



The Do's and Don'ts of Patient Communications

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Do's and Don'ts of Patient Communications in the Pre-Approval Space



Paul J. Savidge
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Spark Therapeutics, Inc.
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The views expressed are my own and may not reflect those of my employer, Spark Therapeutics.

This presentation is not intended to substitute for legal advice and guidance from your own counsel.

Why talk to patients or patient groups prior to product approval?

- Gather patient and caregiver perspectives on product development
- Support disease state education
- Encourage their communication with FDA on the potential value of investigational products and the impact of a disease on their lives (*as FDA has invited*)
- Respond to unsolicited requests for information and be a trusted source of information
Patients and caregivers are increasingly sophisticated and organized
- Gather valuable insights on what information or programs would be meaningful to patients and caregivers if product were approved

For Patients

Home > For Patients > Learn About FDA Patient Engagement

Learn About FDA Patient Engagement

Initiatives for Patients to Engage With FDA

About the FDA Patient Representative Program SM

How to Apply to the FDA Patient Representative Program SM

Patient Engagement Collaborative

FDA and European Medicines Agency Patient Engagement Cluster

Learn About FDA Patient Engagement



The FDA has a difficult task when it comes to evaluating and approving new and innovative medical products.

Individual patients may experience the effects of diseases and therapies differently and each individual patient has a unique perspective about treatments or diagnostic procedures that differ from those perspectives of other patients or of their healthcare provider. The FDA has included the patient perspective in FDA Advisory Committee meetings since 1991. This page summarizes the different opportunities that patient and caregivers can get involved in at the FDA.

On this page you will find information about:

- [Evolution of Patient Engagement at FDA](#)
- [Patient Engagement Collaborative](#)
- [FDA and European Medicines Agency Patient Engagement Cluster](#)
- [FDA Patient Council](#)
- [MOU with the National Organization of Rare Disorders](#)
- [FDA Patient Representative Program](#)
- [Food and Drug Administration Safety and Innovation Act \(FDASIA\) Section 1137](#)
- [Patient Reported Outcomes](#)
- [Patient Focused Drug Development Initiative](#)
- [Device Patient Preference Initiative](#)
- [Devices Patient Engagement Advisory Committee](#)
- [Additional Patient Resources](#)

About the FDA Patient Affairs Staff

[FDA Patient Affairs Staff](#)

PatientAffairs@fda.hhs.gov

FDA is increasingly engaging patients and patient advocacy groups in a variety of programs and regulatory processes

How are communications about unapproved products regulated?

- Under section 502(f)(1) the FDCA, a drug is misbranded if it fails to provide 'adequate directions for use'
- Adequate directions for use are those by which a layperson may safely use the product for its intended purposes (21 CFR §201.5)
- Because such adequate directions cannot be provided for a prescription drug or device, the Act provides an exemption from the requirement if the drug complies with certain requirements (21 CFR §201.115(b))
- One such requirement is 21 CFR §312.7:

Promotion of unapproved products is forbidden under the FDCA

- 21 C.F.R. § 312.7 Promotion of investigational drugs. (a) Promotion of an investigational new drug. **A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.** This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

Recent enforcement letters on pre-approval promotion to consumers

- Crenolanib besylate - June 28, 2018 (Arog)

- On Crenolanib website:

Claims:

Combination Therapy—Future of AML Treatment

CRENOLANIB: Combinable with chemotherapy at full doses

Eradicating Activating Mutations

CRENOLANIB: Potent inhibitor of FLT3, PDGFR α , PDGFR β

The above claims make numerous conclusory statements about the safety and effectiveness of Crenolanib. For example, the webpage states that Crenolanib is “for use” in FLT3-mutated ALM without including information that Crenolanib is an investigational new drug that has not been approved for any use and states that Crenolanib is a “potent inhibitor for FLT3-ITD and secondary KD mutants,” an efficacy claim of clinical benefit that has not been established. Moreover, these claims suggest in a promotional context that Crenolanib, an investigational new drug, has been shown to be different from or superior to other approved therapies for treating AML, and is safe or effective for such uses.



Who's the audience?



