Drugs: @FDA_Drug_Info	Patients: @FDA_Patient_Net	openFDA: @openFDA
Biologics: @FDACBER	Press: @FDAMedia	PrecisionFDA: @precisionFDA
Tobacco: @FDATobacco	Devices Industry: @FDACDRHIndustry	
	Spanish Speakers: @FDA_EnEspanol	



## Global Alliance of Drug Information Specialists (GADIS)

66 members



**Kimberly Wu**  
Pharmacist  
OWNER

... 2w

### Voluntary nationwide recall of oral liquid docusate sodium manufactured by PharmaTech & distributed by Rugby Laboratories

FDA is alerting health care professionals that PharmaTech LLC, Davie, Florida, is voluntarily recalling all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories, Livonia, Michigan. The agency confirmed the p... [Show more](#)

[Like](#) [Comment](#) | 2



**Genevieve Lynn Ness, PharmD** Thank you very much for this information. What symptoms does the Burkholderia cepacia bacteria cause in patients?

[Like](#) | 1

... 2w



**Kimberly DeFronzo** According to the CDC at <https://www.cdc.gov/HAI/organisms/bCepacia.html>, the effects of B. cepacia on people vary widely, ranging from no symptoms at all to serious respiratory infections, especially in patients with cystic fibrosis... [Show more](#)

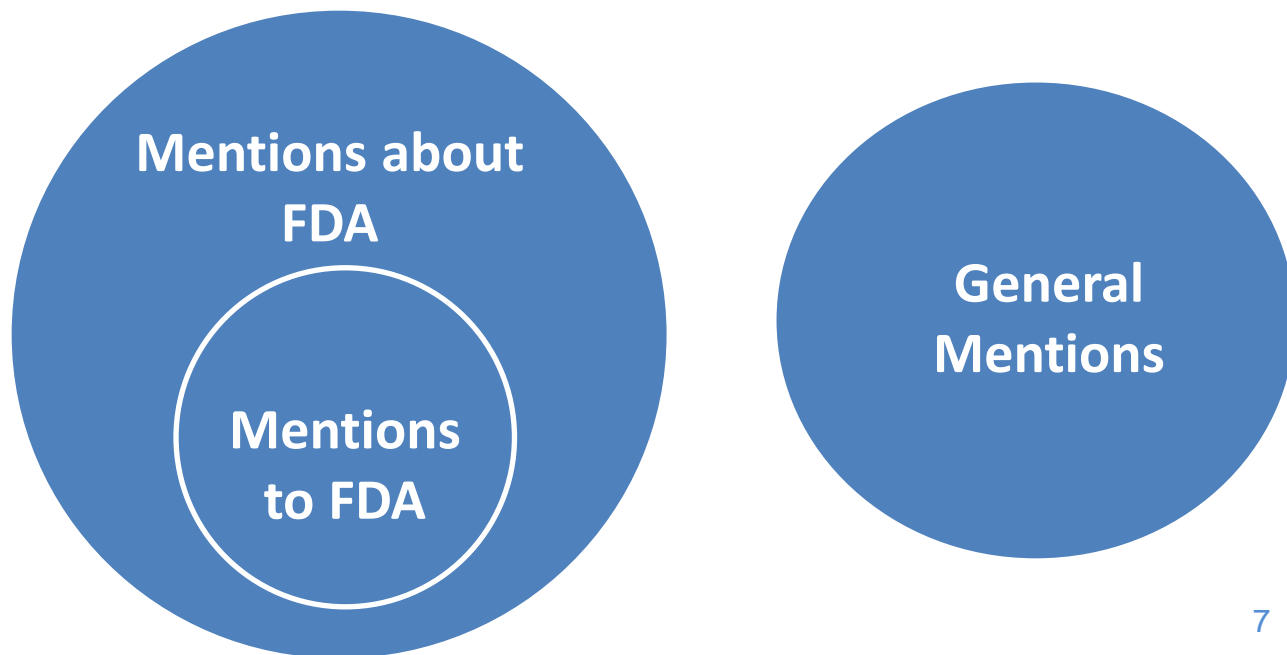
[Unlike](#) | You

... 1w

# Know Your Audience

What are target audience(s) saying?

