Bill as Introduced

HB 695 - AS AMENDED BY THE HOUSE

19Mar2019... 0761h

2019 SESSION

19-0735
01/04

HOUSE BILL ***695***

AN ACT relative to transparency of nonprofit patient advocacy organizations.

SPONSORS: Rep. McBeath, Rock. 26

COMMITTEE: Commerce and Consumer Affairs

AMENDED ANALYSIS

This bill requires nonprofit organizations advocating on behalf of patients or that fund medical research to compile a report relative to payments received from certain manufacturers, insurance carriers, or pharmacy benefit managers. The nonprofit organization shall post the report on its Internet website or file it with the insurance commissioner.

Explanation: Matter added to current law appears in ***bold italics.***
Matter removed from current law appears [~~in brackets and struckthrough.~~]
Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Nineteen

AN ACT relative to transparency of nonprofit patient advocacy organizations.

Be it Enacted by the Senate and House of Representatives in General Court convened:

1 New Section; Transparency of Nonprofit Patient Advocacy Organizations. Amend RSA 400-A by inserting after section 30 the following new section:

400-A:30-a Transparency of Nonprofit Patient Advocacy Organizations.

I. In this section, "patient advocacy organization" means any formally organized nonprofit group that primarily concerns itself with medical conditions or potential medical conditions and has a mission and takes actions that seek to help people affected by those medical conditions or to help their families. "Patient advocacy organization" shall not include a professional organization typically focusing on advancing its profession or serving professional members as a primary goal.

II.(a) On or before January 1 of each year, any patient advocacy organization that has received a payment, donation, subsidy or anything else of value from a pharmaceutical manufacturer, health insurance carrier, or pharmacy benefit manager, or a trade or advocacy group for pharmaceutical manufacturers, health insurance carriers, or pharmacy benefit managers during the immediately preceding calendar year shall compile a report which includes:

(1) For each such contribution, the amount of the contribution and the pharmaceutical manufacturer, affiliated third party, pharmacy benefit manager, or group that provided the payment, donation, subsidy or other contribution; and

(2) The percentage of the total gross income of the organization during the immediately preceding calendar year attributable to payments, donations, subsidies, or other contributions from each pharmaceutical manufacturer, health insurance carrier, pharmacy benefit manager, or group.

(b) Except as otherwise provided in this section, the patient advocacy organization shall post the report on its Internet website which is accessible by the public. If the nonprofit organization does not maintain an Internet website that is accessible to the public, the nonprofit organization shall submit the report compiled pursuant to subparagraph (a) to the insurance department.

III. Any patient advocacy organization that has received a payment, donation, subsidy or anything else of value from a pharmaceutical manufacturer, health insurance carrier, or pharmacy benefit manager, or a trade or advocacy group for pharmaceutical manufacturers, health insurance carriers, or pharmacy benefit managers during the immediately preceding calendar year shall disclose that fact when testifying, lobbying, or otherwise engaging in person with a member of the general court.

IV. Any patient advocacy organization that has a paid employee of the organization who is a

registered lobbyist with the state of New Hampshire and is wearing a name tag in compliance with RSA 15:2 or otherwise identifies him or herself as a lobbyist shall be exempt from this section.

V. Any patient advocacy organization found in violation of this section may be fined up to $1,000 per violation.

2 Effective Date. This act shall take effect upon its passage.

Committee Minutes

SENATE CALENDAR NOTICE
Commerce

Sen Kevin Cavanaugh, Chair
Sen Jon Morgan, Vice Chair
Sen Donna Soucy, Member
Sen Chuck Morse, Member
Sen Harold French, Member

Date: April 18, 2019

HEARINGS

Thursday	04/25/2019
(Day)	(Date)

Commerce	SH 100	1:00 p.m.
(Name of Committee)	(Place)	(Time)

Note: The Committee will meet at 1:00 p.m. or 30 minutes following the end of Session.

1:00 p.m.	**HB 695**	relative to transparency of nonprofit patient advocacy organizations.
1:15 p.m.	**HB 402**	relative to required notice of mortgage funding at a construction jobsite.
1:30 p.m.	**HB 654**	relative to surety required on construction loans.
1:45 p.m.	**HB 740**	exempting certain mortgages from the law regarding licensing of nondepository mortgage bankers, brokers, and servicers.
2:00 p.m.	**HB 268**	relative to real estate commissions paid to unlicensed entities.
2:15 p.m.	**HB 657**	relative to prescription drugs under the managed care law.

EXECUTIVE SESSION MAY FOLLOW

Sponsors:

HB 695
Rep. McBeath

HB 402
Rep. Flanagan

HB 654
Rep. Butler

HB 740
Rep. Butler

HB 268

Rep. Baroody	Rep. Hinch	Rep. DiSilvestro	Sen. Carson

HB 657

Rep. Butler	Rep. Marsh	Rep. Knirk	Rep. Hennessey
Sen. Sherman			

Laura Bryant 271-1403

Kevin Cavanaugh
Chairman

Senate Commerce Committee

Laura Bryant 271-1403

HB 695, relative to transparency of nonprofit patient advocacy organizations.

Hearing Date: April 25, 2019

Time Opened: 11:23 p.m. **Time Closed:**

Members of the Committee Present: Senators Cavanaugh, Morgan, Soucy, Morse and French

Members of the Committee Absent : Senator Morgan

Bill Analysis: This bill requires nonprofit organizations advocating on behalf of patients or that fund medical research to compile a report relative to payments received from certain manufacturers, insurance carriers, or pharmacy benefit managers. The nonprofit organization shall post the report on its Internet website or file it with the insurance commissioner.

Sponsors:
Rep. McBeath

Who supports the bill: None

Who opposes the bill: None

Who is neutral on the bill: None

Summary of testimony presented:

Senator Soucy introduced the bill, on behalf of Representative McBeath, to the committee and read the analysis. No one else was present to testify.

LHB
Date Hearing Report completed: April 25, 2019

SENATE CALENDAR NOTICE
Commerce

Sen Kevin Cavanaugh, Chair
Sen Jon Morgan, Vice Chair
Sen Donna Soucy, Member
Sen Chuck Morse, Member
Sen Harold French, Member

Date: April 25, 2019

HEARINGS

Tuesday	04/30/2019
(Day)	(Date)

Commerce	LOB 102	1:00 p.m.
(Name of Committee)	(Place)	(Time)

1:00 p.m.	**HB 233**	relative to the group and individual health insurance market.
1:15 p.m.	**HB 536-FN**	adding biometric information to the consumer protection act.
1:30 p.m.	**HB 725-FN**	relative to certain standards for managed care organizations.
1:45 p.m.	**HB 558-FN**	restricting the distribution of plastic straws.
2:15 p.m.	**HB 560-FN**	relative to single-use carryout bags.
2:45 p.m.	**HB 695**	relative to transparency of nonprofit patient advocacy organizations. (THE PREVIOUS HEARING FOR HB 695 WAS RECESSED ON APRIL 25th)
3:00 p.m.	**HB 657**	relative to prescription drugs under the managed care law. (THE PREVIOUS HEARING FOR HB 657 WAS RECESSED ON APRIL 25th)

EXECUTIVE SESSION MAY FOLLOW

Sponsors:

HB 233

Rep. Butler	Rep. Marsh	Rep. Ticehurst	Rep. Knirk
Rep. Luneau	Rep. Berrien	Rep. Campion	Rep. Cushing
Sen. Rosenwald	Sen. Hennessey	Sen. Sherman	Sen. Bradley

HB 536-FN

Rep. Luneau	Rep. Hunt	Sen. Cavanaugh	

HB 725-FN

Rep. Knirk	Rep. Williams	Rep. Marsh	Rep. Woods
Sen. Sherman			

HB 558-FN

Rep. Spang	Rep. Balch	Rep. Luneau	Rep. Myler
Sen. Fuller Clark	Sen. Watters		

HB 560-FN

Rep. Spang	Rep. Balch	Rep. Luneau	Rep. Myler
Sen. Watters	Sen. Fuller Clark		

HB 695

Rep. McBeath

HB 657

Rep. Butler	Rep. Marsh	Rep. Knirk	Rep. Hennessey
Sen. Sherman			

Laura Bryant 271-1403

Kevin Cavanaugh
Chairman

SENATE CALENDAR NOTICE
Commerce

Sen Kevin Cavanaugh, Chair
Sen Jon Morgan, Vice Chair
Sen Donna Soucy, Member
Sen Chuck Morse, Member
Sen Harold French, Member

Date: May 2, 2019

HEARINGS

Tuesday	05/07/2019
(Day)	(Date)

Commerce	SH 100	1:00 p.m.
(Name of Committee)	(Place)	(Time)

1:00 p.m.	**HB 695**	relative to transparency of nonprofit patient advocacy organizations. (THE PREVIOUS HEARING FOR HB 695 WAS RECESSED ON APRIL 30th)
1:15 p.m.	**HB 657**	relative to prescription drugs under the managed care law. (THE PREVIOUS HEARING FOR HB 657 WAS RECESSED ON APRIL 30th)
1:30 p.m.	**HB 656**	establishing a commission to study the impact of financial initiatives for commercially insured members by drug manufacturers on prescription drug prices and health insurance premiums.
1:45 p.m.	**HB 277**	establishing a commission to study a public option for health insurance.
2:00 p.m.	**HB 577**	relative to call blocking in an automated telephone dialing system.
2:15 p.m.	**HB 703-FN**	relative to providing notice of the introduction of new high-cost prescription drugs.

EXECUTIVE SESSION MAY FOLLOW

Sponsors:

HB 695

Rep. McBeath

HB 657

Rep. Butler	Rep. Marsh	Rep. Knirk	Rep. Hennessey
Sen. Sherman			

HB 656

Rep. Butler	Rep. Marsh	Rep. Knirk	Rep. Hennessey
Sen. Bradley	Sen. Sherman		

HB 277

Rep. Knirk	Rep. Nutting-Wong	Rep. Campion	Rep. Fothergill
Sen. Sherman	Sen. Hennessey		

HB 577

Rep. Luneau	Rep. Gordon

HB 703-FN

Rep. Butler	Rep. Knirk	Sen. Sherman

Laura Bryant 271-1403

Kevin Cavanaugh
Chairman

Senate Commerce Committee

Laura Bryant 271-1403

HB 695, relative to transparency of nonprofit patient advocacy organizations.

Hearing Date: May 7, 2019

Time Opened: 1:03 p.m. **Time Closed:** 1:26 p.m.

Members of the Committee Present: Senators Cavanaugh, Soucy, and Morse

Members of the Committee Absent : Senators French and Morgan

Bill Analysis: This bill requires nonprofit organizations advocating on behalf of patients or that fund medical research to compile a report relative to payments received from certain manufacturers, insurance carriers, or pharmacy benefit managers. The nonprofit organization shall post the report on its Internet website or file it with the insurance commissioner.

Sponsors:
Rep. McBeath

Who supports the bill: Holly Stevens with New Futures

Who opposes the bill: Maryann May with NEHA, Sarah Lutat, Beverly Goodell

Who is neutral on the bill: Tom Donovan with the NH AG's Office, Tyler Brannen with the NHID

Summary of testimony presented:

Holly Stevens with New Futures:

- Stevens said that New Futures requested that Representative Butler sponsor this bill.
- Stevens said that there has been a lot of people testifying before committees that do not disclose that they are receiving money from pharmaceutical companies.
- She said with a lack of staff and a voluntary legislature, there is not enough people to do research on this issue. She did point out that a US Senate committee found that there were pharmaceutical companies paying groups to testify before committees with testimony that touted pro-opioid policies.
- She said that this bill does not require the companies to disclose donors, because that's a violation of first amendment rights, however she said that if someone is testifying before the committee they should have to disclose if there is a conflict

of interest.

- She said that this bill does exempt a non-profit who has a hired lobbyist and it allows the group to bring forth members to tell their stories.

Maryann May with New England Hemophilia Coalition,

- May said this bill would require their group to have to compile a report that details anything received of value which would inhibit their efforts to advocate for the vulnerable population they serve.
- She added that there is lots of broad and vague language in the bill, and it creates unnecessary suspicion around groups like theirs.
- She concluded that this is a cumbersome bill which aims to regulate a problem that does not exist.

Tom Donovan, Director of Charitable Trusts in the NH Attorney General's Office:

- Donovan said that this is an important issue and the AG's office has been aggressive in going after companies responsible for the opioid crisis.
- He said this bill makes it required for nonprofit groups to disclose on their website and at a committee that they testify before the names and amounts of contributions from pharmaceutical companies.
- He added that there is a policy issue at hand that should be flagged, which is the disclosing of names of people who give to charities.
- He said if donor names to controversial organizations were to get disclosed that could discourage donors to donate to organizations or set them up for harassment. He said that while this bill doesn't go after this, it is the policy issue at hand.
- He concluded that there is a first amendment issue in regards to free association, and agrees to help on an amendment such as the one Holly Stevens had mentioned.

Senator Soucy asked that currently there aren't any disclosures of donors for these organizations.

- **Donovan** responded with yes, not to the public, the IRS does require charities to disclose to the IRS confidentially the names of donors $5,000 and above, this is called Schedule B. He said that currently two states, New York and California, have their charity offices claiming that they have a right to know this information and that issue is currently in the courts.

Sarah Lutat, Executive Director of Dismas Home:

- Lutat said her organization is a small nonprofit whose goal is to help previously incarcerated women return to a normal, healthy life.
- She opposes the bill because the motivation behind it is unclear and irrelevant. She said each year small nonprofits are burdened with regulations and compliance measures.
- She explained that this increases the burden on their small staff, thus taking

them away from helping those who need it most.
- She detailed that none of the contributions they receive affect how they feel about different policies, nor does it change their mission.
- She said that the NH government relies heavily on nonprofits to make up for things that they fail to provide.

Senator Soucy asked Lutat if her organization has a Board of Directors and if that board has a policy on accepting donations.
- Lutat said yes, they do have a BoD that makes those decisions.

Senator Soucy followed up and asked if there was a donation from a particular entity the organization could refuse it.
- Lutat said yes, they could refuse it.

Tyler Brannen, Health Economics Director with the NH Insurance Department:
- Brannen expressed concern with collecting data with an unregulated entity, and while it is not uncommon for the legislature to ask the department to collect data from various entities, this is different.
- Brannen said the amendment should change the language so that the DoJ would collect the data instead of the NHID, since the DoJ would have a better grasp on this issue and enforcing it.

Beverly Goodell with the Lupus Foundation of NE:
- Goodell said most nonprofits are small and understaffed and would prefer to spend their time advocating and helping patients, therefor the extra paperwork this bill requires is cumbersome.

LHB
Date Hearing Report completed: May 8, 2019

Speakers

Senate Commerce Committee

SIGN-IN SHEET, Public Hearing HB 695

Date: 4/30/19 **Time:** 2:45 p.m

Name/Representing ***(please print neatly)***

Name/Representing	Support	Oppose	Speaking?	Yes	No
Holly Stevens New Futures	☑	☐	Speaking?	☑	☐
Tyler Brannen NHID	☐	☐	Speaking?	☑	☐
	☐	☐	Speaking?	☐	☐
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	☐	☐	Speaking?	☐	☐

Senate Commerce Committee

SIGN-IN SHEET, Public Hearing HB 695

Date: 5/7/19 **Time:** 1:00 p.m

Name/Representing ***(please print neatly)***

Name/Representing	Support	Oppose	Speaking? Yes	Speaking? No
Holly Stevens New Futures	☑	☐	☑	☐
Maryann May New England Hemophilia assoc.	☐	☑	☑	☐
Tom Donovan AG's Office	☐ info only	☐	☑	☐
Sara Lufat	~~☑~~	☑ (circled)	☑	☐
Tyler Brannen NHID	☐	☐	☑	☐
Beverly Indell	☐	☑	☑	☐
	☐	☐	☐	☐
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Senate Commerce Committee

SIGN-IN SHEET, Public Hearing HB 695

Date: 5/7/19 **Time:** 1:00 p.m

Name/Representing ***(please print neatly)***

Name/Representing	Support	Oppose	Speaking?	Yes	No
E Goodell	☐	☒	Speaking?	☒	☐
	☐	☐	Speaking?	☐	☐
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	☐	☐	Speaking?	☐	☐

Testimony

New England Hemophilia Association

N | E | B | D | A | C

TESTIMONY

In Opposition To

HB695, Transparency of Nonprofit Patient Advocacy Organization

Maryann May

New England Bleeding Disorder Advocacy Coalition (NEBDAC)
The New England Hemophilia Association (NEHA)

Before the Commerce and Consumer Affairs Committee

May 7, 2019

Chairman Cavanaugh, Vice Chair Morgan and members of the Senate Commerce and Consumer Affairs Committee:

My name is Maryann May. I am offering this testimony today on behalf of the New England Hemophilia Association (NEHA), the New England Bleeding Disorders Advocacy Coalition (NEBDAC), and the bleeding disorder community here in New Hampshire. Since 1957, NEHA has served individuals and families with inherited bleeding disorders, who need information, education and support for their condition. NEBDAC was formed in 2016, as a volunteer advocacy coalition under NEHA. Both NEBDAC and NEHA provide advocacy and education about bleeding disorders in all 6 New England States.

We offer this testimony in opposition to HB695, a bill that would require nonprofit organizations advocating on behalf of patients to compile a report relative to payments received from certain manufacturers, insurance carriers, or pharmacy benefit managers.

New England Hemophilia Association

N | E | B | D | A | C

HB695 contains broad and vague language, striking penalties, and reinforces an unreasonable suspicion of patient advocacy groups. If passed, this legislation would give patient advocacy focused non-profits unreasonable duties to report anything received "of value" or face stark fines. The ambiguous language will not only confuse and frustrate non-profits, but will ultimately serve to inhibit efforts to advocate for the already vulnerable populations that NEHA and NEBDAC serve.

The underlying notion of HB695, is that relationships between grantors and patient advocacy organizations are somehow shameful and something to be exposed. It is already customary for organizations within the non-profit sector to openly thank their grantors in their advertising and marketing materials, on their websites, as well as in their year-end reports. As such, HB695 is a cumbersome attempt to regulate a problem that doesn't exist.

In addition, we would like to point out that NEBDAC is made up of a coalition of volunteers, such as myself, and a part-time coordinator. NEHA, which provides advocacy and education across the six New England states, has a staff of only 4. These are not affluent organizations. We ask that you allow us to focus on the vulnerable patients they serve, such as my family, rather than spending time responding to hypothetical improprieties.

Bleeding disorders are rare, and patient advocacy groups like NEHA and NEBDAC use funding to educate and support consumers and their families. The bleeding disorder community has extremely expensive treatments, with no generic options. Understanding and having support about available products and understanding insurance options is vitally important to our community. Our necessary treatments, including clotting factor and non-factor replacement therapies, prevent and stop bleeding episodes that can be painful, dangerous, and sometimes deadly. Without proper education about our disorders and access to treatments, episodes of bleeding can permanently damage tissue and joints. We hope you recognize that the work we do is vital.

New England Hemophilia Association

N | E | B | D | A | C

We ask you, no, we urge you not to pass HB695.