Crenolanib

A next-gen tyrosine kinase inhibitor for use in FLT3-mutated AML

THE ROLE OF FLT3 MUTATIONS IN AML

Roughly one-third of AML patients harbor an internal tandem duplication (ITD) in FLT3, a receptor tyrosine kinase. Mutations of FLT3 at D835, a point mutation in the tyrosine kinase domain (TKD), have also been observed in AML patients. Both ITD and TKD mutations lead to constitutive activation of the tyrosine kinase function, making FLT3 an attractive drug target in AML patients. Both ITD and TKD mutations render FLT3 resistant to currently approved inhibitors. Moreover, novel activating FLT3 mutations are being identified in patients with AML. As the clinical development of FLT3 inhibitors proceeds into advanced phase trials, FLT3 mutations will represent a new obstacle in the care of FLT3-mutated AML patients.

CRENOLANIB IS A SELECTIVE TYPE I PAN-FLT3 INHIBITOR

Crenolanib, a type I TKI, is a potent inhibitor of FLT3-ITD and secondary KD mutants. Crenolanib represents the first TKI to exhibit both kinase selectivity and invulnerability to resistance-conferring KD mutations. Crenolanib, which spares cKIT, represents a promising therapy for achieving deep and durable responses in FLT3-mutant AML.

Recent enforcement letters on pre-approval promotion to consumers

- 68GA PSMA – December 28, 2017 (UCLA)
 - On UCLA Health Website:

The webpage and brochure contain claims that promote Ga68-PSMA as safe and effective for the purpose for which it is being investigated or otherwise promote the drug, including the following:

- New imaging test accurately detects prostate-cancer cells throughout the body
- 68Ga-PSMA PET/CT imaging, or PSMA-PET imaging for short, represents a major advance in detecting prostate cancer. At UCLA, with the availability of PSMA-PET imaging patients now have a new option of detecting prostate cancer cells anywhere in the body more accurately than traditional methods.
- Since PSMA-PET imaging became available at UCLA in September, patients now have a new option that's better at detecting the location of prostate-cancer recurrences.
- This test has had a tremendous and immediate impact on prostate-cancer patients . . . They can really benefit from this.
- There are no common side effects or significant risks . . .
- In contrast to the traditional studies, PSMA-PET imaging offers high sensitivity and specificity.

Prostate Cancer

- Prostate Cancer**
- Find a Doctor**
- Urologists**
- PSMA-PET Imaging
- Symptoms and Risk Factors
- Types of Prostate Cancer
- Treatment >
- Clinical Trials >
- Research >
- Institute of Urologic Oncology
- Educational Materials >
- Webinars, Videos & Patient Stories

Home > Clinical Programs > Prostate Cancer > PSMA-PET Imaging

Prostate Cancer Imaging: PSMA-PET Imaging for Prostate Cancer

Affiliated: [Find a Doctor](#) | [Symptoms](#) | [Diagnosis](#) | [Treatment](#)

PSMA-PET Imaging for Prostate Cancer

Advanced imaging technique for the detection and visualization of metastatic prostate cancer in newly diagnosed prostate cancer patients and those with recurrent prostate cancer.

Thirty percent of patients treated for prostate cancer — and more than 50 percent in high-risk cases — eventually develop potentially life-threatening recurrences, which are often detected when their prostate-specific antigen levels start rising on routine blood tests. Unfortunately, standard imaging tests aren't good at determining where cancer cells are located.

What is PSMA-PET, also known as 68Ga-PSMA PET/CT?

68Ga-PSMA PET/CT imaging, or PSMA-PET imaging for short, represents a major advance in detecting prostate cancer. At UCLA, with the availability of PSMA-PET imaging patients now have a new option of detecting prostate cancer cells anywhere in the body more accurately than traditional methods. The PSMA-PET imaging test is currently being offered in a UCLA nuclear medicine clinic as part of a diagnostic clinical trial.

How does PSMA-PET imaging work?

The PSMA-PET imaging test works by marking an antigen receptor that sits on the surface of every prostate cancer cell, called PSMA, with a radioactive peptide, Gallium-68. This process allows the cancer cells to be detected wherever they are located, including outside of the pelvic region.

What are the benefits of PSMA-PET imaging for the diagnosis of prostate cancer recurrence?

PSMA-PET imaging offers high sensitivity and specificity. Because the test looks specifically for the antigen that sits on prostate cancer cells, it finds these cancer cells wherever they are located. PSMA-PET allows our UCLA team of doctors to make more informed treatment decisions.

How is PSMA-PET imaging for the diagnosis of prostate cancer performed?

