



# Patient Engagement: Challenges of Engaging Patients and Patient Groups

**Ryan Hohman**, Vice President--Public Affairs, Friends of Cancer Research

**Tim Kreidler**, Sr. Director of Regulatory Affairs – Commercialization, Dermira, Inc.

**Jennifer Romanski**, Principal, Porzio, Bromberg & Newman, P.C.

*Moderated by* **Abraham Gitterman**, Associate, Arnold & Porter LLP

# Speakers\*

- **Ryan Hohman**, Vice President–Public Affairs, Friends of Cancer Research
- **Tim Kreidler**, Sr. Director of Regulatory Affairs – Commercialization, Dermira, Inc.
- **Jennifer Romanski**, Principal, Porzio, Bromberg & Newman, P.C.
- *Moderated by* **Abraham Gitterman**, Senior Associate, Arnold & Porter LLP

\*The views and ideas expressed during this presentation are the speaker's own and should not be attributed to their company, organization, firm or firm clients.

# Agenda

- Brief Overview of Current Landscape
- Q&A

# Why the Focus on Patients?

- FDA and Patient Focused Drug Development (PFDD) meetings
- 21st Century Cures Act and “patient experience data”
- Increased use of social/digital media for branded and unbranded initiatives
- Focus on rare and orphan diseases
- Growth, sophistication of patient organizations
- Significant focus on drug costs and price increases
- Independent co-pay foundation scrutiny, investigations, settlements

# Patient Groups: Overview

- Disease or condition-specific
- Established/historic vs. new
- Vary in size, scope, mission (e.g., international, national, regional, local)
  - Different budgets/operating money
  - Different initiatives or program offerings (e.g., R&D, grants, education)
  - Lobbying vs. no advocacy
  - May interact with government agencies (e.g., FDA, CMS, NIH)
- Conflict of interest policy
- No specific FDA or OIG rules/regulations addressing interactions with patient groups

# Congress and Patient Groups (Jun. 2019)

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

Dr. David Charles  
Chairman  
Alliance for Patient Access  
1275 Pennsylvania Avenue, NW  
Suite 1100A  
Washington, DC 20004

Dear Dr. Charles,

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

This Committee has a long history of examining the relationships between pharmaceutical manufacturers and physicians that influence pain treatment practices and policy. In 2012, Chairman Grassley, along with then-Chairman Max Baucus, initiated a bipartisan investigation into the connection between opioid manufacturers and non-profit medical organizations and physicians.<sup>1</sup> The purpose of this investigation was to understand the nature of these relationships and to determine the extent to which they were responsible for promoting misleading information about opioid safety and effectiveness.<sup>2</sup> During the investigation, the Committee stressed the importance of ensuring that these organizations and their members are adequately disclosing these conflicts to the Federal government to ensure that their guidance remains objective and transparent to the medical community and to patients.<sup>3</sup> It is imperative that Congress ensure that these organizations and their members are adequately disclosing these conflicts to the Federal government to ensure that their guidance remains objective and transparent to the medical community and to patients.

organizations and physicians.<sup>1</sup> The purpose of this investigation was to understand the nature of these relationships and to determine the extent to which they were responsible for promoting misleading information about opioid safety and effectiveness.<sup>2</sup> During the investigation, the

opioid manufacturers.<sup>5</sup> It is imperative that Congress ensure that these organizations and their members are adequately disclosing these conflicts to the Federal government to ensure that their guidance remains objective and transparent to the medical community and to patients.

<sup>1</sup> Baucus, Grassley Seek Answers About Opioid Use, <https://www.finance.senate.gov/cha/members/newsroom/>

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

CHUCK GRASSLEY, IOWA, CHAIRMAN  
MIKE CRAIG, IOWA  
PAT ROBERTS, KANSAS  
MIGUEL L. LISI, ILLINOIS  
JOHN CORNYN, TEXAS  
JOHN THUNE, SOUTH DAKOTA  
ROBERT CORKER, NORTH CAROLINA  
JOHNNY ISAKSON, GEORGIA  
BOB PORTMAN, OHIO  
PATRICK J. TOOMEY, PENNSYLVANIA  
THE SCOTT, SOUTH CAROLINA  
BL. CRIST, VIRGINIA  
JAMES LAMARCO, DELAWARE  
STEVE CARPER, MISSISSIPPI  
TODD YOUNG, INDIANA