Maryann May
New Hampshire resident
NEBDAC Ambassador

Richard Pezzillo
Executive Director
NEHA

Susi Von Ottigen
New Hampshire Lead
For NEBDAC

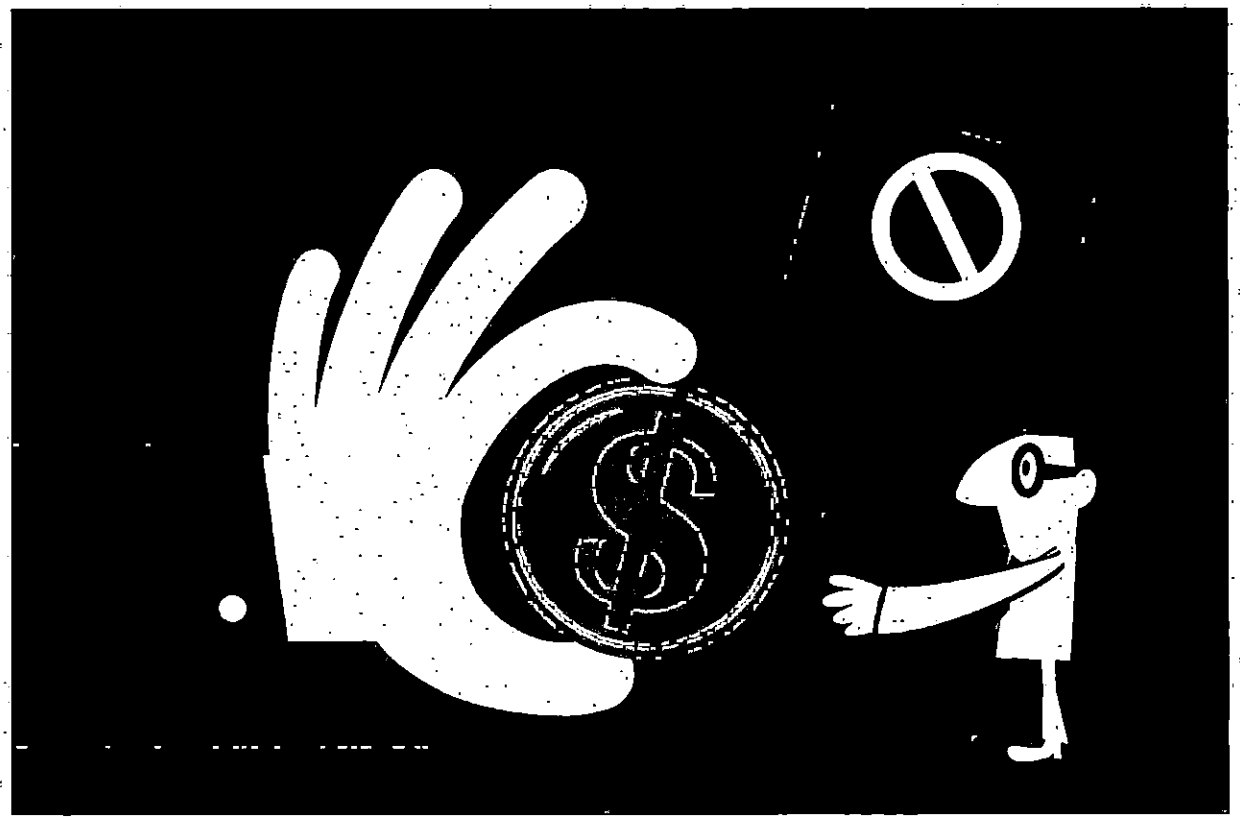
Joseph Zamboni
Advocacy Coordinator
NEBDAC

KHN
KAISER HEALTH NEWS

PRE$CRIPTION FOR POWER

Big Pharma Gave Money To Patient Advocacy Groups Opposing Medicare Changes

By **Sydney Lupkin** and **Elizabeth Lucas** and **Victoria Knight** • MARCH 4, 2019



(Lydia Zuraw/KHN illustration; Getty Images)

Dozens of patient advocacy groups, like the Bonnie J. Addario Lung Cancer Foundation and the National Coalition for Cancer Survivorship, recently appeared in national advertisements objecting to a Trump administration proposal that could limit drugs covered by Medicare providers.

But a Kaiser Health News analysis found that about half of the groups representing patients have received funding from the pharmaceutical industry.

Drugmakers funneled more than $58 million to the groups in 2015 alone, according to financial disclosures in KHN's "Pre$cription for Power" database, which tracks the little-publicized ties between patient advocacy groups and drugmakers. As

patient organizations gain ground lobbying Congress and the administration, experts have begun to question whether their financial ties could push them to put drugmakers' interests ahead of the patients they represent.

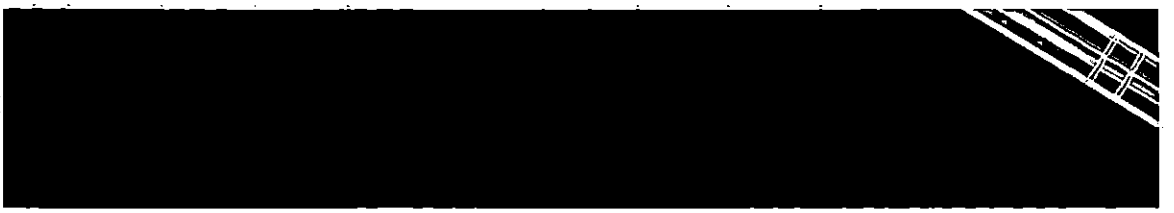
The advertisement, which ran in national newspapers, attacked proposed changes to Medicare Part D's "protected" drug classes, which require that "all or substantially all" drugs must be covered by all insurers. The medicines involved include oral cancer drugs, HIV medicines and antipsychotics.

The protection can have the effect of guaranteeing sales to Medicare patients no matter the price tag.

The proposed rule would give insurers more opportunities to instead steer patients toward lower-cost therapies and generics using prior authorization or step therapy, in which patients must try cheaper drugs before they can switch to options that are more expensive.

It would also allow protected drugs to be left off Medicare Part D formularies when price hikes exceed inflation or new formulations of drugs don't offer a "significant innovation" over existing versions.

"It's wrong and it will put patients' lives at risk," reads the ad paid for by the American Cancer Society Cancer Action Network above a list of 56 other patient advocacy groups who presumably agree. Underneath, a link directs readers to an online form to send pre-written emails to members of Congress and the administration.



Big Pharma Donations To Patient Advocacy Groups Listed In Ad

Half of the advocacy groups listed in the advertisement opposing changes to Medicare Part D drug coverage received money from pharmaceutical companies, according to the Pre$cription for Power database, which compiled these transactions for 2015.

Organization in Ad	Contributions from Big Pharma, 2015
American Autoimmune Related Diseases Association	$152,500
American Cancer Society Cancer Action Network	$671,500
American Heart Association	$15,797,138
American Kidney Fund	$257,484
American Lung Association	$1,178,765
Bladder Cancer Advocacy Network	$343,160
Bonnie J. Addario Lung Cancer Foundation	$713,011
Cancer Support Community	$1,011,429
Colorectal Cancer Alliance	$61,913
COPD Foundation	$928,975
Deadliest Cancers Coalition*	$1,619,292
Epilepsy Foundation	$66,228
Fight Colorectal Cancer	$333,060
FORCE: Facing Our Risk of Cancer Empowered	$324,699
International Myeloma Foundation	$1,575,050
Lung Cancer Alliance	$1,278,395
LUNGevity Foundation	$1,073,283
Lupus Foundation of America	$681,405
MAPRx Coalition*	$9,256,264
Metastatic Breast Cancer Alliance*	$16,002,326
METAvivor Research and Support	$15,000
Movement Disorders Policy Coalition*	$250,346

National Blood Clot Alliance	$155,258

The government proposal's goal, however, isn't to end coverage for drugs in protected classes, said Rachel Sachs, an associate law professor at Washington University in St. Louis who specializes in health care. Its goal is to give plans more leverage to bargain for better discounts. If there's a chance an insurance plan won't cover a drug, the provider has more negotiating power.

The Cancer Action Network's six-figure ad buy ran for three weeks starting Jan. 17. It appeared in print and online in The New York Times and The Washington Post, as well as local publications in Washington, D.C., according to Cancer Action Network spokeswoman Alissa Crispino. About 4,500 people used the online email tool.

It's important to make sure cancer patients can get "cutting-edge" treatments, said Keysha Brooks-Coley, vice president of federal affairs for the Cancer Action Network. "This is really an access issue," she said.

The lobby for brand-name drugmakers, the Pharmaceutical Research and Manufacturers of America, takes the same stance, according to its submitted comments on the proposal.

But access to drugs means more than insurance coverage, said Karuna Jaggar, the executive director of Breast Cancer Action, a patient group that was not invited to be listed in the ad and hasn't accepted corporate funding for two decades to avoid the appearance of bias. "If people can't afford it, the reality is they cannot access it."

Given the ad's selective understanding of "access" to exclude cost and the patient groups' industry ties, she asked, "Can we trust them?"

The American Cancer Society Cancer Action Network communicates with its funders, which include drugmakers and others, but the group sets its own agenda, Brooks-Coley said.

KHN launched its Pre$cription for Power database in spring 2018. It now includes nearly 14,000 transactions, totaling $163 million in donations from 26 drugmakers to 650 patient groups, in 2015. The patient groups often don't disclose their donors, so the information comes from drugmakers' financial disclosures, some of which are voluntary. Not all companies publicly disclose their charitable giving, so KHN estimates are likely low.

Although there are occasions when what's best for patients is the same as what's best for drugmakers, people should consider patient advocacy group statements with a "skeptical eye" if groups have financial ties to the pharmaceutical industry, said Matthew McCoy, a medical ethics and health policy assistant professor at the University of Pennsylvania.

Drugmakers and patient advocacy organizations have fundamentally different missions, he said. One wants to make money for shareholders. The other wants to serve patients. Since their goals will inevitably diverge, it's important that patient groups aren't swayed by their funders, he said.

It can be easy to view a pharmaceutical company as an ally when its contributions help keep the lights on, McCoy said. "I think we have a lot of evidence from research on financial conflicts of interest in other areas of health care to know that the influence often is unconscious to the people who are actually experiencing it."

Still, Sachs said she can understand why patient advocacy groups oppose changes to the six protected classes, even if they lead to lower drug prices.

"The question is, what happens if negotiations between pharmaceutical companies and the Part D plans fail?" Sachs said. "In at least some cases, the Part D plan will be able to say simply it's going to exclude you from coverage because of the price of the drug."

Sydney Lupkin: slupkin@kff.org, @slupkin
Elizabeth Lucas: elucas@kff.org, @eklucas
Victoria Knight: vknight@kff.org, @victoriaregisk

Global Healthy Living Foundation
515 North Midland Avenue
Upper Nyack, New York 10960 USA
+1 845 348 0400
+1 845 340 0210 fax
www.ghlf.org

New Hampshire 165th General Court

Public Hearing for the Commission to Study Greater Transparency in Pharmaceutical Costs and Drug Rebate Programs

Speaker:
Corey Greenblatt

Manager, Policy & Advocacy

Global Healthy Living Foundation

October 10th, 2018

Disclosure: I have no disclosures to make regarding my travel here today. The Global Healthy Living Foundation accepts grants and charitable contributions from pharmaceutical companies, the government, private foundations, and individuals. We have received policy and economic briefings from pharmaceutical companies, insurance companies, Pharmacy Benefit Managers, our independent and staff consultants and advisory boards.

Good Morning Committee Members.

My name is Corey Greenblatt. I am the Manager of Policy and Advocacy for CreakyJoints and the Global Healthy Living Foundation. GHLF is a 20-year-old 501(c)(3) non-profit patient centered organization representing people who have chronic disease and their caregivers across the U.S. We work to improve the quality of life for people living with these chronic diseases, including many of New Hampshire's residents, by making sure their voices are heard and advocating for improved access to care at the community level.

Our patients are suffering from arthritis, psoriasis, osteoporosis, chronic pain, cardiovascular disease and migraine, and many of them have been living with these conditions for years. As a result, these patients are often confronted with a lifetime of interacting with the healthcare system and incur significant costs due to the treatments needed to control their disease. When patients do not maintain their treatment routines, the resulting impact is an individual with crippling symptoms that often make it impossible to work and care for their families. It is essential that treatments needed to manage chronic disease are affordable because we believe that health care is a right.

I want to thank you for allowing me to speak to the committee today about the need for greater transparency in the health care industry and the harm that Pharmacy Benefit Managers, or PBMs, do to patients every day by exacerbating the problem of high drug costs. All too often, patients are subject to higher health care spending because of the deceptive practices used by PBMs' to over-charge enrollees for their prescriptions in order to turn a profit. With the help of this Committee, it is our hope that New Hampshire can join the 28 other states, including 27 that have enacted legislation this year, that have passed reforms to increase transparency into PBMs' practices in an effort to cut health care costs and put patients first.

As you know, PBMs are middlemen paid by insurance companies to develop their drug formularies, with the goal of controlling drug utilization and cost. They have since become incredibly effective at negotiating discounts and rebates from pharmaceutical companies in exchange for inclusion of their drugs on formularies. They are not however, incredibly effective at passing those saving on to patients. In fact, as I will detail in my remarks today, they look at the patient as a profit center outside of the profit that they make on that patient's premium. They have been complicit in creating a perverse incentive structure where pharmaceutical companies need to raise the list prices of their drugs in order to offer higher rebates to entice PBMs into including them on formularies. Because the rebates are not shared with patients, the burden is then passed on to them, as they pay the coinsurance on the higher list price of the drug. Another possible consequence is that insurance companies, who contract with PBMs, can feel pressure to increase their premiums in order to account for these higher prices and ensure they do not suffer a loss of profit.

PBMs also make money by reimbursing pharmacies for dispensing a drug at a lower rate than they charge the health plan for it. The difference in what the PBM charges a health plan for a drug and what it reimburses that pharmacy for it is known as the spread price. This spread price is typically not shared with the pharmacy or the health plan. PBMs use this lack of transparency to keep this spread as a profit while increasing the financial burden on other parts of the healthcare system. In fact, CVS Caremark did exactly this in Ohio. A Bloomberg investigation found that PBMs contracted with the state, including CVS Caremark which manages the drug benefits for 4 out of the 5 state Medicaid managed-care plans, charged the state nearly a quarter of a billion dollars more than was paid out to the pharmacy. This secret nearly quarter of a billion dollars went directly to the PBMs bottom line. If Bloomberg had not exposed this, the taxpayers of Ohio would have continued to fatten the profits of PBMs. We don't know how many other states are victims in this secret scheme.

But there are other ways that PBMs secretly drive profits at the expense of taxpayers and the chronically ill. Thankfully congress was able to address one of these ploys at the federal level and legislation is currently waiting for the President's signature. This legislation deals with what is known as a "gag clause" a provision forced on pharmacists by PBMs that prohibit pharmacists from being able to tell patients if they could get their medicine at a lower price if the pharmacy did not bill insurance. We couldn't believe this practice existed – a patient shows up at the pharmacy and pays a higher price for a drug covered by insurance, than she would if she just paid cash. And, the pharmacist is not allowed to tell her that she can get the drug more cheaply. If she can get it for cash more cheaply, we want to know why she's paying an insurance company for drug coverage?

GHLF is very encouraged by the steps that both the federal and state governments are taking to address the role PBMs play in artificially inflating drug costs to disadvantage the system and benefit their bottom line.

We believe that if New Hampshire enacted legislation to introduce transparency into PBMs, in addition to addressing the issues related to spread-pricing, it will also further reduce the practice of "clawbacks." These are another scheme used by PBMs to engorge their bottom line. A "clawback" is when a pharmacist is forced to overcharge a patient for a medication and send the excess money back to the PBM. PBMs may say that they need to engage in these practices in order to make "ends meet," and they somehow say this keeps the price of drugs down. Of course, we question this logic, but more importantly we question, why they felt the need to keep these practices secret. If they

truly needed to generate extra cash to survive, there are accepted systems at the state level that are in place to accommodate them, which includes making a public case to the legislature, as well as Insurance Commissioners and Governors offices. Instead of doing this, they chose "clawbacks" "gag orders" and "spread-pricing," buried deep in confidential contracts where they hoped public watchdogs, like Bloomberg, would never find them. All of these practices need to be addressed, and steps taken to remedy this problem, and we thank the committee for doing so.

One way to remove some of the perverse incentives that exist, and lower the price of drugs for patients, would be to require that any discounts and rebates the PBMs are able to negotiate with drug companies, are passed on to the patients. GHLF has advocated for a one hundred percent pass-through rate as we believe that this would result in a significant decrease in patient cost. In order to ensure that pass-through policies are effective, GHLF strongly believes that there should be a requirement for a definitional agreement for certain terms that are frequently used by PBMs. This will stop these entities from gaming the system by reclassifying money and avoiding their pass-through obligations.

For years, PBMs have bragged that they are lowering drug prices, we don't see it and neither do the chronically ill patients we represent. Have you ever seen the price of health care go down? But you have seen PBM profits go up. Way up. In 2017, ExpressScripts, one of the largest if not the largest, had net profits of $4.5 billion. This area is ripe for intensive oversight in order bring the pharmacy benefit in line with the hospital and outpatient benefits. For example, patients right here in New Hampshire walk into their physician's office or hospital and they have a coinsurance, copayment or deductible. They pay those out-of-pocket costs based on the negotiated price, not some arbitrary retail price, leaving patients asking why this is different for prescription drugs. Because here is how it works for those prescription drugs, a PBM negotiates a price for drugs but then charges patients the retail price when calculating copays and deductibles. This allows PBMs yet another secret channel of profits, where patients are paying retail and PBMs are buying wholesale with the extra kick-back of rebates based on volume, which they also control through their formularies.

We understand that a one hundred percent pass-through of the wholesale price – after a small administrative cost, and including rebates –coming back to the patient may result in slightly higher premiums, but we feel that when the secret negotiations are made public and PBMs have to defend their profits, that any possible premium increase won't be as big as they have said it would be when we have engaged them on this topic in the past. A transparent and truly competitive market, we think, will prove this. And in the end, we believe the actual savings patients would see from the reduction in out-of-pocket costs for prescriptions would result in net lower costs for them.

Another way to hold PBMs accountable would be to require licensing. Other states, such as California, New York, South Dakota, and Georgia, have passed legislation that would require PBMs to be licensed. These laws vary in how they require PBMs to register and whom they register with, but the overall goal of the legislation is to increase transparency into PBM business practices while increasing their responsibilities to beneficiaries. GHLF encourages the committee to look more into this issue, particularly as to what type of licensing is appropriate and if PBMs should have a fiduciary responsibility to patients. We believe they do. We feel that it is critical to have policies that are uniform, in order to ensure that PBMs do not take advantage of any loopholes, and licensing fits well into this oversight suggestion

It is my hope that following everything you hear from the various patient groups and stakeholders that this committee will recommend legislation, as 28 other states have, to reign in PBMs' influence on drug prices, keep patients at the center of healthcare decision-making, and significantly reduce healthcare spending.

Our team at the Global Healthy Living Foundation is ready to support you with research, economic modeling, patient testimony, and information on other states' legislation in order to ensure New Hampshire is a state that respects its chronically ill patients and provides the environment that improves their quality of life.

Thank you for your time and consideration.

Respectfully,

Corey Greenblatt
Manager, Policy and Advocacy
Global Healthy Living Foundation

April 25, 2019

The Honorable Kevin Cavanaugh, Chair
Senate Commerce Committee
State House Room 100
Concord, NH 03301

Re: New Futures' support of HB 695

Dear Chairman Cavanaugh and Members of the Committee:

New Futures appreciates the opportunity to testify in support of HB 695, which would require non-profit patient advocacy organizations to disclose and report if they receive money or anything else of value from a prescription drug manufacturer, a Pharmacy Benefit Manager (PBM), or an insurer. New Futures is a nonpartisan, nonprofit organization that advocates, educates and collaborates to improve the health and wellness of all New Hampshire residents. In this role, we work extensively with policy makers, health care providers and families to increase access to quality, affordable health care throughout the Granite State.

In April 2018, Kaiser Health Network launched a database that exposed drug manufactures' ties to patient advocacy organizations. Kaiser found that in 2015, pharmaceutical companies gave at least $116 million to patient advocacy groups.[1] That same year, the pharmaceutical companies spent about half that amount on their own lobbying.[2] The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a report exposing the financial ties between opioid manufactures and advocacy groups, primarily advocacy groups associated with pain. The report details the ebb and flow of funding to each advocacy group in conjunction with the acquisition, sale, or release of a drug to market. The report concludes that there is at the very least a suggestion of a direct link between "corporate donations and the advancement of opioids-friendly messaging." It goes on to state that many of the advocacy groups included in the report may have "played a significant role in creating the necessary conditions for the U.S. opioids epidemic."[3]

New Hampshire is not immune to this type of influence. During the last legislative session, it came to our attention that patient advocacy organizations that lobby here in the Granite State accept industry funding. Twice last session, representatives from the Global Health Living Foundation, which accepts funding from pharmaceutical companies, came to New Hampshire from Upper Nyack, New York to testify in opposition to PBMs without consideration of reforms impacting manufacturers. This gave me pause, and it should give you pause, too.

HB 695 will ensure transparency about the financial connections between patient advocacy groups that testify and lobby in New Hampshire and pharmaceutical manufactures, PBMs, and insurers. All lobbyists in this state must wear a bright orange badge for a reason, so that the legislators know that

[1] Patient Advocacy Groups Take in Millions from Drugmakers. Is There a Payback?, Kaiser Health Network, Emily Kopp, Sydney Lupkin, and Elizabeth Lucas.
[2] Id.
[3] Fueling an Epidemic, Exposing the Financial Ties Between Opioid Manufactures and Third Party Advocacy Groups, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office

the lobbyist might be speaking on behalf of a client and not on behalf of him or herself. This bill will apply that same transparency when patient advocacy organizations testify or lobby. All New Hampshire legislators should be aware of potential motivating factors of individuals who lobby and should know if the organization is accepting funding from drug manufactures, PBMs, or insurers. These advocacy organizations are not like other businesses or industries that testify before you. They are generally well trusted organizations that indicate they are speaking on behalf of their members, but also may be advocating on behalf of the industry groups that back them. Either way, it's important that you as lawmakers know of these potential conflicts.