The procedure is similar to other PET/CT scans. The patient is given an intravenous injection of the radioactive peptide (68Ga), followed an hour later by an intravenous injection of contrast dye for the CT portion of the PET/CT scan. The actual scan time is about 20 minutes. There are no common side effects or significant risks, and the procedure takes a maximum of two hours from start to finish.

UCLA Expertise in PSMA-PET Imaging

A multidisciplinary team of UCLA physicians are the study investigators for the first U.S.-based PSMA-PET diagnostic clinical trial that began in September 2016. The results of the study will be submitted to a Food and Drug Administration (FDA) panel. The team of UCLA experts include: Johannes Czernin, MD, Professor of Molecular and Medical Pharmacology and Chief, UCLA Ahmanson Translational Imaging Division; Robert E. Reiter, MD, Bing Professor of Urologic Oncology and Director, UCLA Prostate Cancer Program; Martin Allen-Auerbach, MD, Director of Nuclear Medicine and Professor of Molecular and Medical Pharmacology; Andrew Quon, MD, Professor of Molecular and Medical Pharmacology; Matthew Rettig, MD, Professor of Medicine, Hematology-Oncology.

"With this test, cancer cells light up like lightbulbs on a Christmas tree," says Johannes Czernin, MD, chief of the UCLA Ahmanson Translational Imaging Division. "This test has had a tremendous and immediate impact on prostate cancer patients," says Dr. Reiter, director of UCLA's prostate cancer program. "They can really benefit from this."

New Method for Detecting and Managing Prostate Cancer

Share this

REQUEST AN APPOINTMENT

Phone: (310) 794-7700

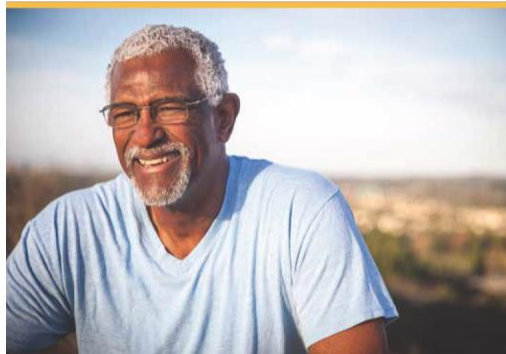


Major Advance in Detecting Prostate Cancer
A new imaging test, PSMA-PET, accurately detects prostate cancer cells throughout the body and better detects prostate cancer recurrences.

The UCLA Health page is aimed at patients and caregivers

Who's the e?

New imaging test accurately detects prostate-cancer cells throughout the body



PSMA-PET imaging better detects recurrences

Thirty percent of patients treated for prostate cancer — and more than 50 percent in high-risk cases — eventually develop potentially life-threatening recurrences, which are often detected when their prostate-specific antigen levels start rising on routine blood tests.

Unfortunately, standard imaging tests aren't good at determining where cancer cells are located, says Robert E. Reiter, MD, Bing Professor of Urologic Oncology and director of UCLA's prostate cancer program. "For the past 20 years, I've had to tell patients with recurrences that I don't know where the cancer is located," Dr. Reiter says. "We've been blind, basically."

Since PSMA-PET imaging became available at UCLA in September, patients now have a new option that's better at detecting the location of prostate-cancer recurrences. "With this test, cancer cells light up like lightbulbs on a Christmas tree," says Johannes Czernin, MD, chief of the UCLA Ahmanson Translational Imaging Division.

"This test has had a tremendous and immediate impact on prostate-cancer patients," Dr. Reiter adds. "They can really benefit from this."

There are about 3 million American men currently living with prostate cancer — and 220,000 new cases diagnosed each year — making it the most common cancer affecting this population. Although cure rates are generally very good, detecting cancer cells that have spread or recurred outside the pelvic region has been an area of weakness in caring for prostate-cancer patients.

To address this issue, UCLA is now the first medical center in Southern California — and one of only a handful across the country — to offer 68Ga-PSMA PET/CT imaging, which can detect prostate-cancer cells anywhere in the body more accurately than traditional methods.

About 68Ga-PSMA PET/CT imaging

68Ga-PSMA PET/CT imaging, or PSMA-PET imaging for short, represents a major advance in detecting prostate cancer. First developed in Germany about three years ago, it's been offered in a UCLA nuclear medicine clinic as part of a diagnostic clinical trial since September 2016. Because it isn't approved by the U.S. Food and Drug Administration, this imaging test is not covered by insurance.