- Current concerns or questions
- Current misperceptions or incorrect information
- Current sentiment



# Know Your Tools

## Best practices

- Graphics and videos increase reach
- Best time and how often
- Remember mobile devices



FDA Drug Information @FDA\_Drug\_Info · Jul 1

Vacations are fun, but risky if your kids get into your medicines. This summer, keep kids [#Safe4Life](#). [#MedsUpAway](#)





# Know Your Tools

- Identify natural partners
  - Stakeholder organizations on social media
  - Medical information resource companies

**Reach**MD™

Be part of the knowledge.™

**Medscape**

# Know Your Tools

Use metrics to optimize SM platforms

March 2015						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2 Twitter: 8 Facebook: Listserv: 1	3 Twitter: 6 Facebook: Listserv:	4 Twitter: 5 Facebook: 2 Listserv: 3	5 Twitter: 6 Facebook: Listserv:	6 Twitter: 3 Facebook: 1 Listserv: 2	7
8	9 Twitter: 1 Facebook: Listserv: 1	10 Twitter: 2 Facebook: 2 Listserv: 1	11 Twitter: 2 Facebook: Listserv: 1	12 Twitter: 0 Facebook: Listserv:	13 Twitter: 0 Facebook: Listserv:	14
15	16 Twitter: 3 Facebook: Listserv:	17 Twitter: 1 Facebook: Listserv:	18 Twitter: 2 Facebook: 1 Listserv: 1	19 Twitter: 2 Facebook: 1 Listserv: 1	20 Twitter: 1 Facebook: Listserv: 1	21
22	23 Twitter: 1 Facebook: 1 Listserv: 1	24 Twitter: 2 Facebook: 1 Listserv: 1	25 Twitter: 1 Facebook: Listserv: 1	26 Twitter: 1 Facebook: 1 Listserv:	27 Twitter: 0 Facebook: Listserv:	28
29	30 Twitter: 3 Facebook: 2 Listserv: 2	31 Twitter: 0 Facebook: Listserv:	Notes: March 2-5: Many tainted product announcements			

# Know Your Tools

Use metrics to optimize SM platforms

Twitter		
	Avg # of Impressions	Avg Engagement Rate
1	DMD Guidance	Drug Approvals
2	Podcasts	Resources
3	Promoting: App	Promoting: App
4	Drug Approvals	ALS Statement
5	Drug Safety Communications	Trivia
6	Division of Online Communications	Drug Safety Communications
7	Drug Info Rounds Video	Exhibit
8	Campaign	Promoting: Webinar

Facebook		
	Avg # Reached	Avg Engagement Rate
1	Safety	Promoting: App
2	Drug Approvals	Drug Approvals
3	Promoting: App	Safety
4	Drug Safety Communications	Promoting: Meeting
5	Patient Focused Drug Development Meeting	Drug Safety Communications
6	Announcements	Division of Online Communications
7	Promoting: Meeting	DMD Guidance
8	Division of Online Communications	Announcements

# Know Your Challenges

- As a Regulatory Agency:
  - Must be neutral
  - Humanize FDA- *“Operation Nice FDA”*
- Other Rules, Regulations or Policies

# Know Your Challenges

FDA's Office of Prescription Drug Promotion

***Draft Guidance: Internet/Social Media Platforms with Character Space Limitations- Presenting Risk & Benefit Information for Prescription Drugs and Medical Devices***

# Know Your Challenges



EU Medicines Agency @EMA\_News · Jul 28

We've published the assessment report for Zepatier (elbasvir / grazoprevir), a [#medicine](#) to treat [#Hepatitis C](#): [bit.ly/2a6Yg1o](https://bit.ly/2a6Yg1o)




FDA Drug Information @FDA\_Drug\_Info · May 19

New Drug Safety Comm. on Nizoral (ketoconazole) oral tabs [go.usa.gov/cJDsh](https://go.usa.gov/cJDsh). View PI: [go.usa.gov/cJZeA](https://go.usa.gov/cJZeA)



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# Know Your Challenges

## Other Rules, Regulations or Policies

- Commercial Confidential Information
- [Paperwork Reduction Act](#)
- [508 Compliance](#)
- [Term of Service \(TOS\) Agreements](#)



# Social Media as a part of communications strategy

# Fluoroquinolones



**U.S. FOOD & DRUG**  
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**Drug Safety and Availability**

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### FDA Drug Safety Communication: FDA advises restricting fluoroquinolone antibiotic use for certain uncomplicated infections; warns about disabling side effects that can occur together