Requiring reporting and disclosure may be cumbersome to these non-profit patient advocacy organizations. But these is an easy out: registering as a lobbyist and wearing an orange badge or having one of the patients the organization represents testify him or herself. The amendment to HB 695 was drafted in a way to have little to no impact to patient advocacy organizations that have a current presence in Concord and have an employee who is a registered lobbyist who testifies on behalf of the organization. Local nonprofits and advocacy organizations have been notified of this bill and the amendment and have expressed no concern when asked by New Futures. For the sake of transparency and the well-being of patients across New Hampshire, we believe that it's important that lawmakers know about the financial ties of nonprofit patient advocacy groups to ensure they have the best interests of Granite Staters at heart. For these reasons, New Futures urges you to vote ought to pass on HB 695.

Please do not hesitate to contact me if you have any questions.

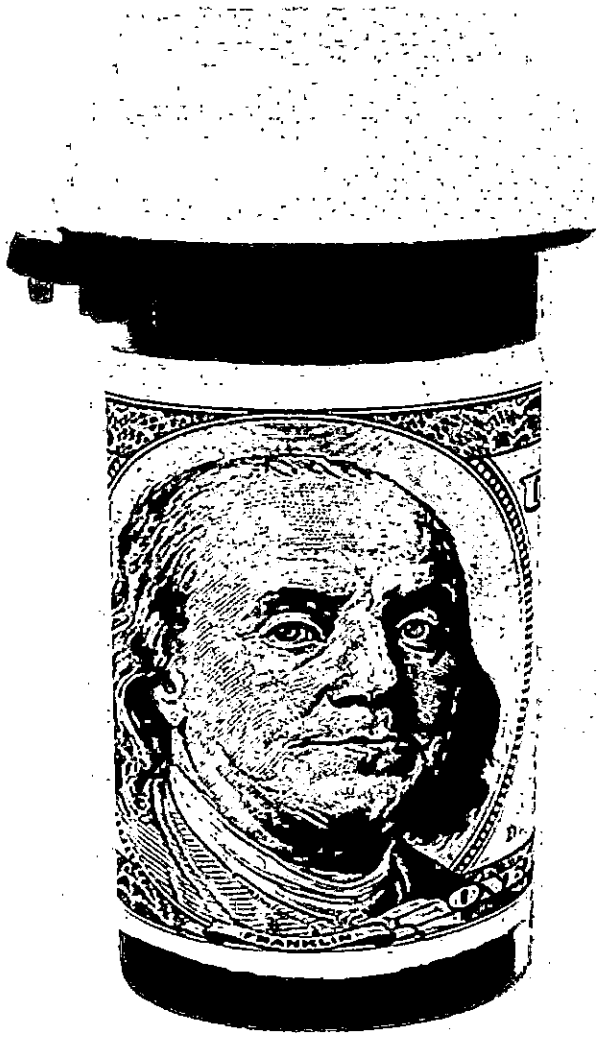
Respectfully submitted,

Holly A. Stevens, Esq.
Health Policy Coordinator

HSGAC
MINORITY STAFF REPORT

Fueling an Epidemic

REPORT TWO



Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups

U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office

HSGAC
MINORITY

Fueling an Epidemic

Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups

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EXECUTIVE SUMMARY

This report provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy. Drawing on disclosures from Purdue Pharma L.P., Janssen Pharmaceuticals, Inc., Mylan N.V., Depomed, Inc., and Insys Therapeutics, Inc., in response to requests from Ranking Member McCaskill, the sections below describe nearly $9 million in payments from these manufacturers to 14 outside groups working on chronic pain and other opioid-related issues between 2012 and 2017. In addition, physicians affiliated with these groups accepted more than $1.6 million in payments from the five manufacturers between 2013 and the present. In total, the five manufacturers have made more than $10 million in payments to these groups and affiliated individuals since January 2012.

Payments from Purdue totaling $4,153,554.33 account for roughly half of the nearly $9 million in funding to groups, and the company provided donations to the most diverse array of groups—a significant majority of the organizations profiled below. Primarily due to large payments to the National Pain Foundation and the U.S. Pain Foundation, Insys had the second-highest contribution total from 2012 to 2017, with $3,146,265 in payments. Depomed contributed the third-highest total—$1,071,116.95—during this period, and Janssen contributed $465,152.85. At the other end of the spectrum, Mylan reported only $20,250 in payments during the same period.

Initiatives from the groups in this report often echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of opioid manufacturers. These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for overprescription and misbranding. Notably, a majority of these groups also strongly criticized 2016 guidelines from the Centers for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain—the first national standards for prescription opioids and a key federal response to the ongoing epidemic.

The fact that these same manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.

INTRODUCTION AND METHODOLOGY

More than 42,000 Americans died from opioid overdoses in 2016, with deaths from natural and semisynthetic opioid painkillers like hydrocodone and oxycodone rising roughly 14% compared to 2015.[1] In Missouri, around 60% of the more than 1,300 drug overdose deaths in 2016 involved opioids,[2] and the epidemic cost the state $12.6 billion the same year, according to the Missouri Hospital Association.[3] Alarmingly, fatal overdoses from fentanyl and other synthetic opioids more than doubled in the United States between 2015 and 2016—"more than an exponential increase," according to the chief of the mortality statistics branch at the National Center for Health Statistics.[4] This surge in overdose deaths resulted in the first two-year drop in average U.S. life expectancy since the early 1960s.[5]

The necessary conditions for this crisis may have arisen, in part, due to the financial relationships between opioid manufacturers and patient advocacy groups and medical professional societies—the precise terms of which parties to these transactions rarely disclose. Patient advocacy organizations and professional societies play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public. Even small organizations—with "their large numbers and credibility with policymakers and the public"—have "extensive influence in specific disease areas."[6] Larger organizations with extensive funding and outreach capabilities "likely have a substantial effect on policies relevant to their industry sponsors."[7]

Nearly all health advocacy groups accept funding from the pharmaceutical industry. According to a recent study from PharmedOut—a Georgetown University Medical Center project focused on pharmaceutical marketing practices—only "a handful of 7,865 health advocacy groups in the U.S. are completely independent of pharmaceutical industry money."[8] As a result, "[t]he voices of independent groups that truly represent patients and consumers are drowned out by the thousands of groups that take money from industry and push industry viewpoints."[9]

Moreover, neither pharmaceutical manufacturers nor advocacy groups fully or routinely disclose the extent of their financial relationships. In a special report published in the *New England Journal of Medicine* in March 2017, for example, researchers found that out of 104 organizations, "at least 83% received financial support from drug, device, and biotechnologies companies, and at least 39% have a current or former industry executive on the governing board."[10] Full disclosure of these payments was limited, with only 57% of organizations disclosing amounts of donations; even then, this disclosure "was typically done with the use of broad ranges rather than exact figures."[11] Moreover, only 12% of the organizations researchers examined "have published policies in place for managing institutional conflicts of interest."[12]

A January 2017 article in *JAMA Internal Medicine* similarly examined relationships between patient advocacy organizations and the pharmaceutical industry. According to the study, more than 67% of 245 examined organizations received industry funding within the last fiscal year, with almost 12% receiving more than half of their funding from industry sources.[13] Only 65% of organizations that provided information on their funding from for-profit sources "provided a detailed breakdown" of this funding, and a similar percentage (63.9%) of 274 responsive organizations "reported having a written organizational conflict of interest policy."[14]

These financial relationships—and the lack of transparency surrounding them—have raised concerns regarding the information and initiatives patient advocacy organizations promote. In the *JAMA* study discussed above, 8% of respondents in the study "reported [that] pressure to conform their organizations' positions to the interests of industry funders is of concern."[15] Without additional disclosure, according to David Mitchell of Patients for Affordable Drugs, "policy makers or patients are unable to make informed judgments about the motives of the information being given, and the credibility of the information."[16]

On March 28, 2017, Ranking Member McCaskill issued wide-ranging requests for documents related to opioid sales and marketing efforts to five major opioid manufacturers: Purdue Pharma L.P., Janssen

Pharmaceuticals, Inc., Mylan N.V., Depomed, Inc., and Insys Therapeutics, Inc.[17] As the requests explain, these companies manufactured the top five opioid products as measured by worldwide 2015 sales.[18] Among other items, the requests required manufacturers to produce records of payments to certain advocacy groups and professional societies since 2012, including the date, amount, and purpose of each payment.[19] (Many of the groups at issue appeared in a previous congressional request from 2012 and feature prominently in nationwide litigation against the opioids manufacturing industry.[20]) In response, manufacturers produced information on payments flowing to many—but not all—of the groups listed in the March 2017 requests. To verify this information, Ranking Member McCaskill issued additional requests directly to 15 of the organizations at issue on October 5, 2017.[21]

The information produced to the Committee demonstrates that many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies.

PAYMENTS BY OPIOID MANUFACTURERS TO PATIENT ADVOCACY ORGANIZATIONS AND PROFESSIONAL SOCIETIES

Between January 2012 and March 2017, the five opioid manufacturers featured in this report contributed nearly $9 million to leading patient advocacy organizations and professional societies operating in the opioids policy area. For some groups, contributions from these manufacturers—alone—constituted significant portions of their total annual contributions and grants.

In addition, the five manufacturers specifically at issue in this report also made substantial payments to individual group executives, staff members, board members, and advisory board members. Physicians affiliated with these groups accepted more than $1.6 million in payments from the five manufacturers between 2013 and the present. These same individuals received payments totaling over $10 million from all opioid manufacturers during this time period.

Opioid Manufacturers Contributed Millions to Patient Advocacy Organizations and Professional Societies

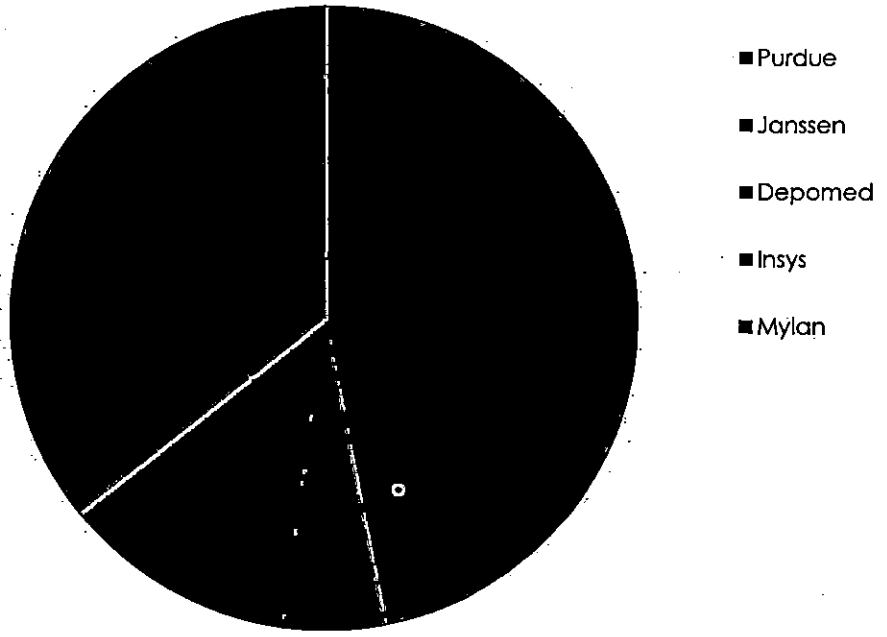
Purdue, Janssen, Mylan, Depomed, and Insys provided at least $8,856,339.13 in funding to 14 outside groups working on chronic pain and other opioid-related issues between January 2012 and March 2017. Detailed information on these payments, including payment totals for each manufacturer and group and the contributions applicable to each relationship, appears below in Figure 1.

FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue[22]	Janssen[23]	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	$1,091,024.86	$128,000.00	$43,491.95	$3,050.00[24]	$0.00	**$1,265,566.81**
American Academy of Pain Medicine	$725,584.95	$83,975.00	$332,100.00	$57,750.00	$0.00	**$1,199,409.95**
AAPM Foundation	$0.00	$0.00	$304,605.00	$0.00	$0.00	**$304,605.00**
ACS Cancer Action Network	$168,500.00[25]	$0.00	$0.00	$0.00	$0.00	**$168,500.00**
American Chronic Pain Association	$312,470.00	$50,000.00	$54,670.00	$0.00	$0.00	**$417,140.00**
American Geriatrics Society	$11,785.00[26]	$0.00	$0.00	$0.00	$0.00	**$11,785.00**
American Pain Foundation	$25,000.00	$0.00	$0.00	$0.00	$0.00	**$25,000.00**
American Pain Society	$542,259.52	$88,500.00	$288,750.00	$22,965.00	$20,250.00	**$962,724.52**
American Society of Pain Educators	$30,000.00	$0.00	$0.00	$0.00	$0.00	**$30,000.00**
American Society of Pain Management Nursing	$242,535.00	$55,177.85[27]	$25,500.00[28]	$0.00	$0.00	**$323,212.85**
The Center for Practical Bioethics	$145,095.00	$18,000.00	$0.00	$0.00	$0.00	**$163,095.00**
The National Pain Foundation[29]	$0.00	$0.00	$0.00	$562,500.00	$0.00	**$562,500.00**
U.S. Pain Foundation	$359,300.00	$41,500.00	$22,000.00	$2,500,000.00[30]	$0.00	**$2,922,800.00**
Washington Legal Foundation	$500,000.00	$0.00	$0.00	$0.00	$0.00	**$500,000.00**
	$4,153,554.33	**$465,152.85**	**$1,071,116.95**	**$3,146,265.00**	**$20,250.00**	**$8,856,339.13**

As shown in Figure 2, payments from Purdue account for roughly half of this funding, and the company provided donations to the most diverse array of groups—a significant majority of the organizations profiled below. Primarily due to large payments to the National Pain Foundation and the U.S. Pain Foundation, Insys had the second-highest contribution total from 2012 to 2017. At the other end of the spectrum, Mylan reported only $20,250 in payments during the same period; in correspondence with the Committee, the company has claimed a "very limited role in the opioid-containing products marketplace."[31]

FIGURE 2: Percentages of Total Payments by Manufacturer, 2012-2017



As shown in Figure 3 below, trends based on yearly payment totals varied between manufacturers from 2012 to 2017. Payments from Purdue, for example, fell dramatically in 2016 after remaining in the $800,000–$1,000,000 range between 2012 and 2015. Conversely, payments from Insys to advocacy groups rose significantly between 2012—when the company received U.S. Food and Drug Administration approval for its fentanyl drug Subsys—and 2017. As Ranking Member McCaskill noted in a recent report entitled, "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization," Insys revenues tripled and profits rose 45% between 2013 and 2015, and the value of company stock increased 296% between 2013 and 2016.[32]

Payments from Janssen to the groups listed above dropped sharply to $0 in 2015 from $126,000 in 2014 (and $99,250 and $239,902.85 in 2013 and 2012, respectively) and remained at $0 for 2016 and 2017. In April 2015, Janssen sold U.S. licensing rights for its major Nucynta opioid product line to Depomed for $1.05 billion.[33] For its part, Depomed more than tripled payments to the advocacy groups featured in this report in 2015 relative to 2014, and the payments total for 2016—$318,257.47—remained steady compared to the 2015 total.

Mylan made a single $15,000 payment to the American Pain Society in March 2015—its first payment to the groups in this report—before making significantly smaller payments to the same group in 2016 and 2017. Also in March 2015, Mylan announced the launch of intermediate dosage strengths for its fentanyl transdermal system.[34] In connection with this launch, according

to the company, Mylan "engaged in marketing efforts to educate doctors about the availability of the intermediate strengths."[35]

FIGURE 3: Manufacturer Yearly Payment Totals, 2012-2017

	2012	2013	2014	2015	2016	2017	Total
Purdue	$824,227.86	$973,328.00	$812,451.95	$935,344.00	$558,067.52	$50,135.00	**$4,153,554.33**
Janssen	$239,902.85[36]	$99,250.00	$126,000.00				**$465,152.85**
Depomed	$73,080.00	$135,300.00	$113,600.00	$350,000.00	$318,257.47	$80,879.48	**$1,071,116.95**
Insys	$14,040.00	$68,000.00	$34,200.00	$530,025.00		$2,500,000.00	**$3,146,265.00**
Mylan				$15,000.00	$2,500.00	$2,750.00	**$20,250.00**
Total	**$1,151,250.71**	**$1,275,878.00**	**$1,086,251.95**	**$1,830,369.00**	**$878,824.99**	**$2,633,764.48**	**$8,856,339.13**

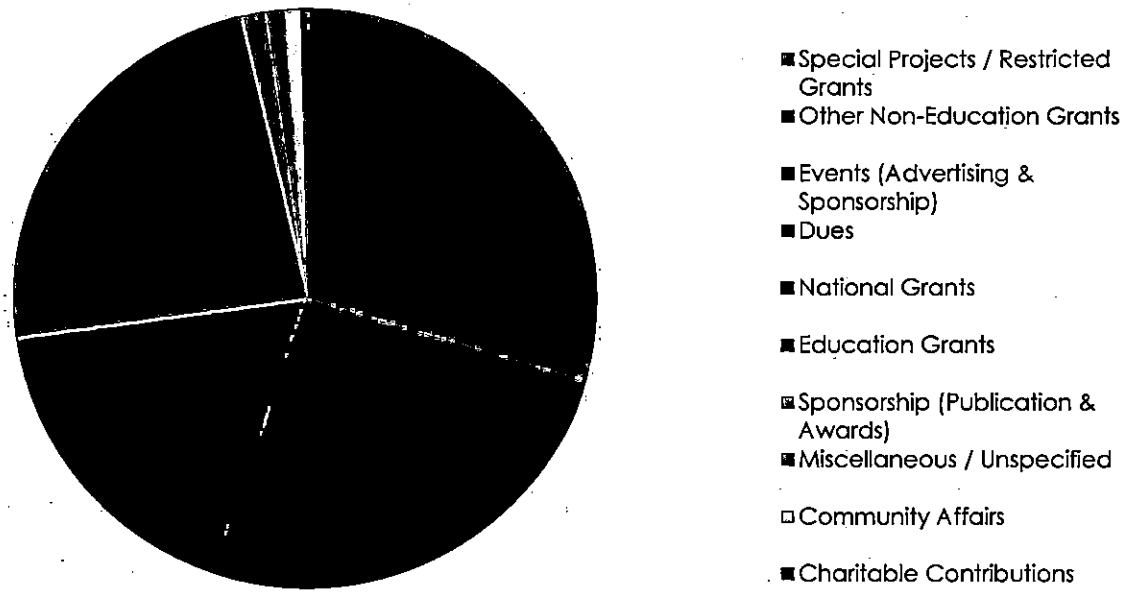
Purpose of Manufacturer Contributions

Based on the descriptions manufacturers submitted in connection with each specific reported payment, the minority staff designated broad payment categories. Payments directed to special projects and restricted grants comprise the largest category of contributions, totaling $2,617,899 and constituting roughly 30% of total contributions between 2012 and 2017. For these types of restricted grants, donors specify a use for their contribution beyond the broad parameters resulting from the nature of the non-profit entity at issue, the environment in which it operates, or the purposes specified in its organizing documents.[37]

Following closely behind the total for special projects and restricted grants is the amount manufacturers contributed in the form of non-education grants, which totaled $2,269,765 and constituted roughly 26% of all contributions. According to a publicly available overview from Purdue, non-education grants provide support for healthcare-related organizations or initiatives focused on patient and public education, scientific research, and other programs.[38]

Payments for advertising and sponsorship related to group events and dues occupy the next tier of categories, with $1,564,215.86 and $1,253,988 in payments and roughly 18% and 14% of the total contributions, respectively. Finally, national grants and education grants occupy the third tier of categories, with similar payments totals of $413,154 and $413,128, respectively, and percentages of roughly 5%. According to Purdue, an education grant "[p]rovides for healthcare professional continuing education (CE) activities designed to foster improved understanding of scientific, clinical, and other healthcare issues that help to improve patient care."[39] *See* Figure 4.

FIGURE 4: Payment Categories as Percentages of Total Payments, 2012-2017



Payments by Organization

The U.S. Pain Foundation received the largest amount of payments during the 2012–2017 period—almost $3 million—which includes $2,500,000 in payments from Insys. The Academy of Integrative Pain Management, formerly the American Academy of Pain Management, received $1,265,566.81 in donations—the second-highest total—followed closely by the American Academy of Pain Medicine with $1,199,409.95 in payments. (The American Academy of Pain Medicine Foundation also received $304,605 in payments from Depomed during the same period.)