“68Ga-PSMA PET/CT represents a major advance in detecting prostate cancer. Because it isn't approved by the US Food and Drug Administration, this imaging test is not covered by insurance.”

Recent enforcement letters on pre-approval promotion to consumers

- Octreotide capsules – December 21, 2016 (Chiasma)

Video posted on YouTube presents claims that promote octreotide as safe and effective for the purpose for which it is being investigated or otherwise promote the drug, including the following:

(1:43) Dr. Shlomo Melmed: “I think the most important result of the trial was that the drug is safe and safety is a paramount concern for any new drug being used and the physician using the new drug should be assured and be able to reassure his or her patients that in fact the drug is safe. Secondly that the drug is efficacious and the effectiveness of the drug was proven in the clinical trials in that about 62% of patients who were known to respond to octreotide were shown to achieve the primary endpoint which was a maintenance of normal IGF 1 levels. Oral octreotide is a capsule of octreotide, the same octreotide which you use in your injections and which is available to be swallowed and absorbed in the gastrointestinal system and exert its effects on the body similarly to the injectable octreotide.”

*(2:51) Jill Sisco: “I think that what matters most **to patients** is a) that it will work for them or that if it doesn’t work for them they can go to a different therapy and there is no harm no foul by trying a new oral alternative.”*

FDA: “We acknowledge that the statement ‘Product is an investigational new drug and not available for commercial distribution,’ is included as a SUPER on the screen for eight seconds at the end of the video. However, there is no disclaimer that would sufficiently mitigate the extensive claims and presentations throughout the majority of this video that suggest in a promotional context that octreotide capsules, an investigational new drug, is safe or effective for such uses, when FDA has not approved octreotide capsules for any use.”

Chiasma's current disease awareness YouTube site for patients and caregivers

chiasma acromegaly

#acromegalycare

AcromegalyCare
97 subscribers

SUBSCRIBE 97

HOME

Uploads PLAY ALL

Teaming Up: The Doctor/Patient Dynamic
438 views • 1 year ago

Acromegaly Awareness Day - Jorge Faccinetti
136 views • 1 year ago

Acromegaly Awareness Day - Dr. Lewis Blevins
167 views • 1 year ago

Amber's Story: My First-Hand Perspective on Unmet Need...
1K views • 1 year ago

Caring for a Loved One with Acromegaly
395 views • 2 years ago

Acromegaly Patient Webinar - Managing Acromegaly as ...
192 views • 2 years ago

Created playlists

Acromegaly Awareness Day 2015
Ellie's Acromegaly Story: Managing Breakthrough Symptoms • 5:31
Casey's Acromegaly Story: Living with Acromegaly as a Chronic Condition • 3:30
VIEW FULL PLAYLIST (3 VIDEOS)

Recent enforcement letters on pre-approval promotion to consumers

- NDA 022324 Remoxy (oxycodone) Extended-Release Capsules MA5 – September 8, 2016 (Durect)

Durect website and Remoxy ER website include inappropriate claims for an investigational product:

“Long-lasting” and “Tamper-resistant” are phrased as established facts

“Nothing in this presentation, which identifies the product by its trade name under which the NDA indicates Pain Therapeutics intends to commercially market the product, discloses that this product is an investigational new drug...and the presentation is thereby misleading.”

Under ‘Potential Benefits’:

“Effective long-term pain control and convenience of twice-daily dosing.”

“Proprietary formulations with several properties designed to deter abuse by the most common methods.”

“The prominent claims under the Product Overview and Potential Benefits headings ...suggest that Remoxy ER is safe and effective for the purpose for which it is being investigated or otherwise promote the drug as having several properties to deter abuse ...and as providing ‘long-term pain control’ ...”

PRODUCTS

IN DEVELOPMENT >

DUR-018

POSIMIR® (SABER®-
Bupivacaine)

REMOXY ER (ORADUR®-
Oxycodone)

ORADUR®-Hydromorphone and
ORADUR®-Oxymorphone

ORADUR®-Methyphenidate

RELDAY® (SABER®-Risperidone)

ELADUR® (TRANSUR®-
Bupivacaine)

SUSTAINED-RELEASE
Ophthalmology Product

COMMERCIAL PRODUCTS

ALZET® Osmotic Pumps

LACTEL® Absorbable Polymers

REMOXY® ER (ORADUR®-Oxycodone)

Product Overview

Based on DURECT's ORADUR technology, REMOXY ER is a unique long-acting formulation of oxycodone designed to discourage common methods of tampering associated with opioid misuse and abuse. It is intended for patients with moderate-to-severe chronic pain.