ROB CORKER, TENNESSEE  
DEBBIE STABENOW, MICHIGAN  
MARK CANTWELL, OREGON  
FRANK RAYBURN, MISSISSIPPI  
THOMAS, CALIFORNIA  
MICHAEL LEE, UTAH  
DICK DURBIN, IOWA  
DICK BLUMENTHAL, CONNECTICUT  
BOBBY COLEBY, INDIANA  
MARK E. BLUMENTHAL, CONNECTICUT  
MAGGIE MESSAN, MISSISSIPPI  
CATHERINE CORTEZ MASTERS, MISSISSIPPI

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF OF STAFF  
JOSHUA BERENSON, SENIOR POLICY STAFF DIRECTOR

# Congress and Patient Groups (cont'd)

2. Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical supplies<sup>8</sup> and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:

3. In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.

4. Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.

CHUCK GRASSLEY, IOWA  
MIKE CRAIG, IDAHO  
PAT ROBERTS, KANSAS  
MICHAEL L. BURG, KENTUCKY  
JOHN CORNYN, TEXAS  
JOHN THUNE, SOUTH DAKOTA  
ROMANOS BURE, NORTH CAROLINA  
JOHNNY ISAKSON, GEORGIA  
BOB PORTMAN, OHIO  
PATRICK J. TOOMEY, PENNSYLVANIA  
THE SCOTT, SOUTH CAROLINA  
BILL CROFT, LOUISIANA  
JAMES LAMARCO, DELAWARE  
STEVE GARRETT, MONTANA  
TODD YOUNG, INDIANA

KOLAN DAVIS, STAFF DIRECTOR  
JOSHUA BERENSON, SENIOR COUNSEL

Dr. David Charles  
Chairman  
Alliance for Patient Access  
1275 Pennsylvania Avenue, N  
Suite 1100A  
Washington, DC 20004

Dear Dr. Charles,

We write to request info with opioid manufacturers and Chairman and Ranking Membe ensure transparency and accou programs and tax-exempt organ which pharmaceutical manufac may influence pain treatment p

This Committee has a l their relationships with tax-exe 2012, Chairman Grassley, alon investigation into the connectio organizations and physicians.<sup>1</sup> these relationships and to deter misleading information about o Committee stressed the import order to prevent improper use c investigation before the end of

<sup>1</sup> [https://www.finance.senate.gov/committees/subcommittees/health\\_affairs/grassley](https://www.finance.senate.gov/committees/subcommittees/health_affairs/grassley)

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

# Patient Groups & Media

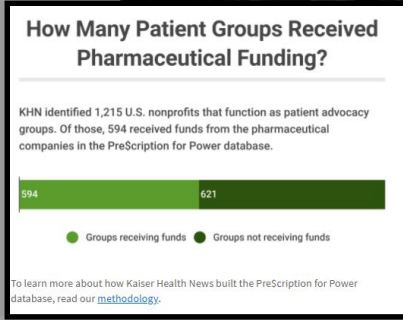


KHN launches “Pre\$cription for Power,” a groundbreaking database to expose Big Pharma’s ties to patient groups.

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.

| Pharmaceutical Company                      | Tracked Donations to Patient Advocacy Groups 2015 | Number of Patient Advocacy Groups 2015 |
|---|---|--|
| <a href="#">Pfizer Inc.</a>                 | \$28,860,052                                      | 390                                    |
| <a href="#">AbbVie Inc.</a>                 | \$24,681,287                                      | 59                                     |
| <a href="#">Bristol-Myers Squibb Co.</a>    | \$20,528,919                                      | 84                                     |
| <a href="#">Eli Lilly and Co.</a>           | \$14,939,403                                      | 70                                     |
| <a href="#">Merck &amp; Co. Inc.</a>        | \$8,634,706                                       | 62                                     |
| <a href="#">Johnson &amp; Johnson</a>       | \$6,063,579                                       | 278                                    |
| <a href="#">Amgen Inc.</a>                  | \$3,165,159                                       | 28                                     |
|   |   | 71                                     |
|   |   | 8                                      |
|   |   | 12                                     |
|   |   | 30                                     |
| <a href="#">Perrigo Co. PLC</a> *           | \$175,300   | 18                                     |
| <a href="#">Baxter International Inc.</a> * | \$154,004   | 123                                    |
| <a href="#">Biogen Inc.</a> *               | \$152,827   | 67                                     |