FIGURE 5: Group Rankings by Manufacturer Payments, 2012-2017

U.S. Pain Foundation	$2,922,800.00
Academy of Integrative Pain Management	$1,265,566.81
American Academy of Pain Medicine	$1,199,409.95
American Pain Society	$962,724.52
The National Pain Foundation	$562,500.00
Washington Legal Foundation	$500,000.00
American Chronic Pain Association	$417,140.00
American Society of Pain Management Nursing	$323,212.85
AAPM Foundation	$304,605.00
ACS Cancer Action Network	$168,500.00
The Center for Practical Bioethics	$163,095.00
American Society of Pain Educators	$30,000.00
American Pain Foundation	$25,000.00
American Geriatrics Society	$11,785.00

Contributions by Selected Manufacturers as a Percentage of Overall Contributions

Based on comparisons between manufacturer contributions to groups and group reporting on contributions and grants in IRS filings between 2013 and 2015, the percentage of total contributions attributable to the five manufacturers discussed in this report vary significantly. Insys contributions to the National Pain Foundation in 2015, for example, actually *exceeded* total contributions the group reported on its Form 990 by $154,800. In a less extreme example, the American Society of Pain Management Nursing received approximately 76% of its funding from Depomed, Janssen, and Purdue in 2013, although this percentage declined for 2014 and 2015. For other groups, the percentages of contributions attributable to the five manufacturers remained consistent during 2013–2015. The Academy of Integrative Pain Management and the American Academy of Pain Medicine, for example, received between 13% and 20% of their contributions from at least one of the five manufacturers during this three-year period. At the other end of the spectrum, the American Cancer Society Cancer Action Network received less than 1% of its contributions from Purdue between 2013 and 2015.

FIGURE 6: Comparison of Contributions from Selected Manufacturers and Total Contributions and Grants, 2013-2015[40]

2013 INFORMATION	Contributions from Selected Manufacturers	Contributions and Grants	% of Selected Contributions
Academy of Integrative Pain Management	$319,929	$1,624,115	19.70%
American Academy of Pain Medicine	$201,944	$1,071,992	18.84%
AAPM Foundation	$50,000	$381,738	13.10%
ACS Cancer Action Network	$28,500	$35,409,632	0.08%
American Chronic Pain Association	$100,970	$564,004	17.90%
American Geriatrics Society	$0	$2,709,179	0.00%
American Pain Foundation	Unavailable	Unavailable	Unavailable
American Pain Society	$161,585	$1,271,537	12.71%
American Society of Pain Educators	$5,000	Unavailable	Unavailable
American Society of Pain Management Nursing	$97,950	$129,167	75.83%
The Center for Practical Bioethics	$101,000	$1,276,473	7.91%
The National Pain Foundation	$50,000	$50,100	99.80%
U.S. Pain Foundation	$84,000	$467,040	17.99%
Washington Legal Foundation	$75,000	$4,113,151	1.82%

2014 INFORMATION	Contributions from Selected Manufacturers	Contributions and Grants	% of Selected Contributions
Academy of Integrative Pain Management	$269,980	$1,929,818	13.99%
American Academy of Pain Medicine	$255,087	$1,346,712	18.94%
AAPM Foundation	$0	$533,776	0.00%
ACS Cancer Action Network	$40,000	$35,288,961	0.11%
American Chronic Pain Association	$85,000	$558,510	15.22%
American Geriatrics Society	$0	$3,197,135	0.00%
American Pain Foundation	Unavailable	Unavailable	Unavailable
American Pain Society	$161,190	$949,867	16.97%
American Society of Pain Educators	$5,000	Unavailable	Unavailable
American Society of Pain Management Nursing	$68,100	$229,732	29.64%
The Center for Practical Bioethics	$30,095	$1,232,768	2.44%
The National Pain Foundation	$0	$3,100	0.00%
U.S. Pain Foundation	$121,800	$791,657	15.39%
Washington Legal Foundation	$50,000	$4,213,431	1.19%

2015 INFORMATION	Contributions from Selected Manufacturers	Contributions and Grants	% of Selected Contributions
Academy of Integrative Pain Management	$275,098	$1,465,067	18.78%
American Academy of Pain Medicine	$239,941	$1,482,707	16.18%
AAPM Foundation	$100,000	$451,835	22.13%
ACS Cancer Action Network	$100,000	$37,925,236	0.26%
American Chronic Pain Association	$30,000	$382,671	7.84%
American Geriatrics Society	$0	$4,041,760	0.00%
American Pain Foundation	Unavailable	Unavailable	Unavailable
American Pain Society	$266,020	$660,894	40.25%
American Society of Pain Educators	$10,000	Unavailable	Unavailable
American Society of Pain Management Nursing	$63,810	$171,256	37.26%
The Center for Practical Bioethics	$3,500	$857,788	0.41%
The National Pain Foundation	$512,500	$357,700	143.28%
U.S. Pain Foundation	$129,500	Unavailable	Unavailable
Washington Legal Foundation	$100,000	$4,583,620	2.18%

Manufacturers Also Provided Payments to Group-Affiliated Individuals

The five manufacturers specifically at issue in this report also made substantial payments to individual group executives, staff members, board members, and advisory board members. Figure 7 below lists totals for these payments between August 2013 and the present, as well as the sum of these payments and the amounts manufacturers contributed to the groups directly. In terms of total contributions, the U.S. Pain Foundation ranks first among the groups despite minimal payments to affiliated individuals, and the National Pain Foundation assumes the second-place ranking due to payments to individual physicians of over $800,000. Notably, the nearly $300,000 in payments to individuals affiliated with the American Society of Pain Educators significantly outweighs the relatively minor amount the group received from Purdue directly. In contrast, manufacturer payments to groups like the Academy of Integrative Pain Management, the American Academy of Pain Medicine, the American Pain Society, and the American Chronic Pain Association far exceeded payments to physicians affiliated with these organizations.

FIGURE 7: Purdue, Janssen, Insys, Depomed, and Mylan Payments to Groups and Group-Affiliated Individuals, 2012-Present[41]

	Payments to Group	Payments to Group-Affiliated Individuals	Total
U.S. Pain Foundation	$2,922,800.00	$126.20	$2,922,926.20
The National Pain Foundation	$562,500.00	$839,848.84	$1,402,348.84
Academy of Integrative Pain Management	$1,265,566.81	$30,223.42	$1,295,790.23
American Academy of Pain Medicine	$1,199,409.95	$16,462.42	$1,215,872.37
American Pain Society	$962,724.52	$95,474.56	$1,058,199.08
AAPM Foundation	$304,605.00	$314,175.58	$618,780.58
Washington Legal Foundation	$500,000.00	N/A	$500,000.00
American Chronic Pain Association	$417,140.00	$31,265.87	$448,405.87
American Society of Pain Management Nursing	$323,212.85	N/A	$323,212.85
American Society of Pain Educators	$30,000.00	$280,765.92	$310,765.92
The Center for Practical Bioethics	$163,095.00	$7,116.86	$170,211.86
ACS Cancer Action Network	$168,500.00	N/A	$168,500.00
American Pain Foundation	$25,000.00	N/A	$25,000.00
American Geriatrics Society	$11,785.00	$194.13	$11,979.13
Total	$8,856,339.13	$1,615,653.80	$10,471,992.93

As shown in Figure 8 below, individuals affiliated with these groups have significant financial ties not only with the five companies at issue in this report, but also with all other opioid manufacturers. According to CMS Open Payments data, for example, the current President of the American Academy of Pain Medicine, Dr. Steven Stanos, received over $90,000 in payments from opioid manufacturers between 2013 and 2016.[42] Additional searches of Open Payments data also show that multiple American Academy of Pain Medicine Corporate Relations Council members made payments directly to at least one American Academy of Pain Medicine board member between 2013 and 2016.[43] In total, between 2013 and 2016, American Academy of Pain Medicine board members received more than $200,000 in payments from opioid manufacturers.[44] In addition, Dr. Charles Argoff, current president of the American Academy of Pain Medicine Foundation, received over $600,000 in payments from opioid manufacturers between 2013 and 2016.[45]

Similarly, Open Payments data indicates that between 2013 and 2016, ten members of the American Chronic Pain Association Advisory Board received more than $140,000 from opioid manufacturers, including Endo, Purdue, Mallinckrodt, Pfizer, Teva, and Depomed.[46] In another prominent example, National Pain Foundation chairman and founder Dr. Daniel Bennett[47] received over $170,000 from Insys Therapeutics, manufacturer of the powerful fentanyl drug Subsys, between 2013 and 2016.[48] Members of the National Pain Foundation Board of Directors, which include Dr. Bennett, received more than $950,000 from opioid manufacturers, including more than $250,000 from Insys Therapeutics, during the same period.[49] In addition, at least half of the members of the National Pain Foundation Clinical and Scientific Advisory Council[50] have received general payments—totaling more than $7,900,000—from opioid manufacturers between 2013 and 2016.[51] Manufacturer payments to all individuals affiliated with the National Pain Foundation total more than $8,000,000 since 2013—by far the largest total for the groups profiled in this report.

FIGURE 8: Payments from All Opioid Manufacturers to Group-Affiliated Individuals, 2013-Present[52]

	Manufacturer Payments to Affiliated Individuals
The National Pain Foundation	$8,307,243.47
AAPM Foundation	$798,051.22
American Society of Pain Educators	$749,564.78
American Academy of Pain Medicine	$204,631.53
American Pain Society	$187,699.34
ACS Cancer Action Network	$154,578.09
American Chronic Pain Association	$145,861.30
Academy of Integrative Pain Management	$82,596.98
The Center for Practical Bioethics	$16,945.88
American Geriatrics Society	$7,548.35
U.S. Pain Foundation	$138.91
American Pain Foundation	N/A
American Society of Pain Management Nursing	N/A
Washington Legal Foundation	N/A
Total	$10,654,859.85

GROUPS FAIL TO ADEQUATELY DISCLOSE MANUFACTURER CONTRIBUTIONS

Due to their classification under the U.S. tax code, the groups profiled in this report have no obligation to disclose their donors publicly; as a result, each group maintains different levels of transparency regarding its financial connections to the pharmaceutical industry. Specifically, as either 501(c)(3), 501(c)(4), or 501(c)(6) public charities, the groups discussed below have no obligation to publicly disclose the list of donors they provide to the Internal Revenue Service with their annual Form 990 filing.[53] Instead, these organizations have the ability to selectively disclose donors, donations, and other support—or no information at all. Importantly, no organization profiled in this report provides an online

list linking donors, their specific donations, and the projects or events benefiting from each donation for each of the years between 2012 and 2017.

The minority staff reviewed disclosure policies available online for each of the groups listed in the March 28, 2017, requests. Several groups—the American Society of Pain Educators, the National Pain Foundation, and the Academy of Integrative Pain Management—provided no information concerning their policies for disclosing donors and donations. Other groups stated explicitly that they do not disclose any information concerning donor relationships. The Washington Legal Foundation, for example, states in its 2016 Annual Report: "All contributions to WLF are strictly confidential. WLF does not disclose, publish, or trade the names of its donors."[54]

Other groups simply list donors, "corporate members," or "corporate partners" without indicating specific donation amounts or even the range of donations for each category of contributor. The website for the American Geriatrics Society, for example, states that "AGS corporate arrangements will be disclosed regularly as part of the organization's financial reporting to the Board of Directors," but for the public, the organization simply lists three "corporate partners" without details of the amounts donated or any related arrangements.[55] The U.S. Pain Foundation similarly lists "Platinum," "Gold," and "Basic" corporate members—including opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, and Mallinckrodt—without indicating the level of donations required for each classification.[56] The American Chronic Pain Association lists many of the same corporations as "Partners & Contributors" at the "Champion," "Ambassador," "Educator," and "Builder" levels without specifying the applicable ranges of contributions.[57] Both the American Cancer Society Cancer Action Network and the Center for Practical Bioethics also list corporate or individual donors without including donation amounts.[58] Finally, the American Academy of Pain Medicine website lists donors between January 1, 2017, and October 31, 2017, and describes the list as including "matching gifts from companies," but no companies appear on the list.[59]

A handful of groups disclose both their donors and list the ranges of donations applicable to each category of contributor. The American Pain Society, for example, specifies that "Corporate Council" contributors donated at least $25,000, "Executive" donors provided at least $15,000, and "Associate" contributors donated at least $7,500.[60] Opioid manufacturers, including Pfizer, Teva, Depomed, Purdue, and Mallinckrodt, appear at all three donor levels.[61] The website of the American Society of Pain Management Nursing similarly specifies that all listed corporations contributed more than $5,000.[62]

GROUP ACTIVITIES CONTRIBUTING TO OPIOID OVERPRESCRIPTION AND OVERUSE

Many of the groups discussed in this report have amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain. Several groups have also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding.

Minimizing the Risk of Addiction

Many of the groups have issued guidelines to physicians and other health practitioners that minimize the risk of opioid addiction or emphasize the long-term use of opioids to treat chronic pain. According to a complaint from the City of Chicago, for example, the American Academy of Pain Medicine and the American Pain Society issued a consensus statement in 1997 "which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low."[63] Dr. J. David Haddox, then a paid speaker for Purdue and now the Vice President

of Health Policy at the company, co-authored the statement.[64] The American Academy of Pain Medicine and the American Pain Society also allegedly issued guidelines in 2009 that "promote[d] opioids as 'safe and effective' for treating chronic pain, despite acknowledging limited evidence, and conclude[d] that the risk of addiction is manageable for patients regardless of past abuse histories."[65]

Similarly, the American Geriatrics Society released guidelines in 2009 for the management of persistent pain in older patients.[66] While acetaminophen remained the preferred option for the treatment of chronic pain patients, the American Geriatrics Society recommended opioids—as opposed to aspirin or ibuprofen—for those unable to gain relief from Tylenol and similar products.[67] According to the City of Chicago complaint, the guidelines included these recommendations: "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[68] The American Geriatrics Society also partnered with the American Academy of Pain Medicine and Janssen to create the 2009 patient education guide entitled, "Finding Relief: Pain Management for Older Adults," which stated that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain."[69]

Lobbying to Defeat Measures to Restrict Overprescription

Advocacy groups have engaged in extensive lobbying efforts to either defeat legislation restricting opioid prescribing or promote laws encouraging opioid treatment for pain. In 2014, for example, the Academy of Integrative Pain Management and the American Cancer Society Cancer Action Network led an effort to protect a 2001 Tennessee law that made it difficult to discipline doctors for overprescribing opioids and prohibited them from refusing to prescribe opioids unless they referred the patient to another "opioid-friendly" doctor.[70]

According to a joint investigation by the *Associated Press* and the Center for Public Integrity, the Academy of Integrative Pain Management and the American Cancer Society Cancer Action Network have contacted legislators and other officials about opioid measures in at least 18 states.[71] More broadly, the American Cancer Society Cancer Action Network reportedly maintains "about 200 lobbyists around the country opposed to opioid restrictions even in some cases where they specifically exempted cancer patients."[72] In an example of the general legislative reach of these groups, the U.S. Pain Foundation has "participated in more than 30 state and national advocacy coalitions, alliances, and task forces ... [and is] actively engaged in 70 legislative bills in 20 states with the support of 250 advocates engaged in outreach to policymakers."[73]

Efforts to Criticize or Undermine CDC Guidelines

On March 15, 2016, the CDC issued guidelines providing prescribing recommendations for "primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care."[74] In introducing these guidelines—"the first national standards for prescription painkillers,"[75] as the *New York Times* reported—the CDC noted that opioid prescriptions per capita had increased 7.3% from 2007 to 2012, "more than 165,000 persons died from overdose related to opioid pain medication in the United States" from 1999 to 2014, and "the death rate associated with opioid pain medication" had increased "markedly" in the previous decade.[76] The guidelines explained that non-opioid therapies are preferred for chronic pain and recommended that physicians prescribe immediate-release opioids at the lowest effective dosage and evaluate the benefits and harms of continued opioid use within one to four weeks of starting opioid therapy.[77] The guidelines also noted that for opioid therapy for acute pain, "[t]hree days or less will often be sufficient; more than seven days will rarely be needed."[78]

These guidelines represented an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain in the face of an unprecedented

public health crisis. A majority of the groups described in this report, however, strongly criticized the content of the guidelines, the process by which the CDC drafted them, or the experts who assisted during their development. In fact, the *New York Times* reported that the release of the CDC guidelines ended "months of arguments with pain doctors and drug industry groups, which had bitterly opposed the recommendations on the grounds that they would create unfair hurdles for patients."[79] As Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing, has explained, "[t]he opioid lobby has very actively blocked interventions that might result in more cautious prescribing or reduced prescribing. They've very clearly defended their financial stake in the status quo."[80]

In 2016, for example, the immediate past president of the American Academy of Pain Medicine, Daniel Carr, criticized the prescribing guidelines, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."[81] Similarly, several advocacy groups criticized draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliations, and conflicts of interest of the individuals who participated in the construction of these guidelines."[82] Dr. Richard Payne, a physician affiliated with the Center for Practical Bioethics, made a similar argument, criticizing the CDC guidelines as the product of "conflicts of interests in terms of biases [and] intellectual conflicts"—while himself maintaining "financial links to numerous drug companies."[83] The Washington Legal Foundation also strongly criticized the guidelines on procedural grounds, claiming CDC had developed its guidelines in an "overly secretive manner" and in violation of the Federal Advisory Committee Act, which called "into question the viability of the entire enterprise."[84] The Washington Legal Foundation claimed, moreover, that "[s]tate governments and the medical community are unlikely to accept any guidelines tainted by charges that they were prepared in secret without meaningful stakeholder input."[85] When the CDC published its final opioid prescribing guidelines, Richard A. Samp, Washington Legal Foundation general counsel, reportedly believed the guidelines "were inherently biased, crafted by people who already had strong views about what opioid policy should look like."[86]

The fact that these groups registered their opposition while receiving funding from the opioids industry raises the appearance—at the very least—of a direct link between corporate donations and the advancement of opioids-friendly messaging. Relatedly, in a March 2017 article published in *JAMA Internal Medicine*, researchers from Johns Hopkins University and Brandeis University examined industry payments to over 150 organizations that had submitted comments on the draft CDC guidelines.[87] After coding guideline comments by supportiveness and reviewing financial disclosures, including annual reports, tax returns, and self-reported information, researchers found "opposition to the guidelines was *significantly* more common among organizations with funding from opioid manufacturers than those without funding from the life sciences industry."[88] Accordingly, a "major concern is that opposition to regulatory, payment, or clinical policies to reduce opioid use may originate from groups that stand to lose financially if opioids sales decline."[89] In an extended version of their findings, the researchers are more explicit: "[O]pposition to more conservative opioid use may, at least in part, be financially motivated."[90]

Efforts to Limit Accountability

Certain advocacy groups and professional societies have also organized legal efforts to challenge government actions to punish physicians engaging in opioid overprescription and executives responsible for fraudulent marketing of opioid products. In 2005, for example, the National Pain Foundation submitted to the U.S. Court of Appeals for the Fourth Circuit an amicus brief in support of Dr. William Hurwitz,[91] a doctor convicted "of 16 counts of drug trafficking, [for] prescrib[ing] massive quantities of medicine to patients in chronic pain."[92] Prosecutors asserted that Dr. Hurwitz "prescribed excessive amounts of Oxycodone and other dangerous narcotics—in one instance more than 1,600 pills a day—to addicts and others, some of whom then sold the medication on a lucrative black market."[93] In defense of Dr. Hurwitz, the National Pain Foundation suggested that

"[t]he conviction [in the trial court] broke ground by holding that a doctor acting in the good faith belief that he was serving the best medical interest of his patient could be found to be a drug dealer."[94] Similarly, the Washington Legal Foundation filed an amicus brief challenging the exclusion of three former Purdue executives from participation in federal healthcare programs for 12 years for their admitted failure to prevent the fraudulent marketing of OxyContin.[95] In a brief filed with the U.S. Court of Appeals for the District of Columbia Circuit, the Washington Legal Foundation argued—unsuccessfully—that the exclusion raised serious constitutional due process concerns.[96]

FULL EXTENT OF INDUSTRY INFLUENCE ON GROUPS IS UNKNOWN

This report does not capture the full extent of the financial ties between opioid manufacturers and patient advocacy groups and professional societies. According to the *Associated Press* and the Center for Public Integrity, for example, opioid manufacturers "spent more than $880 million nationwide on lobbying and campaign contributions from 2006 through 2015—more than 200 times what those advocating for stricter [opioid] policies spent."[97]

Moreover, payments between 2012 and 2017 may not fully reflect historical funding activities by manufacturers, given that several of the most prominent advocates in this space historically—the American Pain Foundation, for example—no longer operate. The fact that opioid prescribing, as measured in morphine milligram equivalents (MME) per capita, peaked between 2010 and 2012 before declining from 2012 to 2015 may also suggest more robust financing of advocacy groups in the pre-2012 period.[98]

In addition, the data contained in this report may not even capture the full extent of payments between the covered manufacturers and patient advocacy groups and professional societies. This report is based on information provided voluntarily to the Committee at the request of the Ranking Member—information which certain manufacturers changed following further inquiries from the minority staff. A timeline of interactions between the Committee, manufacturers, and advocacy groups appears below as Figure 9.