When taken as prescribed, opioid analgesics allows individuals suffering from chronic pain to sufficiently control their pain and resume many of their daily activities. However, this class of drugs may be abused, misused, and diverted, which has led to a major public healthcare crisis.

Potential Benefits



Commercial Opportunity



Current Status



Commercial Rights



[Explore REMOXY ER publications >](#)

[Learn more about ORADUR abuse-deterrent technology >](#)

There are risks and uncertainties associated with our business. Please see our most recent SEC filings (10-K or 10-Q) for a complete description of these risks and uncertainties, which are incorporated herein by reference.



Examples from Spark Therapeutics

Disease Awareness

aShared
VisionSM



Understanding
IRDs

Gene Therapy
Research

Genetic
Testing

Community
Stories

Resources

For Health Care
Professionals

Get Our Newsletter

a Shared **Vision**SM

Retinal gene therapy research is bringing hope to the inherited retinal disease (IRD) community.



We're now on Facebook. See what we're talking about.

Join us on Facebook



Inherited retinal diseases (IRDs).

The conditions vary, but those with IRDs may face many similar challenges, including night blindness (nyctalopia), declining vision, or blindness at birth.

See the conditions

Cutting edge science.

Are you following the always evolving field of gene therapy research? Deepen your understanding of how researchers are approaching IRDs in this fascinating field.

See how the science works

Pinpoint your mutation location.

Science can now decipher which gene is responsible for causing a number of IRDs. Here's a simple overview to help you understand the basics of the genetic testing process.

Learn about genetic testing

Disease Awareness



About Gene Therapy

Hemophilia Stories

Resources

Stay Connected

For residents of the U.S. only



Resources for hemophilia, genetics, and gene therapy research

The resources listed below may help you learn more about hemophilia, living with hemophilia, the complexity of genetics, and gene therapy research. The groups, agencies, and resources included in this list are independent organizations and are not affiliated with Spark Therapeutics. By clicking a link on this page, you are leaving the Hemophilia ForwardSM website. Spark assumes no responsibility for any content you may encounter outside of this website.

Hemophilia

National organizations:

- [American Thrombosis and Hemostasis Network](#)
- [Hemophilia Federation of America](#)
- [Hope for Hemophilia](#)
- [National Hemophilia Foundation](#)
- [The Coalition for Hemophilia B](#)
- [World Federation of Hemophilia](#)

Regional organizations directories:

- [Hemophilia Federation of America Local Member Organization Directory](#)
- [Hemophilia Treatment Center \(HTC\) Directory](#)
- [National Hemophilia Foundation Regional Chapter Directory](#)

About Gene Therapy

Information about investigational gene therapy for genetic diseases organized by topic and depth of scientific detail

Get started >

Hemophilia Stories

Videos and blogs relating the experiences and perspectives of individuals from the hemophilia community

Go there >

Stay Connected

Pre-Approval Do's and Don'ts

Do's	Don'ts
<i>Listen:</i> Engage patients and patient advocacy groups as valuable sources of insights for product development.	Promote or otherwise suggest that an investigational product is safe or effective
Support disease educational activities that meet the needs of patients.	Patronize patient advocacy groups by expecting them to adopt or champion company positions or interests
Encourage patients and patient advocacy groups to engage with FDA to voice their opinions on risks and benefits of therapies and the impact of disease on their lives.	Deploy patient advocacy employees without appropriate training on pre-approval restrictions or without clear and appropriate roles and responsibilities.
Be a dependable, objective information resource	Give medical advice

Arnold & Porter

The Do's and Don'ts of Patient Communication

Abraham Gitterman, Associate, Arnold & Porter LLP

FDA Advertising & Promotion General Principles

- Promotional materials and communications should:
 - Not include false or misleading information
 - Be supported by “substantial evidence”
 - Not lack in “fair balance”
 - Not discuss off-label uses or broaden indication/population
 - Not overstate efficacy or safety
 - Not make unsubstantiated comparative/superiority claims
- Violative promotional materials could result in civil, criminal, and administrative actions under FDCA
 - “Prohibited acts”
 - Misbranding, adulteration
 - OPDP Warning/Untitled Letter
 - Also *qui tams* under federal/state False Claims Act (FCA)