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The FDA has issued new information about this safety issue, see the FDA Drug Safety Communication issued **July 26, 2016**

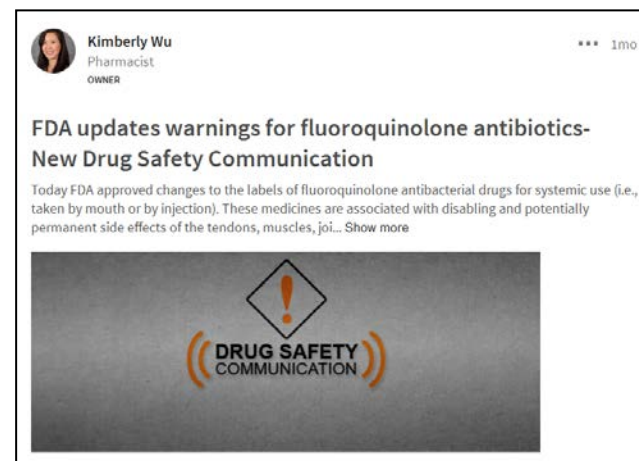
**Safety Announcement**

**[ 05-12-2016 ]** The U.S. Food and Drug Administration is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

An FDA safety review has shown that fluoroquinolones when used systemically (i.e. tablets, capsules, and injectable) are associated with disabling and potentially permanent serious side effects that can occur together. These side effects can involve the tendons, muscles, joints, nerves, and central nervous system.

As a result, we are requiring the drug labels and Medication Guides for all fluoroquinolone antibacterial drugs to be updated to reflect this new safety information. We are continuing to investigate safety issues with fluoroquinolones and will update the public with additional information if it becomes available.

# Social Media Outreach



# Listen and Answer

Date	Topic	Notes (Inquiry/Request)	POC	Demographic	State	Country
08/04/2016	Cipro	Could my fever blister be caused by Cipro?	VM - Phone	Consumer	AL	USA
08/03/2016	Cipro	Patient developed CNS side effects. Is there anything else they should do besides stopping the medication?	Live - Phone	MD	MI	USA
07/27/2016	Drug Interactions	if ciprofloxacin can be used in Mucopurulent conjunctives, Endo ophthalmitis	Email	Pharmacist	-	USA
08/09/2016	FQ	treated for pneumonia in ICU via IV - had complete Achilles tendon rupture - recovering after 2 months	Live - Phone	Consumer	CA	USA
08/08/2016	FQ	Dr. concerned about topical formulations of FQs and absorption thru mucous membranes. Asking does the DSC include topical products as well.	Live - Phone	MD	OR	USA
08/08/2016	FQ	We required following reference sample Please arrange it in urgent basis. 1. Azithromycin Dihydrochloride 2. Ciprofloxacin Hcl. 3. Ceftriaxone 4. Cefixime 5. Cephadrin 6. Dexamethason 7. Levofloxacin	Email	Industry	-	Bangladesh
08/08/2016	FQ	I have had a torn Achilles tendon due to levofloxacin 750mg	Live - Phone	Consumer	VA	USA
08/08/2016	FQ	Was given levofloxacin. Has seizures and is on generic Keppra. Doctor insisted she take levofloxacin. Had red pin point spots. Yesterday started to have muscle pain in shoulder and right side of body.	Live - Phone	Consumer	NJ	USA
08/08/2016	FQ	How long will levaquin stay in the body?	Live - Phone	Consumer	OH	USA
08/05/2016	FQ	Wrote in asking about if the studies for fluoroquinolones is published anywhere to read.	Email	Insurance Provider	-	USA
08/05/2016	FQ	The patient called to report ADR of possible tendon weakness which led to muscle tearing due to using cipro	Live - Phone	Consumer	TX	USA
08/05/2016	FQ	Can levaquin help with mosquito bites or have any relationship with the zika virus?	Live - Phone	Consumer	CT	USA
08/05/2016	FQ	The Dr. gave my Levaquin (levofloxacin) for bronchitis and I also have chronic leukemia. I have SE of all my muscles in my shoulder, arm being tensed. How long will it take for the SE to go away? I called my physician but he does not know the answer.	VM - Phone	Consumer	NJ	USA
08/05/2016	FQ	I was prescribed Ciprofloxacin for a kidney infection and I had bad SE such as burning of the skin, diarrhea, pins and needles in my elbow. I have contacted my physician.	VM - Phone	Consumer	MD	USA
08/05/2016	FQ	Wrote in asking about if the studies for fluoroquinolones is published anywhere to read.	Email	Insurance Provider	-	USA
08/05/2016	FQ	Patient called to report ADRs of ciprofloxacin; according to her she possibly have had weakened tendon which led to muscle tearing due to using cipro	Live - Phone	Consumer	TX	USA
08/05/2016	FQ	Patient called to report ADRs of constipation, muscle soreness, sore spot on shit bone (felt like bruise but wasn't bruise), tingling sensation around mouth, and acid reflux associated with taking ciprofloxacin for 2 days	Live - Phone	Consumer	OR	USA