As mentioned above, Ranking Member McCaskill sent requests for payments information to Purdue, Janssen, Insys, Depomed, and Mylan on March 28, 2017.[99] On April 25, 2017, Depomed provided an initial response, closely followed a response from Purdue on May 11, 2017, and a response from Janssen on June 12, 2017.[100] Following extensive discussions with minority staff, Mylan provided payments information on October 5, 2017.[101]

On October 5, 2017, Ranking Member McCaskill sent requests for payment information directly to 15 advocacy groups and professional societies.[102] Following these letters, several manufacturers volunteered additional or revised data. After further due diligence, for example, Janssen reported an additional $7,500 payment to the American Academy of Pain Medicine and an additional $128,000 in cumulative payments to the Academy of Integrative Pain Management.[103] Purdue also provided updated information showing an additional $70,552 in payments to the American Academy of Pain Medicine, $415,574 in payments to the American Pain Society, and $17,755 in payments to the American Society of Pain Management Nursing.[104] For the first time, Purdue also reported $1,091,025 in payments to the Academy of Integrative Pain Management—the company had not searched for payments to the American Academy of Pain Management, the previous name of the organization—and $168,500 in payments to the American Cancer Society Cancer Action Network .[105] Purdue additionally reported over $91,000 in payments associated with incomplete entity names in company records.[106]

A comparison of payments information from the five manufacturers and the information advocacy groups provided directly to the Committee revealed several discrepancies. Most significantly, Insys Therapeutics initially failed to report $2,500,000 in responsive payments to the U.S. Pain Foundation for the "Gain Against Pain" patient assistance program.[107] The company also did not report $12,500 in

FIGURE 9

TIMELINE of FINANCIAL DISCLOSURES

from opioid manufacturers to the United States Senate

On March 28, 2017, minority staff on the homeland security committee requested documents from 5 opioid manufacturers showing financial contributions to third-party advocacy groups.

$4.4 million was initially reported.

Purdue provides initial response

Depomed provides initial response

REQUESTS TO OPIOID MANUFACTURERS

Janssen provides initial response

MARCH 2017

APRIL

MAY

JUNE

JULY

AUGUST

SEPTEMBER

On October 5, the Committee requested corresponding documentation from third-party advocates.

4 of the 5 opioid manufacturers later reported an additional $4.7 million in financial contributions.

NEW INFO: Depomed

NEW INFO: Purdue

NEW INFO: Insys

NEW INFO: Janssen

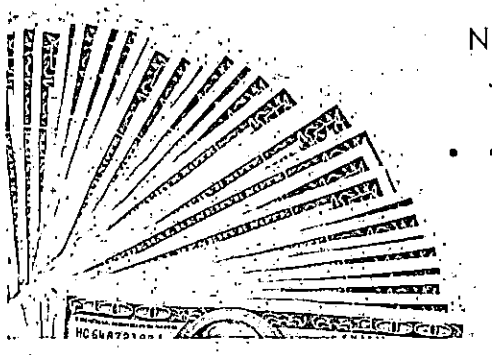
NEW INFO: Purdue

NEW INFO: Janssen

Insys provides initial response

REQUESTS TO ADVOCACY GROUPS

Mylan provides initial response



JANUARY 2018

DECEMBER

NOVEMBER

OCTOBER

HSGAC MINORITY

payments the Academy of Integrative Pain Management reported receiving in 2014 and 2015 and could not confirm or deny these payments after further due diligence.[108] (Insys did, however, report an additional $3,050 in payments to the Academy of Integrative Pain Management during 2012.[109]) Purdue also failed to report $40,000 in corporate roundtable dues to the American Geriatrics Society Health in Aging Foundation; according to the American Geriatrics Society, this foundation received all payments Purdue directed to the organization between 2012 and 2017.[110]

In addition, Depomed later reported five additional responsive payments—totaling $17,600 to the American Chronic Pain Association and $28,174.95 to the Academy of Integrative Pain Management—after receiving further correspondence from minority staff.[111] According to Depomed, these payments "were for advertising or promotional purposes," and the company initially considered them outside the scope of the March 28, 2017, requests.[112] Finally, in response to information from minority staff, Janssen representatives also reported the company had made an additional $68,500 in payments to the American Pain Society and an additional $76,475 in payments to the American Academy of Pain Medicine via a third party during the 2012-2017 time period.[113]

CONCLUSION

The privacy the advocacy groups discussed above have guarded for their donors has come at a high price for the public debate on chronic pain and opioid use in the United States. As a 2011 study in the *American Journal of Public Health* noted, a tension exists between the status of advocacy organizations as "among the most influential and trusted stakeholders in U.S. health policy," and the reality that their "positions closely correspond to the marketing aims of pharmaceutical and device companies."[114] The findings in this report indicate that this tension exists in the area of opioids policy—that organizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use. By aligning medical culture with industry goals in this way, many of the groups described above may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.

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[4] *CDC Releases Grim New Opioid Overdose Figures: "We're Talking About More Than an Exponential Increase,"* Washington Post (Dec. 21, 2017).

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[7] *Id.*

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[12] *Id.*
[13] Susannah L. Rose et al., *Patient Advocacy Organizations, Industry Funding, and Conflicts of Interest*, JAMA Internal Medicine (Mar. 2017).
[14] *Id.*
[15] *Id.*
[16] *More Than 80 Percent of Patient Groups Accept Drug Industry Funds, Study Shows*, New York Times (Mar. 1, 2017) (www.nytimes.com/2017/03/01/health/patient-groups-drug-industry-money.html).
[17] *See, e.g.*, Letter from Sen. Claire McCaskill to Santosh Vetticaden, Interim Chief Executive Officer of Insys Therapeutics, Inc. (Mar. 28, 2017).
[18] *Id.*
[19] *Id.*
[20] *See, e.g.*, Letter from Sen. Baucus and Sen. Grassley to Catherine Underwood, Executive Director, American Pain Society (May 8, 2012); Third Amended Complaint (Oct. 25, 2016), *City of Chicago v. Purdue Pharma L.P., et al.*, N.D. Ill. (No. 1:14 CV 04361).
[21] *See, e.g.*, Letter from Sen. Claire McCaskill to Steven P. Stanos, President, American Academy of Pain Medicine (Oct. 5, 2017).
[22] Purdue also reported $91,449 in payments to entities with incomplete names like "American Academy of Pain" and "American Society of." Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017)
[23] Payments from Janssen include payments from Johnson & Johnson Health Care Systems, Inc. Letter from Daniel F. Donovan, Counsel for Janssen, to Sen. Claire McCaskill (Nov. 10, 2017).
[24] Insys was unable to account for $12,500 in payments to the Academy of Integrative Pain Management for expenses related to the organization's 2014 and 2015 annual meetings. Brian D. Smith, Counsel for Insys Therapeutics, Briefing with Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Nov. 28, 2017)
[25] Payments from Purdue to the American Cancer Society Cancer Action Network include payments to the American Cancer Society that could potentially have applied to the Cancer Action Network. Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017)
[26] The American Geriatrics Society reported that Purdue also provided $40,000 in "corporate roundtable dues" to its AGS Health in Aging Foundation, a 501(c)(3) organization affiliated with the group, between 2012 and 2015. Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).
[27] Payments from Janssen to the American Society of Pain Management Nursing include two payments to Rockpointe Corporation for an educational grant with signatories including the American Society of Pain Management Nursing. Production from Johnson & Johnson to the Senate Homeland Security and Governmental Affairs Committee (Nov. 10, 2017)
[28] This total includes $4,500 in reported payments from Depomed to the "American Society of Pain Management Nurses." Production from Depomed to the Senate Homeland Security and Governmental Affairs Committee (Apr. 25, 2017)
[29] The National Pain Foundation changed its name to the Global Pain Initiative in mid-2017. Email from Dr. Daniel Bennett, Chairman, Board of Directors, Global Pain Initiative, to Committee on Homeland Security and Governmental Affairs Minority Staff (Jan. 10, 2018). According to Dr. Bennett, the Global Pain Initiative board decided in the fourth quarter of 2016 not to accept contributions from pharmaceutical or device manufacturers. This decision "permits an academic 'hands off' approach, which is crucial to [the Global Pain Initiative's] public credibility and mission." *Id.*
[30] An additional payment from Insys to the U.S. Pain Foundation of $250,000—on April 7, 2017—fell outside the scope of the March 28, 2017, requests and is not included in this total.
[31] Letter from Jonathan C. Su, Counsel for Mylan, to Sen. Claire McCaskill (Sept. 15, 2017).
[32] *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, Wall Street Journal (Nov. 22, 2016) (www.wsj.com/articles/fentanyl-billionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968); *An Opioid Spray Showered Billionaire John Kapoor in Riches. Now He's Feeling the Pain*, Forbes (Oct. 4, 2016) (www.forbes.com/sites/matthewherper/2016/10/04/death-kickbacks-and-a-billionaire-the-story-of-a-dangerous-opioid/).
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[34] Mylan N.V.: *Mylan Launches First and Only Available Intermediate Dosage Strengths of Fentanyl Transdermal System 37.5, 62.5 and 87.5 mcg/hr* (March 11, 2015).
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[37] Financial Accounting Standards Board, *Not-for-Profit Entities (Topic 958)* (Aug. 2016) (asc.fasb.org/imageRoot/56/92564756.pdf).

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[39] *Id.*

[40] Data on contributions and grants are taken from line 8 of Form 990 for each group. The American Pain Foundation ended its operations in 2012.

[41] These totals consist of payments in the Open Payments database from the five opioid manufacturers at issue to physician board members, advisory board members, advisory council members, staff members, and officers and executives of the advocacy groups listed. The totals only include payments from manufacturers to physicians since August 2013, when the first reporting period for the CMS Open Payments database began. *See* Centers for Medicare and Medicaid Services, *How Open Payments Works* (Sept. 2, 2015) (www.cms.gov/OpenPayments/About/How-Open-Payments-Works.html). The listed payments from manufacturers to the groups occurred between January 2012 and March 2017.

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(openpaymentsdata.cms.gov/physician/591428/payment-information) (accessed Dec. 22, 2017). *See also* American Chronic Pain Association, Advisory Board (theacpa.org/Advisory-Board) (accessed Dec. 22, 2017).

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[105] *Id.* As stated above, the total for the American Cancer Society Cancer Action Network also included payments from Purdue to the American Cancer Society that could potentially apply to the Cancer Action Network.

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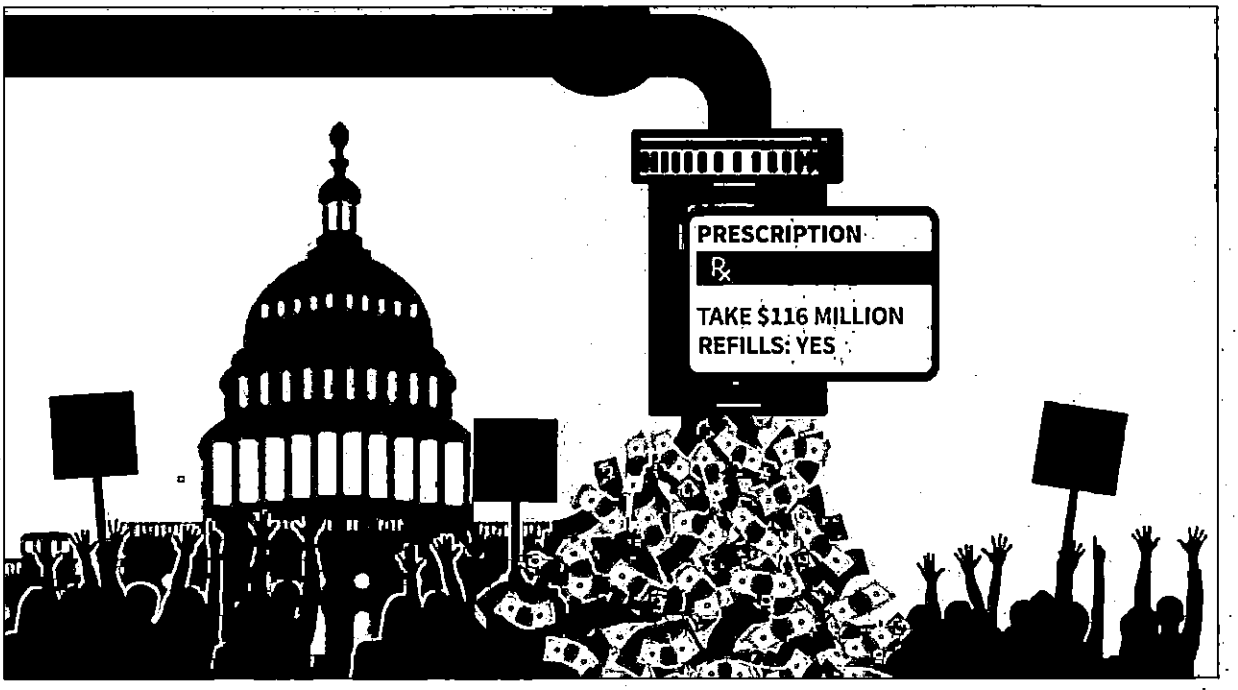


PRE$CRIPTION FOR POWER

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

(Illustration created using Getty Images)

KHN launches "Pre$cription for Power," a groundbreaking database to expose Big Pharma's ties to patient groups.

By **Emily Kopp** and **Sydney Lupkin** and **Elizabeth Lucas**
APRIL 6, 2018

KHN staffers Vickie Connor, Julie Appleby, Melissa Bailey, Rachel Bluth, Terry Byrne, Doug Carroll and Brianna Labuskes also contributed.

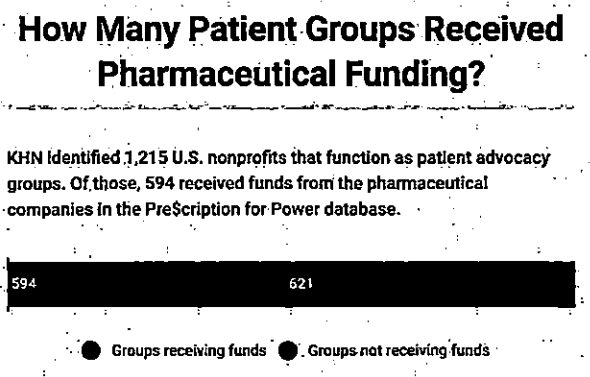
Pharmaceutical companies gave at least $116 million to patient advocacy groups in a single year, reveals a new database logging 12,000 donations from large publicly traded drugmakers to such organizations.

Even as these patient groups grow in number and political influence, their funding and their relationships to drugmakers are little understood. Unlike payments to doctors and lobbying expenses, companies do not have to report payments to the groups.

The database, called "Pre$cription for Power," shows that donations to patient advocacy groups tallied for 2015 — the most recent full year in which documents required by the Internal Revenue Service were available — dwarfed the total amount the companies 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.

Though their primary missions are to focus attention on the needs of patients with a particular disease — such as arthritis, heart disease or various cancers — some groups effectively supplement the work lobbyists perform, providing patients to testify on Capitol Hill and organizing letter-writing and social media campaigns that are beneficial to pharmaceutical companies.

Six drugmakers, the data show, contributed a million dollars or more to individual groups that represent patients who rely on their drugs. The database identifies over 1,200 patient groups. Of those, 594 accepted money from the drugmakers in the database.



pa·tient ad·vo·ca·cy group

noun

A patient advocacy group is a nonprofit that has pledged to help patients with a particular disease, disability or condition. This assistance excludes direct care but can involve research, raising awareness and lobbying to support or oppose policies, regulations, drug approvals or government funding decisions. KHN included patient assistance groups in the Pre$cription for Power database. No federal statute defines or identifies patient advocacy groups.

To learn more about how Kaiser Health News built the Pre$cription for Power database, read our methodology.

The financial ties are troubling if they cause even one patient group to act in a way that's "not fully representing the interest of its constituents," said Matthew McCoy, a medical ethics professor at the University of Pennsylvania who co-authored a 2017 study about patient advocacy groups' influence and transparency.

Notably, such groups have been silent or slow to complain about high or escalating prices, a prime concern of patients.

"When so many patient organizations are being influenced in this way, it can shift our whole approach to health policy, taking away from the interests of patients and towards the interests of industry," McCoy said. "That's not just a problem for the patients and caregivers that particular patient organizations serve; that's a problem for everyone."

Bristol-Myers Squibb provides a stark example of how patient groups are valued. In 2015, it spent more than $20.5 million on patient groups, compared with $2.9 million on federal lobbying and less than $1 million on major trade associations, according to public records and company disclosures. The company said its decisions regarding lobbying and contributions to patient groups are "unrelated."

"Bristol-Myers Squibb is focused on supporting a health care environment that rewards innovation and ensures access to medicines for patients," said spokeswoman Laura Hortas. "The company supports patient organizations with this shared objective."

> *"There aren't a lot of large pockets of funding outside of the pharmaceutical money. We take it where we can find it.*
>
> - LORREN SANDT, CARING AMBASSADORS PROGRAM

The first-of-its-kind database, compiled by Kaiser Health News, tallies the money from Big Pharma to patient groups. KHN examined the 20 pharmaceutical firms included in the S&P 500, 14 of which were transparent — in varying degrees —

about giving money to patient groups. Pre$cription for Power is based on information contained in charitable giving reports from company websites and federal 990 regulatory filings.

It spotlights donations pharma companies made to patient groups large and small. The recipients include well-known disease groups, like the American Diabetes Association, with revenues of hundreds of millions of dollars; high-profile foundations like Susan G. Komen, a patient group focused on breast cancer; and smaller, lesser-known groups, like the Caring Ambassadors Program, which focuses on lung cancer and hepatitis C.

The data show that 15 patient groups — with annual revenues as large as $3.6 million — relied on the pharmaceutical companies for at least 20 percent of their revenue, and some relied on them for more than half of their revenue. The database explores only a slice of the pharmaceutical industry's giving overall and will be expanded with more companies and groups over time.

"It's clear that more transparency in this space is vitally important," said Sen. Claire McCaskill (D-Mo.), who has been investigating the links between patient advocates and opioid manufacturers and is considering legislation to track funding. "This database is one step forward in that effort, but we also need Congress to act."

What Drives The Money Flow

The financial ties between drugmakers and the organizations that represent those who use or prescribe their blockbuster medicines have been of growing concern as drug prices escalate. The Senate investigated conflicts of interest in the run-up to the passage of the 2010 Physician Payments Sunshine Act — a law that required payments to physicians from makers of drugs and devices to be registered on a public website — but patient groups were not addressed in the bill.

Some of the patient groups with ties to trade groups echo industry talking points in media campaigns and letters to federal agencies, and do little else. And patients, supported by pharma, are dispatched to state capitals and Washington to support research funding. Some groups send patients updates on the newest drugs and industry products.

"It's through groups like this that patients often learn about illnesses and treatments," said Rick Claypool, a research director for Public Citizen, a consumer advocacy group that says it does not accept pharmaceutical funding.

> *"It's clear that more transparency in this space is vitally important.*
>
> - SEN. CLAIRE MCCASKILL (D-MO.)

For the patient group Caring Ambassadors Program, industry funds are needed to make up for a lack of public funding, said the group's executive director, Lorren Sandt. According to IRS filings and published company reports, in 2015 the group received $413,000, the bulk of which came from one company, AbbVie, which makes a hepatitis C treatment and has been testing a new lung cancer drug, Rova-T, not yet approved. She said the money had no influence on the Caring Ambassadors Program's priorities.

"There aren't a lot of large pockets of funding outside of the pharmaceutical money," Sandt said. "We take it where we can find it."

Other patient groups such as The National Women's Health Network, based in Washington, D.C., make sacrifices to avoid pharmaceutical funding. That includes operating with a small staff in a "modest" office building with few windows and outdated computers, according to executive director Cindy Pearson. "You can see the effect of our approach to funding as soon as you walk [in] the door."

Pearson said it's hard for patient groups not to be influenced by the funder, even if they proclaim independence. Patient groups "build relationships with their funders and feel in sync and have sympathy" for them. "It's human nature. It's not evil or weak, but it's wrong."

Charity As Marketing

Patients newly diagnosed with a disease often turn to patient advocacy groups for advice, but the money flow to such groups may distort patients' knowledge and public debate over treatment options, said Dr. Adriane Fugh-Berman, the director of PharmedOut, a Georgetown University Medical Center program that is critical of some pharmaceutical marketing practices.