Patient Advocacy Groups Take Millions From Drugmakers. Is There A Payback?



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 Groups & Media (cont'd)

**PRO PUBLICA** Journalism in the  
**American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics**

**Dollars for Doctors**  
How Industry Money Reaches Physicians

## How Much Money Do Groups Receive From Industry?

Show All

**Professional Health Care Groups**

- American Academy of Orthopaedic Surgeons
- American Academy of Allergy Asthma & Immunology
- American Academy of Dermatology
- American Academy of Family Physicians
- American College of Obstetricians & Gynecologists
- American College of Surgeons
- American Dental Association
- American Dietetic Association
- American Medical Association
- American Psychological Association
- American Society of Anesthesiologists
- American Society of Colon and Rectal Surgeons
- American Society of Consultant Pharmacists
- American Society of Health-System Pharmacists
- American Society of Hypertension
- American Society of Nephrology
- American Society of Plastic Surgeons

Search...

**Alzheimers Assoc**  
A volunteer organization helping those affected funding research.

**American Acad**  
**Asthma and Imm**  
A professional organization dedicated to those practicing in the allergy/immunology field.

**American Acad**  
**Dermatology**  
A professional organ practicing national

**Emails Show Drug Company Used Third-Party Medical Groups to Influence Regulators, Undercut Rivals**

**Cardiac Society Draws Bulk of Funding From Stent Makers**

**Reports Detail More Drug Industry Ties to Medical Societies**

**The New York Times**

**Senator Grassley Seeks Financial Details From Medical Groups**

# Calls for Increased Transparency

NEWS / IN THE NEWS

September 24, 2019

## Senator Hassan Op-Ed on Healthcare: To Hold Big Pharmaceutical Companies Accountable, First We Need Transparency

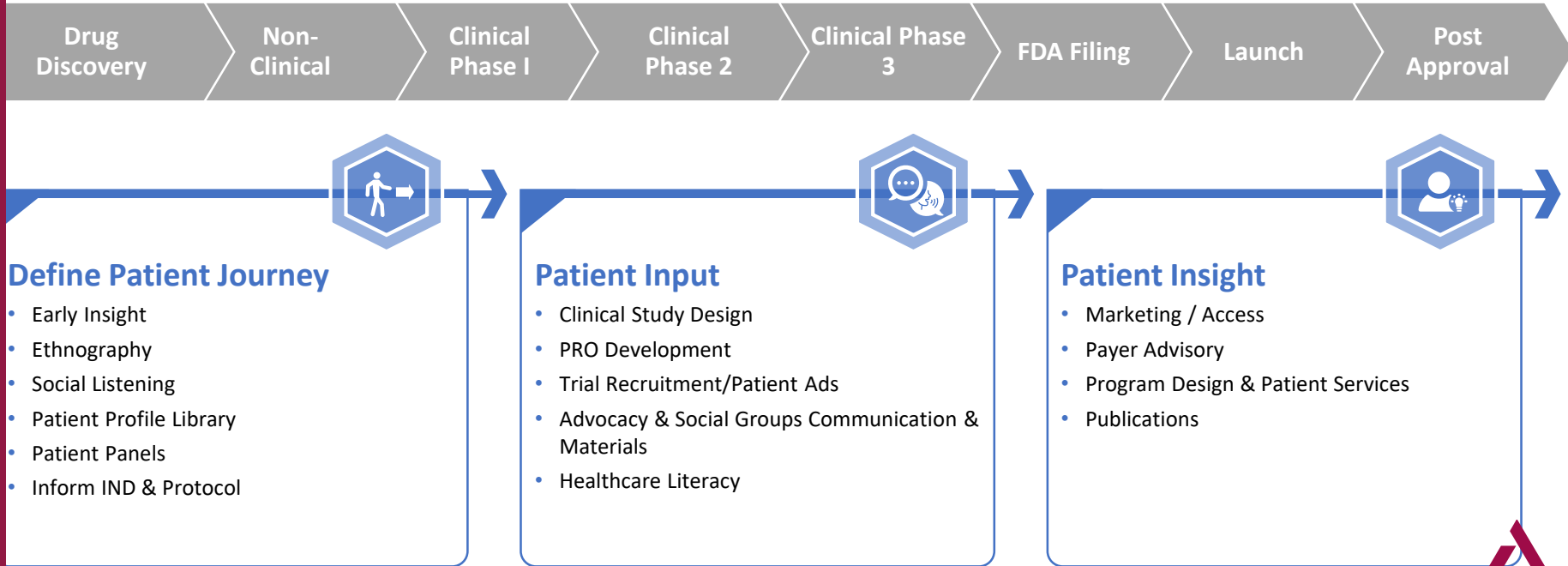
WASHINGTON – In case you missed it, Senator Maggie Hassan's op-ed for Modern Healthcare highlighting the need to increase transparency in the pharmaceutical industry in order to shed light on decisions that are unnecessarily driving up prescription drug costs.