OPDP Priority Areas

- Regardless of promotional medium, OPDP has historically focused on:
 - Newly approved products
 - Products with significant risks
 - Products cited for violations in the past
 - Products cited in complaints
 - Products promoted with far reaching campaigns
- FDA will consider
 - Nature of the violation and how egregious
 - Magnitude of impact on public health
 - Need for corrective action
 - Repetitive violations

“Kardashian” Warning Letter

I’m “partnering with Duchesnay USA to raise awareness about treating morning sickness.”



kimkardashian

464k likes

kimkardashian OMG. Have you about this? As you guys know #morningsickness has been tried changing things about like my diet, but nothing talked to my doctor. #Diclegis, I felt importantly was no... the ba... ex... and happy with my res... partnering with Duchesnay USA awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more www.diclegis.com; www.DiclegisImportantSafetyInfo.com

view all 10,983 comments

imoumima @...
flawlessfashi...
paid for this a...
for mom & ba...
because i cou...

♡ Add a c...

“The social media post is false or misleading in that it presents efficacy claims for DICLEGIS, but fails to communicate any risk information associated with its use and it omits material facts. Thus, the social media post misbrands DICLEGIS ... and makes its distribution violative. These violations are concerning from a public health perspective because they suggest that DICLEGIS is safer than has been demonstrated.”

“the statement, “[F]ind out more www.diclegis.com; www.DiclegisImportantSafetyInfo.com[,]” appears at the end of the social media post; however, this does not mitigate the misleading omission of risk information.” The post also “is misleading because it fails to provide material information regarding DICLEGIS’ full approved indication, including important limitations of use.”



Kim Kardashian West
@KimKardashian

Follow

OMG. Have you heard about this? As you guys know my #morningsickness has been pretty bad. I tried...
[instagram.com/p/5Vr42NOS0B/](https://www.instagram.com/p/5Vr42NOS0B/)
9:14 PM - 19 Jul 2015

568 2,372

“Ty Pennington” Warning Letter



“Now once I got on medication it’s just **amazing** the transformation I made. I - It **literally changed my life**, and **gave me the confidence to achieve my goals**, like being an artist. ... But with the medicines like **Adderall XR, it’s truly a transformation**. I mean talk about an Extreme Makeover, I’m like living it. ... It’s **not easy to communicate with people**, including your own family. So as someone who has had ADHD, and is overcoming it, **proper treatment has truly changed my life and made an amazing difference.**”

“This video overstates the efficacy of Adderall XR by implying that this product will “transform” patients’ lives and improve their “confidence.” ... “Furthermore, the video overstates the efficacy of Adderall XR by implying that Adderall XR will help patients overcome communication difficulties and help them to “fit in” and not feel “different” or “alienated.””

Copaxone Warning Letter

Before Treatment

- “It’s hard to believe that just a few years ago [David] had to use a cane for mobility and often could barely muster enough energy to work half a day. This was the case for David, who was diagnosed with multiple sclerosis (MS) in 2002. David awoke one morning experiencing numbness in his toes.”
- “Over the course of a few weeks, the numbness moved up his body and he eventually became partially paralyzed from the chest down.”



After Treatment

- “With the help of his doctor, David began COPAXONE® (glatiramer acetate injection) therapy in 2003”
- “After a year and a half of hard work and determination, David was the USA Triathlon National Champion in the physically challenged category.”
- David went on to compete and win numerous national and international triathlons from 2005-2008.

FDCA & Social Media: Owned or Controlled Sites

- FDA also regulates social or interactive promotional media (e.g., blogs, Facebook, Twitter, YouTube, etc.)
 - “Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics” (2014)
- A firm **is** responsible for promotional communications on sites that are:
 - Owned, controlled, created, influenced or operated by, or on behalf of, the firm (e.g., Twitter, Facebook, blogs, etc.)
- FDA looks at whether firm or “anyone acting on its behalf,” influences or controls promotional activity or communication, *in whole or in part*
- Firm’s are responsible for content if they:
 - Exert influence over a site “in *any* particular, even if influence is limited in scope”
 - “collaborate[] on or ha[ve] **editorial, preview, or review privilege**” over content
- **Not** responsible if *only* financial support (e.g., unrestricted educational grant) *and* no other control or influence