"[The money flow limits] their advocacy agenda to competing branded products when the best therapy might be generics, over-the-counter drugs or diet and exercise," she said.

AbbVie — whose specialty drug Humira made up 65 percent of the company's net revenue in 2017 and is used to treat patients with autoimmune diseases, including Crohn's disease and certain kinds of arthritis — gave $2.7 million to the Crohn's & Colitis Foundation and $1.6 million to the Arthritis Foundation, according to the company's public disclosures included in the database. The list price for a month's supply of Humira, a biologic drug, is $4,872, according to Express Scripts, a pharmacy benefits manager.

Even though Humira will face competition from near-copycat drugs called biosimilars, it is expected to remain the highest-grossing drug in the United States through 2022, according to drug industry analysts at EvaluatePharma.

The Arthritis and Crohn's foundations have been largely silent on the cost of Humira and vocal on safety concerns about biosimilars. The Arthritis Foundation has championed state laws that could add extra steps for consumers to receive biosimilars at the pharmacy counter, potentially keeping more patients on the brand-name drug. Experts say those laws could help protect Humira's market share from generic competitors.

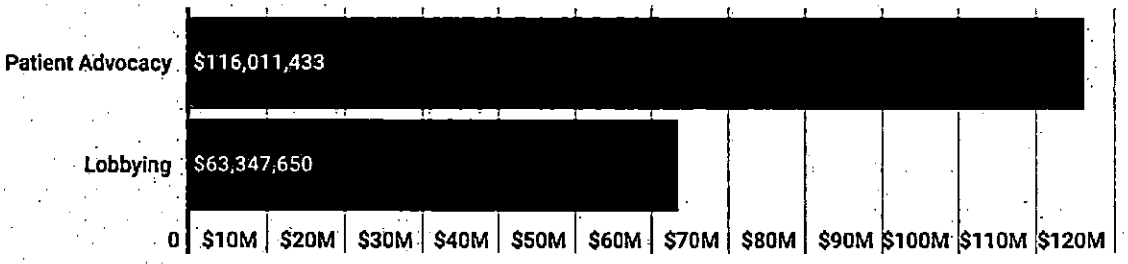
A coalition of patient groups, Patients for Biologics Safety & Access, opposes the automatic substitution of a cheaper biosimilar when doctors prescribe a biologic. In 2015, members of that coalition, including the Crohn's & Colitis Foundation, the Arthritis Foundation and the Lupus Foundation of America, accepted about $9.1 million from pharmaceutical companies in the database, according to public disclosures. They include AbbVie and Johnson & Johnson, makers of blockbuster biologics.

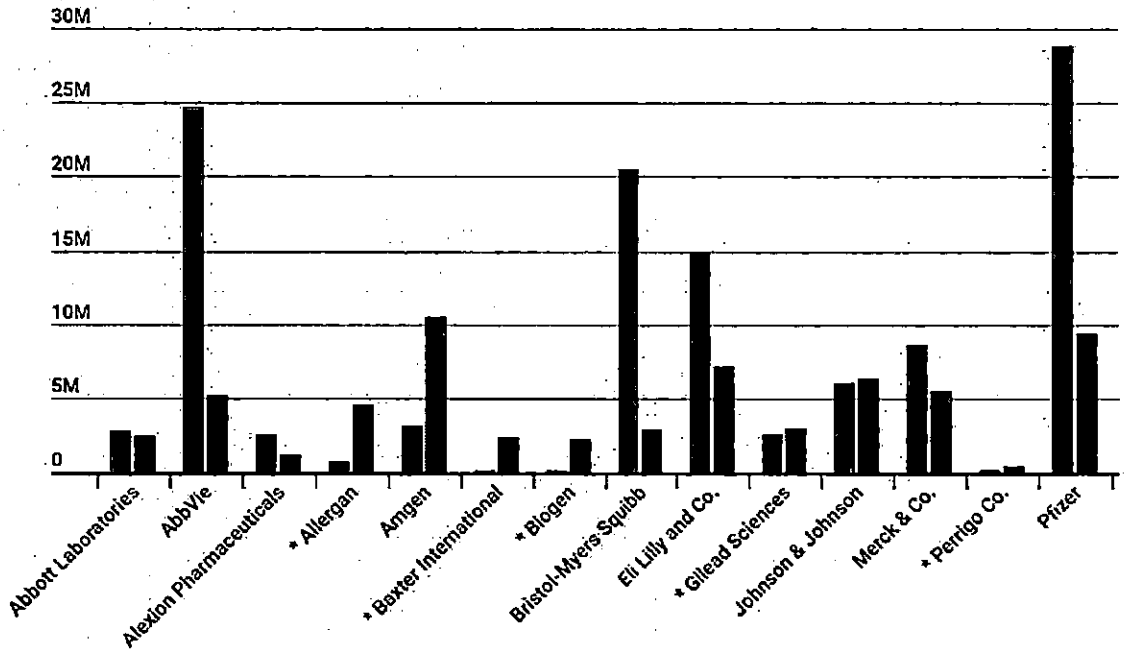
The Arthritis Foundation did not deny receiving the money but said the foundation represents patients, not sponsors. It is "optimistic" about biosimilars' ability to help patients and save them money, said Anna Hyde, vice president of advocacy and access. "The Foundation supports the Food and Drug Administration's scientific standards in evaluating the safety and efficacy of biosimilars, and we support policies that encourage innovation and foster a competitive marketplace."

(Story continues below.)

Patient Advocacy vs. Lobbying

The 14 drugmakers in the Pre$cription for Power database spent $116 million on patient advocacy in 2015, compared with $63 million on lobbying that same year. Explore the breakdown for each drugmaker, below.





Donations to patient advocacy groups (Source: PreScription for Power)

Lobbying expenditures (Source: Center for Responsive Politics)

**These drugmakers disclosed charitable giving only from their foundations. They may have given additional dollars to patient groups directly from company coffers, but they did not disclose it.*

To learn more about how Kaiser Health News built the Pre$cription for Power database, read our methodology.

The Crohn's & Colitis Foundation maintains "more than an arm's-length distance" from its donors in the pharmaceutical industry, who have no say over the foundation's strategic objectives, said president and CEO Michael Osso.

He added that the foundation's position on biosimilars is "evolving."

Lupus Foundation CEO Sandra Raymond said she could not explain how her group, also based in Washington, was involved in the coalition. She confirmed the Lupus Foundation received $444,000 from Pfizer in 2015 but said the money was not linked to any relationship with Patients for Biologics Safety & Access.

"I never went to a meeting," Raymond said. "A former employee signed us up for a whole host of coalitions. I think we put our name on something or someone did."

She said the Lupus Foundation was no longer a member of the coalition. Days after Kaiser Health News reached out to the coalition, its website was updated, excluding the Lupus Foundation.

For its part, AbbVie — which overall donated $24.7 million to patient groups in 2015, according to the new database — stipulates that its grants to nonprofits are "non-promotional" and provide no direct benefit to its business, according to a company statement. The company gives to patient groups because they serve as an "important, unbiased and independent resource for patients and caregivers."

Insulin And Influence

The American Diabetes Association said in an email to KHN that it received $18.3 million in pharmaceutical funding in 2017, accounting for 12.3 percent of its revenue; that was down from $26.7 million in 2015. The money flowed in as insulin makers continued to hike prices in those years — up to four times per product — leading to hardships for patients.

The only "Big Three" insulin maker in the database, Eli Lilly, gave $2.9 million to the American Diabetes Association in 2015, according to disclosures from the company and its foundation. Sanofi and Novo Nordisk are the other two major insulin makers, but neither was in the S&P 500 and therefore not included in the database. Over the past 20 years, Eli Lilly has repeatedly raised prices on its

bestselling insulins, Humalog and Humulin, even though the medicines have been around for decades. The drugmaker faced protests — by people demanding to know the cost of manufacturing a vial of insulin — at its Indianapolis headquarters last fall.

The ADA launched a campaign decrying "skyrocketing" insulin in late 2016 but did not call out any drugmaker in its literature. When legislators in Nevada passed a bill last year requiring insulin makers to disclose their profits to the public, the ADA did not take a public stance.

The American Diabetes Association said it doesn't confront individual companies because it is seeking action from "all entities in the supply chain" — manufacturers, wholesalers, pharmacy benefit managers and insurers.

"As a public health organization, the ADA's commitment and focus is on the needs of the more than 30 million people with diabetes," said Dr. William Cefalu, its chief scientific and medical officer. "The ADA requires support from a diverse set of partners to achieve this objective."

Eli Lilly said it contributes money to the American Diabetes Association because the two share a "common goal" of helping diabetes patients.

"We provide funding for a wide variety of educational programs and opportunities at ADA, and they design and implement those programs in ways that are aligned with their goals," Eli Lilly said in a statement. "We're proud to support the ADA on important work that helps millions of people living with diabetes."

Most patient groups say that funders have little or no influence in shaping their programs and policies, but their agreements are private.

They Weren't Always Backed By Pharma

Into the '80s and early '90s, patient lobbying was generally limited and self-funded with only one or two affluent patients from an organization traveling to Washington on a given day, said Diana Zuckerman, president of the nonprofit National Center for Health Research.

But the power of patient-lobbyists became apparent after a successful campaign by AIDS patients led to government action and a national push to find drugs to treat the then-terminal disease. Zuckerman said she will never forget when two women visited her office and asked how breast cancer patients could be as effective as the AIDS patients.

"At the time, there were no breast cancer patients advocating for money or anything else. It's hard to believe," she said. "I still remember that conversation, because it was really a turning point."

Soon after, breast cancer patients started visiting the Hill more frequently. Patients with other diseases followed. Over time, patients' voices became a potent force, often with industry support.

> *"Sick consumers make for good press.*
>
> - DR. ADRIANE FUGH-BERMAN, PHARMEDOUT

Even some wealthy, high-profile organizations take industry money: For example, $459,000 of Susan G. Komen's $118 million in 2015 revenue came from drugmakers in the database, according to public disclosures. Asked about the pharma money, the foundation said it has institutional processes in place to ensure that "no corporate partner — pharma or otherwise — decides our mission priorities," including a scientific advisory board — free of sponsor influence — that reviews its research program.

Today, patient advocacy groups flush with more industry dollars fly patients in for testimony and training about how to lobby for their drugs.

Some years ago, as the groups increased in number, Zuckerman said, she started getting email invitations from advocacy groups to attend so-called lobbying days explicitly sponsored by the pharmaceutical industry. The hosts often promised

training and usually some kind of keynote speaker at a luncheon in Washington — plus a potential scholarship to cover travel. Now, lobbying days involving dozens of patients from a single group are part of the landscape.

Dan Boston, president of lobbying firm Health Policy Source, said, "It would be naive to think these people on a Tuesday afternoon just happen to turn up in XYZ places," adding that the money isn't necessarily a bad thing. Money tends to flow toward citizen groups that already have the same priorities as their funders, he said.

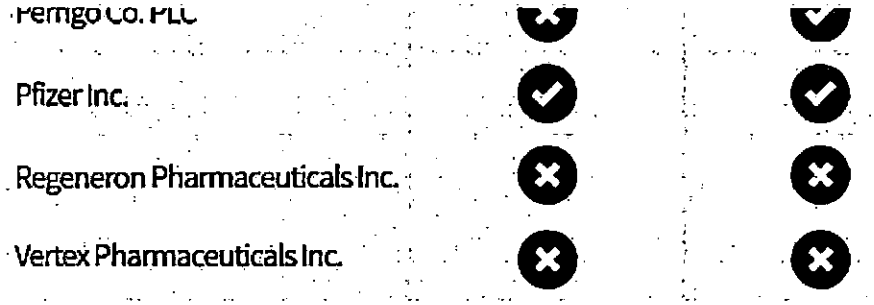
Marching Into The Future

Patient groups have been successful at campaigning for drug approvals, at times sparking controversy.

Who Discloses What? A Breakdown

Kaiser Health News sought two types of documents: voluntary reports available on company websites, and annual tax forms filed by companies' foundations. Not all companies are transparent about their donations to patient advocacy groups, and not all companies maintain private foundations.

Pharmaceutical Company	Company Giving	Foundation Giving
Abbott Laboratories	✓	✓
AbbVie Inc.	✓	✓
Alexion Pharmaceuticals Inc.	✓	✓
Allergan PLC	✗	✓
Amgen Inc.	✓	✓
Baxter International Inc.	✗	✓
Biogen Inc.	✗	✓
Bristol-Myers Squibb Co.	✓	✓
Celgene Corp.	✗	✗
Eli Lilly and Co.	✓	✓
Endo International PLC	✗	✗
Gilead Sciences Inc.	✗	✓
Johnson & Johnson	✓	✓
Mallinckrodt PLC	✗	✗
Merck & Co. Inc.	✓	✓
Mylan NV	✗	✓
Perrigo Co. PLC	✗	✓



To learn more about how Kaiser Health News built the Pre$cription for Power database, read our methodology.

When scientists within the FDA advised against the approval of Exondys 51, a drug to treat Duchenne muscular dystrophy, parents of children with the rare genetic disorder and patients rallied to lobby for it in Washington. They were seen as pivotal to the FDA's 2016 decision to grant approval for the drug, made by Sarepta Therapeutics. The decision was controversial in part because the FDA noted that clinical benefits of the drug — aimed at a subset of people with Duchenne muscular dystrophy — were not yet established.

Sarepta Therapeutics, which is not featured in the database, has taken measures to support its patient base. In March, it announced an annual scholarship program — 10 grants of up to $10,000 each for students with Duchenne muscular dystrophy to attend university or trade schools. Sarepta Therapeutics is also among the funders of Parent Project Muscular Dystrophy, a patient advocacy group at the forefront of the push for Exondys 51's approval.

The Pre$cription for Power database will grow to include new disclosures. Not all drugmakers are willing to disclose their company giving. Eleven of the 20 companies examined — Allergan, Baxter International, Biogen, Celgene, Endo International, Gilead Sciences, Mallinckrodt, Mylan, Perrigo Co., Regeneron Pharmaceuticals and Vertex Pharmaceuticals — declined to disclose their company giving or did not respond to repeated calls.

Paul Thacker, a former investigator for Sen. Chuck Grassley (R-Iowa) who helped draft the Physician Payments Sunshine Act in 2010, said there is reason to question the flow of money to patient advocacy groups. The pharmaceutical industry has fostered relationships in every link of the drug supply chain, including payments to researchers, doctors and professional societies.

"There's so much money out there, and they've created all of these allies, so nobody is clamoring for change," Thacker said.

Since the Physician Payments Sunshine Act began requiring the industry to report its payments to physicians, the industry is more reluctant to co-opt them, so "pharma has to find other megaphones," PharmedOut's Fugh-Berman said.

And in times of public outrage over high drug prices and soaring insurance costs, patients are particularly sympathetic messengers, she said.

"Sick consumers make for good press," Fugh-Berman said. "They make for good testimony before Congress. They can be very powerful spokespeople for pharmaceutical companies."

To learn how Kaiser Health News created the Pre$cription for Power database, read the full methodology, here.

KHN's coverage of prescription drug development, costs and pricing is supported in part by the Laura and John Arnold Foundation.

Emily Kopp: ekopp@kff.org, @emilyakopp
Sydney Lupkin: slupkin@kff.org, @slupkin
Elizabeth Lucas: elucas@kff.org, @eklucas

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SPECIAL REPORT

Conflicts of Interest for Patient-Advocacy Organizations

Matthew S. McCoy, Ph.D., Michael Carniol, M.B.A., Katherine Chockley, B.A., John W. Urwin, B.S., Ezekiel J. Emanuel, M.D., Ph.D., and Harald Schmidt, Ph.D.

Patient-advocacy organizations are nonprofit groups whose primary mission is to combat a particular disease or disability or to work toward improving the health and well-being of a particular patient population.[1] As political actors, such organizations play an influential role in shaping health policy, pursuing agendas that include expanding coverage for drugs, devices, and diagnostic procedures; increasing support for medical research; and streamlining approval of experimental therapies.[2-5]

Reports by media and watchdog groups have drawn critical attention to financial relationships between patient-advocacy organizations and drug, device, and biotechnology companies.[6-11] Industry support can be an important resource for patient-advocacy organizations but can also give rise to institutional conflicts of interest,[2,12] which exist when "an institution's own financial interests or the interests of its senior officials pose risks to the integrity of the institution's primary interests and missions."[13] In the context of organization–industry relations, concerns have been raised that industry-supported patient-advocacy organizations have spoken out for access to drugs with questionable therapeutic benefit and remained silent on policy proposals, such as drug-pricing reforms, that might benefit their constituents.[6,7]

Despite these concerns, there have been few systematic attempts to quantify the frequency and scope of industry financial support for patient-advocacy organizations, the extent to which such organizations voluntarily disclose this support, the frequency of other industry–organization relationships that may give rise to conflicts of interest, or the policies that patient-advocacy organizations have in place to manage conflicts of interest. The few studies that exist have limitations. Many have been published outside peer-reviewed journals.[9,14-16] Some are small, involving no more than 35 patient-advocacy organizations.[14,16] Others examine samples of patient-advocacy organizations that include small organizations, rather than focusing on those likely to have the largest effect on the public.[17] Others have restricted their focus to patient-advocacy organizations that are active in a particular disease area.[18] Others are outdated.[15,17] We are not aware of previous studies that have examined conflicts of interest arising from the presence of industry executives on the boards of patient-advocacy organizations.

We analyzed the Form 990 tax records, annual reports, and websites of 104 U.S.-based patient-advocacy organizations with annual revenues of at least $7.5 million to answer three specific questions. First, to what extent do patient-advocacy organizations disclose information necessary for assessing possible financial and other conflicts of interest? Second, how frequently do patient-advocacy organizations have financial and other conflicts of interest? Third, do patient-advocacy organizations have policies to minimize and manage conflicts of interest?

METHODS

SAMPLE

To focus on organizations likely to have a major effect in terms of outreach and advocacy, we used a purposive sampling strategy that was designed to capture the largest patient-advocacy organizations, on the basis of annual revenue, that were operating at the national level in the United States. To construct the sample, we searched the GuideStar charity database for 501(c)(3) charities with annual revenues of at least $7.5 million and National Taxonomy of Exempt Entities codes in groups G (Disease,

the current disclosure practices of such organizations provide strong reasons in favor of creating a "sunshine" law to cover industry payments to patient-advocacy organizations. Although the 2009 Institute of Medicine report on conflict of interest[13] recommended such a provision, it was not included in the Sunshine Act passed in 2010. However, other countries, such as France, have enacted requirements for companies to disclose payments to patient-advocacy organizations, which shows the feasibility of such measures.[20] Greater transparency would enable citizens, researchers, policymakers, and others to assess the possible conflicts of interest of patient-advocacy organizations in a way that is not currently possible. Greater transparency would also benefit organizations that receive only modest industry donations, by allowing third parties to differentiate them from patient-advocacy organizations that are highly dependent on industry funding. Short of legislative change, greater transparency could be achieved by strengthening disclosure requirements for patient-advocacy organizations that testify before federal advisory committees.[21] Finally, patient-advocacy organizations should also consider strengthening their own reporting practices.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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From the Department of Medical Ethics and Health Policy, Perelman School of Medicine (M.S.M., K.C., J.W.U., E.J.E., H.S.), and the Wharton School (M.C.), University of Pennsylvania, Philadelphia. Address reprint requests to Dr. McCoy at the Department of Medical Ethics and Health Policy, Perelman School of Medicine at the University of Pennsylvania, Blockley Hall, 14th Fl., 423 Guardian Dr., Philadelphia, PA 19104-4884, or at mmcco@mail.med.upenn.edu.

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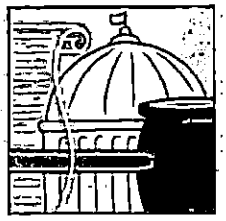


Health Advocacy Organizations and the Pharmaceutical Industry: An Analysis of Disclosure Practices

Sheila M. Rothman, PhD, Victoria H. Raveis, PhD, Anne Friedman, BA, and David J. Rothman, PhD

Health advocacy organizations (HAOs) are influential stakeholders in health policy. Although their advocacy tends to closely correspond with the pharmaceutical industry's marketing aims, the financial relationships between HAOs and the pharmaceutical industry have rarely been analyzed.

We used Eli Lilly and Company's grant registry to examine its grant-giving policies. We also examined HAO Web sites to determine their grant-disclosure patterns. Only 25% of HAOs that received Lilly grants acknowledged Lilly's contributions on their Web sites, and only 10% acknowledged Lilly as a grant event sponsor. No HAO disclosed the exact amount of a Lilly grant.