# Listen and Answer on Social Media

**I experienced an adverse event due to a fluoroquinolone.**

**How will doctors learn this information?**

**FDA needs to take more action.**



# Listen on Stakeholder/Patient Sites



THIS IS HUGE!!!!!!

"FDA is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options."

An FDA safety review has shown that fluoroquinolones when used systemically (i.e. tablets, capsules, and injectable) are associated with disabling and potentially permanent serious side effects that can occur together. These side effects can involve the tendons, muscles, joints, nerves, and central nervous system.

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PLEASE SHARE!!

<http://www.fda.gov/.../SafetyAlertsforHumanMed.../ucm500665.htm...>

## Fluoroquinolone Antibacterial Drugs: Drug Safety Communication - FDA Advises Restricting Use for...

Serious side effects associated with fluoroquinolones generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options.

FDA.GOV

105

24 Comments 143 Shares



This is wonderful coverage of the dangers of fluoroquinolones in Runner's World magazine. Athletes should never take fluoroquinolones.

<http://www.runnersworld.com/.../fda-warns-of-tendon-damage-li...>



## FDA Warns of Tendon Damage Linked to Antibiotics

Runners can be vulnerable to injuries months—even years—after taking fluoroquinolones.

RUNNERSWORLD.COM

44

11 Comments 34 Shares



The information that the FDA put out about the depth and breadth of fluoroquinolone reactions is wonderful and greatly appreciated. Unfortunately, they're not sending out a "dear doctor" letter to physicians. Please send the FDA announcements and/or this post to doctors, the media, your loved ones, and anyone else who needs to know about the dangers of FQs. Thank you!

As Missy noted on the Floxie Hope facebook page, "When a new drug hits the market there are drug reps out and about educating healthcare providers and promoting prescriptions. Now that this "old" drug has restrictions there are no drug reps out and about educating healthcare providers of the dangers and limiting prescriptions." Exactly. For better or worse, we need to be anti-pharmaceutical-reps and tell physicians about the dangers of these drugs.



## Publicizing Fluoroquinolone Warnings

I have such mixed feelings about the FDA's resp the November, 2015 Antimicrobial Drugs Advisor Committee meeting regarding fluoroquinolone saf one hand, I feel like they really...

FLOXIEHOPE.COM

Like Comment Share

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Chro



## FDA Fails to Go The Distance, Yet Again - My Quin Story

Without formal notification, some doctors could hide behind the cloak of plausible deniability when it comes to the new label changes. Read more...

MYQUINSTORY.INFO | BY MY QUIN STORY

Like Comment Share

14

14

Chronological



# Duchenne Muscular Dystrophy (DMD)



**YES** jenn mcnary  
ON SCIENCE @jennmcnary



@US\_FDA When your 14 yr old brother with #Duchenne is able to carry you around in the pool #thedrugworks #etep \$SRPT



RETWEETS  
12

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5:23 PM - 29 Jul 2016

12 53 ...



Jenn McNary's Photos  
on Mobile Upload

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**Jett Foundation**  
@JettFoundation



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**jenn mcnary**  
@jenmcnary



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Boys gripping their speeches in their hands,  
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**Joining Jack**  
@alljoinjack



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On our way to Washington for the Sarepta  
@US\_FDA AdComm. Quick team talk from  
our little man #MakeDuchenneHistory



RETWEETS  
37

LIKES  
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12:01 AM - 23 Apr 2016

# Questions? Comments?



(855) 543-3784 or (301) 796-3400



druginfo@fda.hhs.gov



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