FDA & Social Media: UGC

- Introduces concept of user generated content (UGC)
 - Anything people write, say, post on social media platforms
- A firm is *not* responsible for UGC that is “truly independent of the firm”
 - *e.g.*, not produced by or on behalf of, or prompted by the firm in any particular. *Cf.* 47 U.S.C. 230(c)(1)
- FDA will not ordinarily view UGC on firm-owned or firm-controlled venues (*e.g.*, blogs, message boards, and chat rooms) as promotional content on behalf of the firm as long as:
 - The user has no affiliation with the firm **and**
 - The firm had no influence on the UGC

FDA & Social Media: Third-Party Sites

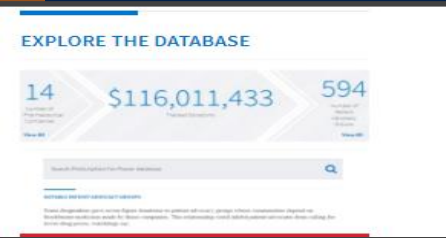
- Firm's are responsible for promotion on third-party sites if they have *any control* or *influence*, *even* if limited in scope
 - *E.g.*, the firm collaborates or has editorial, preview, or review privilege” over content.
- **Not** responsible if *only* financial support (e.g., unrestricted educational grant) *and* no other control or influence
- Providing promotional materials (e.g., banner ads)
 - A firm is only responsible if it *directs* the placement of the promotion within the site
 - Otherwise, firm is only responsible for promotional materials disseminated on site (e.g., comply with FDA regulations), not the third-party site itself

Patient Communications: Other Considerations

- FDA 2004 Disease Awareness Guidance (2015 withdrawn)
- Correcting Independent Third-Party Misinformation (FDA draft guidance)
- HIPAA, COPPA, other privacy laws
- Compassionate Use / Right to Try / Expanded Access
- Adverse event reporting, monitoring
- Transparency, endorsements (FTC) and use of patient consultants
- Fraud & Abuse / Healthcare compliance (e.g., Anti-Kickback Statute)
 - Discussion of reimbursement, coverage, patient assistance programs (PAPs), etc.
 - Interactions with patient advocacy groups, guidelines committees, professional medical associations

Patient Advocacy Groups

KHN launches “Pre\$cription for Power,” a groundbreaking database to expose Big Pharma’s ties to patient groups.



Pharmaceutical companies gave at least \$116 million to patient advocacy groups in a single year, reveals a new database [logging 12,000 donations](#) from large publicly traded drugmakers to such organizations.

**Patient Advocacy Groups
Millions From Drugmakers
There A Payback**

How Many Patient Groups Received Pharmaceutical Funding?

KHN identified 1,215 U.S. nonprofits that function as patient advocacy groups. Of those, 594 received funds from the pharmaceutical companies in the Pre\$cription for Power database.



To learn more about how Kaiser Health News built the Pre\$cription for Power database, read our [methodology](#).

Pharmaceutical Company	Tracked Donations to Patient Advocacy Groups 2015	Number of Patient Advocacy Groups 2015
Pfizer Inc.	\$28,860,052	390
AbbVie Inc.	\$24,681,287	59
Bristol-Myers Squibb Co.	\$20,528,919	84
Eli Lilly and Co.	\$14,939,403	70
Merck & Co. Inc.	\$8,634,706	62
Johnson & Johnson	\$6,063,579	278
Amgen Inc.	\$3,165,159	28
Abbott Laboratories	\$2,788,737	71
Gilead Sciences Inc. *	\$2,576,404	8
Alexion Pharmaceuticals Inc.	\$2,574,555	12
		30
		18
		123
Biogen Inc. *	\$152,827	67

spent on federal lobbying. The [14 companies](#) that contributed \$116 million to [patient advocacy groups](#) reported only about \$63 million in [lobbying activities](#) that same year.

Patient Communications: Considerations

- Comply with applicable FDA regulations, guidance (e.g., branded, unbranded, social media, transparency, etc.)
 - Fair balance; on-label, no overstatement of efficacy, superiority, QOL
 - Address unique aspects of social media (e.g., “like,” “share,” commenting, personal blogs)
- Appropriate patients/caregivers, objective criteria (e.g., on-label, representative)
- Not intended to interfere with clinical decision-making; not medical advice
- Not a reward to patient or their HCP for using product now/future
- Respect patient privacy, comply with HIPAA/privacy laws
- Contracts for services (written agreement, FMV); require company training
- Limited role access, coverage, reimbursement, lobbying
- Comply with patient advocacy group rules
- Consider policies, SOPs, centralized function to handle patient engagement