As highly trusted organizations, HAOs should disclose all corporate grants, including the purpose and the amount. Absent this disclosure, legislators, regulators, and the public cannot evaluate possible conflicts of interest or biases in HAO advocacy. (*Am J Public Health.* 2011;101:602–609. doi: 10.2105/AJPH.2010.300027)

HEALTH ADVOCACY ORGANI-zations (HAOs) are among the most influential and trusted stakeholders in US health policy, pursuing an agenda that includes expanding government support for medical research and the availability of health care services. In addition, HAOs advocate for members' unrestricted access to all drugs, devices, and diagnostic tools relevant to their health conditions, almost always favoring branded drugs over generics, new screening technologies over older ones, and open formularies rather than closed ones. These positions closely correspond to the marketing aims of pharmaceutical and device companies; each position would help to increase product sales. Yet, despite the overlapping interests of HAOs and the pharmaceutical industry, the financial relationships between them have remained relatively unexplored. We conducted the current study in an effort to fill this knowledge gap.

This investigation is feasible because data on industry contributions to HAOs have recently become publicly available, which allows for an examination of HAOs' disclosure practices. In response to US Department of Justice criminal prosecutions and state legislative mandates, some drug and device companies now report on their Web sites the precise dollar amounts of the grants and gifts they make to HAOs. Thus, it is now possible to analyze which HAOs the industry selects for funding and the HAOs' degrees of transparency in reporting that funding.

We selected Eli Lilly and Company for analysis because it was the first company to make its grant registry public. The Lilly registry identifies the HAOs receiving support and the exact level of support each HAO receives. Lilly's registry provides specific information about the company's grant-giving policies and practices; this information is made even more useful when supplemented by Lilly's financial reports on its best-selling drugs. On the other side of the grant equation, it would be reasonable to expect HAOs to be fully transparent about their grantors, given the credibility that HAOs enjoy. An examination of the Web sites of the HAOs that received funding from Lilly makes it possible to determine the degree to which each HAO has disclosed its Lilly funding.

ACTIVITIES OF HEALTH ADVOCACY ORGANIZATIONS

HAOs range in size from national organizations with thousands of members concerned with a widespread disease (diabetes, cancer) to smaller organizations that have a narrower focus (alpha-1 antitrypsin deficiency, trisomy 18). Typically, HAOs conduct campaigns to promote disease awareness, update members about new diagnostic tests and drugs, facilitate physician referrals, deliver health care services, and advocate for policies that they believe are in their members' best interests. HAO leaders and members testify at congressional and state hearings, lobby legislators, negotiate with regulators, serve on federal advisory panels, and inform the media.

HAOs are highly effective advocates, deftly putting a human face on advocacy around a particular disease. As an oncology journal editorial explained, "There is one activity that lobbyists or public relations firms, no matter how well paid, will never be able to perform in place of advocacy groups. This is the ability to acknowledge what it actually means to be a cancer patient."[1]

HAOs appeal to members and to the community at large for support—"Help Find a Cure. Donate Today"[2]—and conduct well-publicized fundraising events, from weekend races to annual galas. But what information do they share with members and the public about their funders? This question, always relevant to public charities, has now assumed exceptional importance. In part, this reflects an intensified commitment to transparency as evidenced by

congressional investigations, particularly by Senator Charles Grassley; new information from the US Department of Justice about pharmaceutical and device company payments to physicians and professional medical associations; preliminary findings from a handful of researchers, in the United States and abroad,[3–6] about HAOs operating under a "veil of secrecy"[7]; and media exposés of some HAOs' dependence on drug company funding.[8,9]

HAOs' advocacy agenda overlaps with industry marketing interests, making the need to evaluate disclosure practices more urgent.[10,11] "A message's credibility is greater when delivered by impartial third parties than by entities seeking to profit from it," observed a public relations firm. "Advocacy groups who know a company and its values can be counted on to speak out for it and relevant issues in times of need."[12] Although HAOs are not legally required to disclose the names of their corporate sponsors, their advocacy activities and the level of public trust that they enjoy makes transparency more obligatory.

THE CHANGED MISSION OF HEALTH ADVOCACY ORGANIZATIONS

Organizations that once served the public interest have become devoted to their members' interests. This transformation also enhances the need to evaluate levels of transparency. In the opening decades of the 20th century, philanthropic citizens joined with public health officials and civic-minded physicians to spearhead campaigns against deadly diseases.[13] Although each organization targeted a specific disease, they allied to advance sweeping social changes. Attentive to the needs of the poorest and most vulnerable members of the population, they promoted such public health measures as tenement house reform, urban playgrounds, child labor laws, and maternal and child health care.[14]

Private individuals and charitable foundations—not corporations—openly underwrote the campaigns. The National Tuberculosis Association, established in 1904, was supported by John D. Rockefeller and Jacob Schiff.[15] When the American Society for the Control of Cancer, later the American Cancer Society, began its work in 1913, the *New York Times* reported: "Rich Women Begin a War on Cancer."[16] The same newspaper also informed readers that the Association for the Prevention and Relief of Heart Disease, later the American Heart Association, was organized by "philanthropic New Yorkers" dismayed by the number of schoolchildren and industrial workers who were "suffering from heart disease in this city."[17]

Contemporary HAOs advocate almost exclusively for members' special interests. AIDS activists inaugurated the new HAO model in the 1980s. They advocated to make AIDS research a priority[18]; to make experimental drugs available to all AIDS patients, not only those in clinical trials; and to speed up the Food and Drug Administration (FDA) drug approval process for AIDS drugs.[19] Unlike their predecessors, they were confrontational, aggressively picketing the FDA and holding marches and vigils.[19] A circumscribed angle of vision and hard-line tactics soon became the hallmarks of other HAOs, including those focusing on breast cancer,[20,21] mental illness,[22] and epilepsy.[23]

METHODS

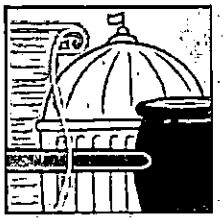
Eli Lilly's Grant Office released the Lilly Grant Registry (LGR) on May 1, 2007.[24,25] We obtained the data for this study from the LGR. Because we wanted to identify an unobtrusive measure for our analysis of disclosure patterns before HAO policies might be affected by pharmaceutical companies' disclosures, we selected Lilly, the first pharmaceutical company to publicly release its grant registry, and examined its grant giving and the grants it awarded to HAOs during the first 2 quarters of 2007.

We designed data-collection methods that made maximum use of the publicly available information about Lilly's grant-giving criteria and the detailed funding information in the LGR.[24] First, we analyzed Lilly's funding criteria. Lilly's Grant Office specified the therapeutic areas for which Lilly would accept grant requests and the types of programs it would support. One area so identified was "patient advocacy and consumer education programs."[26] Lilly's grants policy, as specified in the LGR, was not to make "unrestricted educational grants"; rather, "the purpose of the grant must be designated," and awarded funds could only be used for the stated grant purpose.[26] To determine whether there were links between Lilly's grant giving and its marketing goals, we gathered information from the company's 2007 annual report on the net sales of its best-selling pharmaceutical products and the aggregated net sales for each of the company's therapeutic areas.[27]

Second, we used the LGR information to compile a list of HAOs receiving Lilly grants. We defined HAOs as not-for-profit organizations concerned with health care in which both the leadership and membership were drawn predominantly from the general public. The LGR listed 188 organizations that met these criteria. They included groups concerned with specific diseases and disabilities and with general health issues. National organizations, chapters of national organizations, and regional, state, county, and community organizations were represented. We then organized the information obtained from the LGR about HAOs' grant awards, making use of the following LGR categories:

- "Requestor": The name of the HAO that received the award.
- "Program/Project Description": Stated purpose of the award. The program or project description varied from a named event to a broad statement of purpose.
- "Individual Payment Amount": Exact dollar amount awarded.

Third, we then searched the World Wide Web to identify the Web sites associated with these 188 HAOs. We chose to examine the HAOs' Web sites because the



Internet is now recognized as a primary information portal for obtaining information about health and disease. Health organizations regard their Web sites as their public face. HAOs update them regularly to keep members and the public informed of activities and to disseminate information about disease management, clinical trials, and policy issues. They also use Web sites to solicit donations.

We identified the HAOs' Web sites by searching on Google.com for the exact name or acronym of the HAO, as listed in the LGR under Requestor. When the Google search returned an exact match, that HAO Web site was included in data collection. An exact match occurred for 161 (86%) of the 188 HAOs listed on the LGR. These 161 Web sites constituted the sample for the current study. The other 27 eligible HAOs could not be matched to a Web site and were excluded from further study.

Fourth, we accessed each of the 161 Web sites to determine the disease or health category the HAO addressed. We classified the HAOs into therapeutic areas on the basis of the Segment Information table in Lilly's 2007 annual report.[27] Lilly pharmaceuticals cover 6 therapeutic areas: neurosciences (mental disorders and disabilities and neurologic disorders), oncology, endocrinology, cardiovascular, animal health, and other pharmaceuticals.[27] We obtained information on each HAO's geographic scope (national, chapter, regional, county, etc.) from the HAO's Web site.

Finally, we conducted a systematic click search of the 161 HAO Web sites to identify information about the specific Lilly grant and to determine the degree to which the HAO acknowledged its relationship with Lilly. The secure areas of Web sites, restricted to HAO members, were not included in this click search. When HAOs were chapters of national organizations and did not manage their own Web sites, the parent organization Web site was subjected to the click search. The click search was carried out between September 30, 2008, and January 12, 2009.

The following activities were performed during the click search:

1. We clicked through every available page on the HAO Web site and systematically searched for reference to the program/project description and the individual payment amount. These pages typically covered the following topics: organizational history ("About Us"), current news and reports, action updates, events, strategic plans, advocacy pages, lobbying toolkits, policy positions, donation information, clinical trials, and annual and regional conferences. If the Lilly grant did not specify an event, the entire Web site was examined for information about Lilly funding.
2. We applied a systematic click-search pattern to site maps and search engines on the HAO Web site.
3. We searched HAO Web sites for their 2007 annual report and their 2007 federal tax Form 990, and when we found those forms, we examined them for information about the Lilly grant.
4. When Lilly was acknowledged or mentioned on the HAO Web site or in a document posted or linked to it, we searched to see whether the program/project description was listed and whether an individual payment amount, by exact amount or by range, was specified.

We used the information collected from the click search of HAO Web sites to create 4 dichotomous yes/no variables: (1) Lilly was acknowledged in the HAO's 2007 annual report, (2) Lilly was acknowledged on a corporate sponsors page, (3) Lilly was acknowledged as a grant event sponsor, and (4) the amount of the Lilly grant was reported. A fifth variable, "Lilly acknowledged anywhere," was a summary of the 4 variables. We used SPSS version 16 (SPSS, Chicago, IL) to perform statistical analysis on the data.

RESULTS

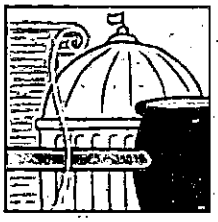
Examination of the LGR information revealed that during the first 2 quarters of 2007, Lilly gave $3 211 144 to HAOs, representing 10.22% of its total grant giving. The funding was closely aligned with the company's therapeutic areas of interest. HAOs active in Lilly's 3 main therapeutic areas (accounting for 87% of its total US sales)—neurosciences, endocrinology, and oncology—received 94% of Lilly's grants to HAOs. The match of therapeutic area to HAO was not consistent; neuroscience and oncology HAOs received proportionately more grant funds than Lilly's sales percentages in these therapeutic areas, and endocrinology received less. But overall it was evident that the company targeted HAOs concerned with its areas of therapeutic interest.

Grants Made by Therapeutic Area

Lilly's grants to HAOs also mirrored its therapeutic areas with the strongest sales. In 2007, Lilly reported annual US net sales of $10 145 500 000.[27] Of this total, 45% came from neurosciences, 31% from endocrinology, 11% from oncology, and 13% from miscellaneous health (Figure 1). Lilly only reports sales on an annual basis, but there is no reason to believe that therapeutic sales patterns varied substantially between the first and second halves of 2007.

Neurosciences. Lilly's 2 best-selling products in 2007, Zyprexa and Cymbalta, were approved by the FDA for mental and neurological disorders such as schizophrenia, bipolar mania, and depressive disorders.[27] Of Lilly's 8 new drug applications to the FDA, 4 were in this category. During the first 2 quarters of 2007, 66% of Lilly's HAO grants went to organizations concerned with neurosciences.

Oncology. Lilly's fifth-best-selling product was Gemzar, approved for treating a variety of cancers,



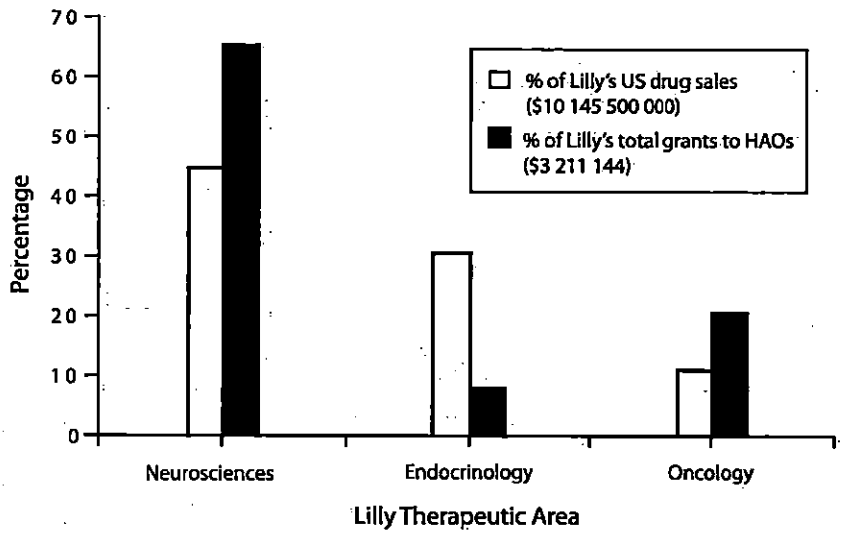


FIGURE 1—Lilly and Company's US sales and grants to US health advocacy organizations (HAOs), by therapeutic area, 2007.

including lung cancer, pancreatic cancer, bladder cancer, metastatic breast cancer, and recurrent ovarian cancer.[27] Lilly's 10th-best-selling product was Alimta, a treatment for lung cancer.[27] Of Lilly's 8 new drug applications to the FDA, 4 were in this category. During the first 2 quarters of 2007, 21% of Lilly's HAO grants went to organizations concerned with oncology.

Endocrinology. Lilly's third- and fourth-best-selling products were Humalog for the treatment of type 1 and type 2 diabetes and Evista for osteoporosis.[27] Other diabetes-related drugs included Byetta for glucose control and weight reduction. Two of the 8 Lilly products under FDA review were in this category. During the first 2 quarters of 2007, 8% of Lilly grants went to HAOs concerned with endocrinology.

Lilly Funding Acknowledged on Web Sites

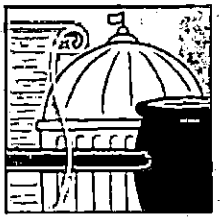
Of the 161 sample HAOs that received Lilly funding, 137 (85%) were in neurosciences (n=114), endocrinology (n=6), and oncology (n=17). In terms of geographic scope, endocrinology and oncology HAOs were predominantly national organizations. Specifically, 4 of the endocrinology HAOs that received funding had a national scope, and 2 were chapters of national organizations. Similarly, 13 of the oncology HAOs were national, 1 was a chapter, and 3 had a regional or local scope. The neurosciences and miscellaneous health categories of HAOs had organizations in all 3 geographic scope categories. For the neuroscience HAOs, the majority (n=93) were chapters, 11 were national, and 10 were regional or local. Most of the HAOs in the miscellaneous health category were either national (n=12) or regional or local (n=10); only 2 were chapters.

As an aggregate, 25% of HAOs acknowledged Lilly funding anywhere on their Web site. Eighteen percent acknowledged Lilly in their 2007 annual report, 1% acknowledged Lilly on a corporate sponsors page, and 10%

TABLE 1—Health Advocacy Organizations (HAOs) That Acknowledged Lilly Funding on Their Web Sites, by Therapeutic Area: United States, 2007

HAO Therapeutic Area	No.	Lilly Acknowledged Anywhere, % (no.)[a]	Lilly Acknowledged in 2007 Annual Report, % (no.)	Lilly Acknowledged on Corporate Sponsors Page, % (no.)	Lilly Acknowledged as Grant Event Sponsor, % (no.)	Lilly Grant Amount Reported, % (no.)
Neurosciences	114	18 (20)	11 (13)	2 (2)	7 (8)	1 (1)
Endocrinology	17	59 (10)	47 (8)	0 (0)	29 (5)	0 (0)
Oncology	6	67 (4)	50 (3)	0 (0)	17 (1)	0 (0)
Miscellaneous health	24	25 (6)	21 (5)	0 (0)	8 (2)	0 (0)
Total	161	25 (40)	18 (29)	1 (2)	10 (16)	0.6 (1)

[a]The percentage of HAOs acknowledging Lilly anywhere is less than the sum of the composite variable because some HAOs acknowledged Lilly in multiple places on their Web site.



acknowledged Lilly as the sponsor of the grant event reported in the LGR (Table 1).

Grant Disclosure by Therapeutic Area

We then explored HAO disclosure information by Lilly's therapeutic areas.

Neurosciences. Disclosure rates were low among the 114 neuroscience HAOs. Eighteen percent acknowledged Lilly anywhere on their Web site. Eleven percent acknowledged Lilly in their annual report, 2% acknowledged Lilly on the corporate sponsors page, and 7% acknowledged Lilly as a grant event sponsor. One neuroscience HAO, Mental Health America Southeastern Pennsylvania, disclosed the amount of Lilly funding, but funding was disclosed as a range, not an exact amount.

Oncology. Of the 6 HAOs concerned with oncology, 67% acknowledged Lilly anywhere on their Web site. Fifty percent acknowledged Lilly in their annual report, none acknowledged Lilly on a corporate sponsors page, and 17% acknowledged Lilly as a grant event sponsor. None disclosed the amount of the Lilly grant.

Endocrinology. Of the 17 HAOs concerned with endocrinology, 59% acknowledged Lilly anywhere on their Web site. Forty-seven percent acknowledged Lilly in their annual report, none acknowledged Lilly on a corporate sponsors page, and 29% disclosed Lilly as a grant event sponsor. None disclosed the amount of the Lilly grant.

Miscellaneous health. Disclosure rates were low among the 24 miscellaneous health HAOs; 25% acknowledged Lilly anywhere on their Web site. Twenty-one percent acknowledged Lilly in their annual report, none acknowledged Lilly on a corporate sponsors page, and 8% acknowledged Lilly as a grant event sponsor. None disclosed the exact amount of the Lilly grant.

HAOs exhibited significant differences in disclosure rates by their therapeutic area of interest (χ^2 [3]=19.387; $P<.001$). Post hoc tests demonstrated that HAOs concerned with endocrinology and oncology disclosed at a significantly higher rate than those concerned with neurosciences.

Neuroscience Disclosure by Geographic Scope

National organizations were the most common type of grant recipient for the oncology, endocrinology, and miscellaneous health HAOs. However, sufficient diversity the neuroscience HAOs differed sufficiently to examine disclosure of Lilly funding by HAO geographic scope, e.g., national, chapter, or other (Table 2).

National organizations. Of the 11 national neuroscience HAOs, 36% acknowledged Lilly anywhere on their Web site. Sixty-four percent acknowledged Lilly in their annual report, 18% acknowledged Lilly on a corporate sponsors page, and 55% listed Lilly as a grant event sponsor. None disclosed the amount of the grant.

Chapters. Of the 93 neuroscience chapters, 88 were chapters of 2 national organizations: the National Alliance on Mental Illness (NAMI) and Mental Health America. Fourteen percent of the chapters acknowledged Lilly on their Web site. Four percent acknowledged Lilly in their annual report, 1% acknowledged Lilly on a corporate sponsors page, and 1% acknowledged Lilly as a grant event sponsor. One chapter, Mental Health America of Southeastern Pennsylvania, disclosed the amount of funding and reported it as a range.

Other organizations. Of the 10 neuroscience county and regional HAOs, 30% acknowledged Lilly anywhere on their Web site. Twenty percent acknowledged Lilly in their annual report, none acknowledged Lilly on a corporate sponsors page, and 10% acknowledged Lilly as a grant event sponsor. None disclosed the amount of the Lilly grant.

There was no significant difference in the neuroscience HAO disclosure rates among national, chapter, and other organizations (χ^2 [2]=4.58; P=.101).