In July, Senator Hassan worked with colleagues to develop bipartisan legislation, the *Prescription Drug Pricing Reform Act*, which was introduced to the Senate Finance Committee. The bill would enact a cap on prescription drug costs for Medicare Part D beneficiaries and hold pharmaceutical companies that raise drug prices high. Senator Hassan pushed to include stiffer penalties for manufacturers of prescription drugs in the Senate bill, and will continue to work on this specific problem. According to the non-partisan Congressional Budget Office, the bill would save Medicare beneficiaries more than \$100 billion in premiums and out-of-pocket costs, and would save taxpayers \$100 billion in Medicare and Medicaid spending over ten years.

*As the Finance Committee works to address drug pricing, one of my top priorities has been holding pharmaceutical companies accountable for their actions, including by increasing transparency around the tactics these companies use. In particular, Chairman Chuck Grassley (R-Iowa) and ranking member Ron Wyden (D-Ore.) are conducting important oversight investigating the ways drug companies are using foundations to provide misinformation on pain management and the safety of opioids.*

*One way we can jump-start that effort is expanding the Medicare Open Payments database to include payments made by opioid manufacturers to not-for-profit foundations and require these foundations to submit annual disclosures to HHS' Office of Inspector General. By increasing transparency and eliminating these deceptive anti-competitive practices, we can improve our healthcare system, lower costs for taxpayers and, most importantly, save lives.*

# Integrating the Patient Voice



# Q&A

- What function within a pharmaceutical or medical device manufacturer should “own” interactions with patient groups?
  - Commercial (e.g., sales/marketing)?
  - Medical?
  - Corporate Affairs/Communications?
  - Other (dedicated function i.e., Patient Affairs)
- Why? What are some of the potential issues/concerns?

# Q&A

- Is it appropriate for manufacturers and patient groups to collaborate on unbranded or disease awareness activities?
- If so, what things should both parties consider?
  - Transparency?
  - Accuracy and consistency in content?
  - Financial relationship?
  - FDA regulations?
- What are some of the potential risks?

# Q&A

- Are there any recent FDA or other enforcement updates to consider for branded content including patients?
  - Patient ambassadors?
  - Patient testimonials?
  - Social media?
- What interactions, if any, should manufacturers have with patient groups regarding branded content?

# Q&A

- Are manufacturers or patient groups ready to for consistent with FDA-label (CFL) data?
- Can manufacturers use CFL data with a patient or patient group audience?

# Q&A

- What are some of the risks or issues associate with patient support or access materials?
  - Adherence or reminder messaging?
  - Convenience or quality of life messaging?
  - Product administration and training?
  - Fraud and abuse risks?
- Are these types of materials important to patient groups?
  - What information are they looking for?