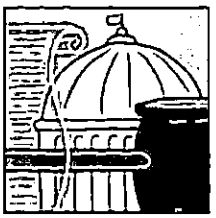
DISCUSSION

Lilly's grants went primarily to HAOs working in its areas of therapeutic interest and in areas related to its best-selling products. Lilly has acknowledged this type

TABLE 2—Neurosciences Health Advocacy Organizations (HAOs) That Acknowledged Lilly Funding on Their Web Sites, by Geographic Scope: United States, 2007

HAO Geographic Scope	No.	Lilly Acknowledged Anywhere, % (no.)[a]	Lilly Acknowledged in 2007 Annual Report, % (no.)	Lilly Acknowledged on Corporate Sponsors Page, % (no.)	Lilly Acknowledged as Grant Event Sponsor, % (no.)	Lilly Grant Amount Reported, % (no.)
National	11	36 (4)	64 (7)	18 (2)	55 (6)	0 (0)
Chapter	93	14 (13)	4 (4)	1 (1)	1 (1)	1 (1)
Other	10	30 (3)	20 (2)	0 (0)	10 (1)	0 (0)
Total	114	18 (20)	11 (13)	3 (3)	7 (8)	0.9 (1)

[a]The percentage of HAOs acknowledging Lilly anywhere is less than the sum of the composite variable because some HAOs acknowledged Lilly in multiple places on their Web site.



of correlation between its business interests and its grant giving. Its "Principles for Interacting with Health Care Professional Associations" state that grantees should be committed to "market oriented solutions to important health care issues" and that Lilly expects to "build long term relationships ... based on mutual support." The principles state that organizations receiving grants are not "obligated or directed to use these funds in a manner that benefits the company or its products,"[28] but the distribution of grants makes clear that formal stipulations were not required to satisfy Lilly's marketing interests.

Lilly has cited the public release of its grant registry as evidence of its commitment to transparency: "We regularly publish U.S. grant funding on line and encourage advocacy organizations to consider their own transparency efforts."[28] But as the present analysis has demonstrated, HAOs generally did not follow this recommendation. Only 25% of the HAOs that received Lilly grants acknowledged Lilly's contributions on their Web sites. Only 10% acknowledged Lilly as the sponsor of a grant event. None disclosed the amount of a Lilly grant. Thus, in most cases, neither policymakers nor the public can readily learn about the financial relationship between an HAO and Lilly.

This lack of transparency is disappointing because, either by design or through a convergence of interests, the HAOs in the current study pursued activities that promoted the sale of Lilly products. In the area of neurosciences, Lilly gave NAMI $450 000 for its Campaign for the Mind of America. NAMI has advocated that cost should not be a consideration when prescribing for patients. "For the most severely disabled," insisted NAMI, "effective treatment often means access to the newest medications such as atypical antipsychotic and anti-depressive agents.... Doctors must be allowed to utilize the latest breakthrough in medical science ... without bureaucratic restrictions to the access for life-saving medications."[29] To the degree that NAMI's campaign succeeded, the market for Lilly's neuroscience drugs expanded.

In the area of oncology, Lilly granted the National Breast Cancer Coalition (NBCC), which represents 25 state and national organizations, $50 000 to support its annual advocacy training program. Researchers have concluded that the NBCC is "a powerful force in Washington politics—and everybody knows it."[20] One industry trade magazine has called the NBCC "one of America's most powerful pressure groups" and has described its president as one of "the most influential people in the industry."[30]

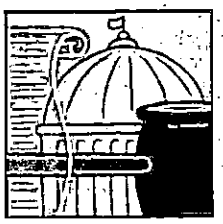
The NBCC advocated for a "comprehensive strategy to end the [breast cancer] epidemic," including greater access to screening, insurance coverage for participation in clinical trials, and expanded Medicare coverage for all oral cancer drugs.[20,31] The organization conducted advocacy training sessions for survivors and organized a "lobby day": "Advocates held over 400 meetings with federal officials.... In that single day NBCC advocates persuaded 40 additional House members and 10 additional Senators to commit to cosponsoring one of NBCC's top legislative priorities."[32] In 2007, NBCC members served on 11 influential national committees, including the National Advisory Council of the Agency for Healthcare Research and Quality, the Cochrane Collaboration Consumer Coalition, the Roundtable on Evidence-Based Medicine of the Institute of Medicine, and the Task Force on Conflicts of Interest in Clinical Research of the Association of American Medical Colleges.[33] In all these ways, the policies and practices implemented by NBCC fit Lilly's criterion of "mutual support."

In the area of endocrinology, Lilly granted the American Diabetes Association (ADA) $250 000 for its Cardiovascular Risk Initiative.[34] The program taught patients and providers strategies for preventing cardiac disease among people with type 2 diabetes, including weight management and better drug use to control glucose levels.[35] Personal connections also linked the ADA to Lilly. One of the ADA's major supporters and officers, Joe Cook Jr, was a Lilly vice president before becoming the CEO of Amylin Pharmaceuticals in 1998. Amylin Pharmaceuticals partners with Lilly in developing and marketing Byetta.[36] As the ADA noted, "A logical relationship evolved between the Cooks and ADA. Ultimately, Joe ... helped raise funds for the organization."[37]

Limitations

This analysis is based on data drawn from the LGR, sales reports of Eli Lilly over 2 quarters in 2007, and the content of the Web sites of HAOs that received Lilly funding. Before industry-wide and HAO-wide conclusions are drawn, further research is necessary to establish whether other companies and HAOs fit the patterns described here. Moreover, this investigation of HAO transparency practices focused on publicly accessible information posted on HAO Web sites. It is possible that some HAOs may have distributed printed materials that included an acknowledgment to Lilly or that some HAOs may have posted acknowledgments on a members-only section of their Web site that was not open to the public.

These limits recognized, the disclosure patterns we reported are not likely to be unique. The National Health Council, an industry-funded umbrella organization of HAOs, promulgated principles that did not encourage transparency. "Companies are increasingly basing decisions regarding relationships with not-for-profit organizations on whether these relationships support business goals," it informed members. Rather than give guidance on procedures to avoid or manage conflicts of interest, the National Health Council told HAOs "to enhance their ability to accomplish their mission in areas where the interest of the not-for-profit and the for-profit organizations overlap." The organization acknowledged the "possible negative impact [on] ... public image and integrity, whether real or imagined," so it concluded that HAOs should "disclose financial and other benefits it receives from a corporate relationship, when asked."[38]



Conclusions

HAOs are powerful stakeholders in shaping health policies, and they enjoy considerable public trust. Thus, they should become far more detailed in disclosing corporate grants, including the grant's purpose and amount. HAOs should also disclose their industry relationships when testifying before legislative or regulatory committees, serving on advisory panels, and communicating with the media.

Absent substantial changes in HAO reporting practices, state and federal regulations should require that HAO–industry relationships become transparent. To this end, the Sunshine Act provisions in the recently enacted US health reform law, which require companies to report gifts to physicians, should be amended to include company payments to HAOs. Federal income tax regulations should also mandate public disclosure of HAO donors and sums on Form 990. If these changes were implemented, legislators, regulators, and the public would more easily be able to follow the money and evaluate possible biases and conflicts of interest in HAO advocacy.■

About the Authors

Sheila M. Rothman is with the Division of Sociomedical Sciences, Mailman School of Public Health, Columbia University, New York, NY, and the Center for the Study of Society and Medicine, College of Physicians and Surgeons, Columbia University. Victoria H. Raveis is with the Psychosocial Unit on Health, Ageing, and Community, New York University College of Dentistry, New York. At the time of the study Anne Friedman was with the Center on Medicine as a Profession, College of Physicians and Surgeons, Columbia University. David J. Rothman is with the College of Physicians and Surgeons, Columbia University.

Correspondence should be sent to Sheila M. Rothman, Center for the Study of Society and Medicine, College of Physicians and Surgeons, Columbia University, 630 West 168th St, PH 15-25, New York, NY 10032 (e-mail: smr4@columbia.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints/Eprints" button.

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Contributors

S.M. Rothman, D.J. Rothman, and V.H. Raveis conceptualized and designed the study. S.M. Rothman and A. Friedman collected the data. S.M. Rothman, V.H. Raveis, and D.J. Rothman wrote and revised the article. S.M. Rothman supervised all aspects of the study.

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Human Participant Protection

No protocol approval was required because no human research participants were involved in this study.

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34. American Diabetes Association launches "CheckUp America" to curb rise in type 2 diabetes, heart disease [press release]. Alexandria, VA: American Diabetes Association; April 18, 2007. Available at: http://www.diabetes.org/for-media/2007/checkup-america-2007-release.html. Accessed April 27, 2010.

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36. Eli Lilly and Company. Amylin Pharmaceuticals. Available at: http://www.lilly.com/about/partnerships/profiles/amylin. Accessed April 6, 2010.

37. American Diabetes Association. 2007 annual report. Available at: http://www.diabetes.org/assets/pdfs/2007-ada-annual-report.pdf. Accessed April 8, 2010.

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Publisher's Note: During the copyediting process, reference #38 in the above article was changed and erroneously cited the current (2008) "Standards of Excellence" from the National Health Council. The authors actually used the "Guiding Principles for Voluntary Health Agencies in Corporate Relationships" from 1998, a document that was available online when the study was conducted. Reference #38 has been corrected to link to the document used for the study. The National Health Council's "Standards of Excellence" is the policy currently applicable to, among other things, the issues discussed by the authors. The policy articulates different standards of transparency for health advocacy organizations than the document used by the authors. It can be viewed at http://www.nationalhealthcouncil.org/forms/soe.pdf.

The Association of Changes in Local Health Department Resources With Changes in State-Level Health Outcomes

Paul Campbell Erwin, MD, DrPH, Sandra B. Greene, DrPH, Glen P. Mays, PhD, MPH, Thomas C. Ricketts, PhD, MPH, and Mary V. Davis, DrPH, MSPH

We explored the association between changes in local health department (LHD) resource levels with changes in health outcomes via a retrospective cohort study.

We measured changes in expenditures and staffing reported by LHDs on the 1997 and 2005 National Association of County and City Health Officials surveys and assessed changes in state-level health outcomes with the America's Health Rankings reports for those years. We used pairwise correlation and multivariate regression to analyze the association of changes in LHD resources with changes in health outcomes.

Increases in LHD expenditures were significantly associated with decreases in infectious disease morbidity at the state level (P=.037), and increases in staffing were significantly associated with decreases in cardiovascular disease mortality (P=.014), controlling for other factors. (*Am J Public Health.* 2011;101:609–615. doi:10.2105/AJPH.2009.177451)

THE ULTIMATE AIM OF LOCAL health departments (LHDs) is to improve the quality of life for the communities they serve—a part of the larger mission of public health, which is "the fulfillment of society's interest in assuring the conditions in which people can be healthy."[1(p7)] Since the Institute of Medicine's 1988 report, *The Future of Public Health,* there have been numerous studies that have described and measured the performance of LHDs, the characteristics associated with performance, and whether and how such performance affects health.[2] Studies have most often described associations of performance with LHD size, jurisdictional size, and funding: LHDs with larger staffs, serving populations greater than 50 000 persons, and with higher funding per capita were more often higher performing.[3–14] Higher performing LHDs also had greater community interaction, a director with higher academic degrees, and leadership functioning within a management team.[5,9,11,15]

Only 4 published studies have attempted to link LHD characteristics, activities, or performance to health outcomes.[9,13,16,17] All of these studies are limited by their cross-sectional design. One study has examined the longitudinal relationship between LHD inputs and health outcomes, showing significant associations between changes in local public health spending and infant mortality and deaths attributable to cardiovascular disease (CVD), diabetes, and cancer at the county level.[18]

We focused on the relationship between changes in LHD inputs (financial resources, staffing), aggregated to the state, and changes in state-level health measures (smoking and obesity prevalence, infectious disease morbidity, infant mortality, cancer and CVD mortality, and premature death). Aggregating LHD inputs to a state level not only allows the opportunity to explore the impact of LHDs' combined resources but also reduces the complexities inherent in studies

ARS
AIDS Response Seacoast
COMPASSION CARE PREVENTION

May 7, 2019

The Honorable Kevin Cavanaugh, Chair
The Honorable Jon Morgan, Vice-Chair
Senate Commerce Committee
Legislative Office Building
33 North State Street
Concord, NH 03301

Dear Chairman Cavanaugh, Vice-Chair Morgan and members of the Committee:

My name is Richard Wagner, I am the Executive Director of AIDS Response Seacoast and am writing the Committee today in opposition to House Bill 695.

AIDS Response Seacoast is a non-profit community-based AIDS Service Organization dedicated to providing education, direct assistance and advocacy for persons and communities affected by HIV/AIDS. ARS has been providing services in the communities of Rockingham and Strafford counties in New Hampshire since 1987.

As a small non-profit, we are constantly struggling to manage the overwhelming amount of paperwork necessary to adhere to local, state and federal regulations. Unfortunately, we spend more time catching up on redundant paperwork than focusing on the health and wellbeing of the patients we serve. If HB695 passes, more time will be wasted on tracking, filing paperwork and updating the website. I prefer to spend our staffs time on patient treatment, however, this bill will limit our face-time with patients even more which is why I am asking you to vote "No."

HB695 implies a nefarious relationship between grant money and patient advocacy, this could not be farther from the truth. Our organization depends on grant money in order to survive, and to be able to provide services to the AIDS community. We cannot operate without meeting our fiscal responsibilities, I should be able to accept legal contributions to our organization without fear of retribution from a state watchdog.

ARS works with a unique healthcare community in New Hampshire that the state government is not equipped to handle, yet this bill seeks to make our work more difficult without the state having an vested interest in the wellbeing of the patients we serve. We will continue to exceed expectations for the AIDS community, please do not make our work more difficult. I am asking you to oppose HB695.

Respectfully,

Richard B. Wagner

Executive Director

7 Junkins Avenue • Portsmouth, NH 03801 • 603-433-5377, 603-278-7994 (fax) • info@aidsresponse.org
www.aidsresponse.org, AIDS Response Seacoast, a 501 (c) (3) charitable organization FEIN 22-288488

Breathe
NEW HAMPSHIRE
Improving lung health since 1916

May 7, 2019

The Honorable Kevin Cavanaugh, Chair
The Honorable Jon Morgan, Vice-Chair
Senate Commerce Committee
Legislative Office Building - Room 102
33 North State Street
Concord, NH 03301

Re: Opposition to House Bill 695 - Relative to the Transparency of Nonprofit Patient Advocacy Organizations

Dear Chairman Cavanaugh, Vice-Chair Morgan and members of the Committee:

I am submitting this letter in opposition to House Bill 695, Relevant to the Transparency of Nonprofit Patient Advocacy Organizations.

Breathe New Hampshire, a 501c(3), public health nonprofit, has been focused on lung health in the Granite State since our founding in 1916. Our mission is to eliminate lung disease and improve the quality of life for those living with lung disease in New Hampshire. The focus of our work has been about the elimination and management of lung disease and the prevention of nicotine addiction.

Breathe NH has always considered its work to be in the interest of everyone in New Hampshire. While we have never viewed ourselves as a Patient Advocacy organization, albeit our work of preventing disease and educating and supporting patients like those with Chronic Obstruction Pulmonary Disease, (approximately 65,000 diagnosed in New Hampshire), could fall within the scope of definition of patient advocacy.

As a small organization, with annual revenues less than $1 million, we work hard to ensure that we are prudent and responsible with everything that we do operationally. On occasion and not in every fiscal year, we have received small amounts of support from organizations such as those mentioned in House Bill 695, although in the aggregate the total amount has never exceeded more than 3% of our annual operating revenue. Irrespective, our opposition is in regards to the added administrative responsibilities for a small organization as we work hard to devote as much of our resources as possible to advancing our mission.

Thank you for all you do in the interest of our state.

Sincerely,

Daniel Fortin (LM)

Daniel Fortin
President & CEO

145 Hollis St., Unit C | Manchester, NH 03101 | phone 603.669.2411 | fax 603.645.6220 | www.breathenh.org

Voting Sheets

Senate Commerce Committee

EXECUTIVE SESSION RECORD

2019-2020 Session

Bill # 695

Hearing date: 5/7

Executive Session date: 5/19/19

Motion of: ITL **Vote:** 4-0

Committee Member	Made by	Second	Yes	No
Sen. Cavanaugh, Chair	☐	☐	☑	☐
Sen. Morgan, V- Chair	☐	☐	☑	☐
Sen. French	☐	☑	☑	☐
Sen. Morse	☑	☐	☑	☐
Sen. Soucy	☐	☐	☐	☐

Motion of: _____ **Vote:** _____

Committee Member	Made by	Second	Yes	No
Sen. Cavanaugh, Chair	☐	☐	☐	☐
Sen. Morgan, V-Chair	☐	☐	☐	☐
Sen. French	☐	☐	☐	☐
Sen. Morse	☐	☐	☐	☐
Sen. Soucy	☐	☐	☐	☐

Motion of: _____ **Vote:** _____

Committee Member	Made by	Second	Yes	No
Sen. Cavanaugh. Chair	☐	☐	☐	☐
Sen. Morgan, V- Chair	☐	☐	☐	☐
Sen. French	☐	☐	☐	☐
Sen. Morse	☐	☐	☐	☐
Sen. Soucy	☐	☐	☐	☐

Reported out by: Cavanaugh

Committee Report

STATE OF NEW HAMPSHIRE

SENATE

REPORT OF THE COMMITTEE

Tuesday, May 21, 2019

THE COMMITTEE ON Commerce

to which was referred **HB 695**

AN ACT relative to transparency of nonprofit patient advocacy organizations.

Having considered the same, the committee recommends that the Bill

IS INEXPEDIENT TO LEGISLATE

BY A VOTE OF: 4-0

Senator Kevin Cavanaugh
For the Committee

Laura Bryant 271-1403

COMMERCE

HB 695, relative to transparency of nonprofit patient advocacy organizations.
Inexpedient to Legislate, Vote 4-0.
Senator Kevin Cavanaugh for the committee.

General Court of New Hampshire - Bill Status System

Docket of HB695

Docket Abbreviations

Bill Title: relative to transparency of nonprofit patient advocacy organizations.

Official Docket of **HB695.:**

Date	Body	Description
1/17/2019	H	**Introduced** 01/03/2019 and referred to Commerce and Consumer Affairs **HJ 3** P. 26
2/6/2019	H	Public Hearing: 03/05/2019 10:30 am LOB 302
2/27/2019	H	Subcommittee Work Session: 03/06/2019 08:30 am LOB 302
3/6/2019	H	Subcommittee Work Session: 03/08/2019 09:00 am LOB 302-304
2/28/2019	H	Executive Session: 03/08/2019 01:30 pm LOB 302-304
3/12/2019	H	Committee Report: Ought to Pass with Amendment **#2019-0761h** for 03/19/2019 (Vote 18-2; CC) **HC 16** P. 6
3/19/2019	H	Amendment **#2019-0761h**: AA VV 03/19/2019 **HJ 10** P. 16
3/19/2019	H	**Ought to Pass with Amendment** 2019-0761h: MA VV 03/19/2019 **HJ 10** P. 16
4/1/2019	S	Introduced 03/28/2019 and Referred to Commerce; **SJ 12**
4/18/2019	S	==RECESSED== **Hearing:** 04/25/2019, Room 100, SH, 01:00 pm; **SC 19**
4/25/2019	S	==RECESSED== **Hearing:** 04/30/2019, Room 102, LOB, 02:45 pm; **SC 20**
5/2/2019	S	==RECONVENE== **Hearing:** 05/07/2019, Room 100, SH, 01:00 pm; **SC 21**
5/21/2019	S	Committee Report: Inexpedient to Legislate, 05/30/2019; **SC 24**
5/30/2019	S	Inexpedient to Legislate, MA, VV === BILL KILLED ===; 05/30/2019; **SJ 18**

NH House	NH Senate

Other Referrals

Senate Inventory Checklist for Archives

Bill Number: HB695 **Senate Committee:** Commerce

Please include all documents in the order listed below and indicate the documents which have been included with an "X" beside

X Final docket found on Bill Status

Bill Hearing Documents: {Legislative Aides}

X Bill version as it came to the committee

X All Calendar Notices

___ Hearing Sign-up sheet(s)

X Prepared testimony, presentations, & other submissions handed in at the public hearing

X Hearing Report

___ Revised/Amended Fiscal Notes provided by the Senate Clerk's Office

Committee Action Documents: {Legislative Aides}

All amendments considered in committee (including those not adopted):

___ - amendment # _____ ___ - amendment # _____

___ - amendment # _____ ___ - amendment # _____

X Executive Session Sheet

X Committee Report

Floor Action Documents: {Clerk's Office}

All floor amendments considered by the body during session (only if they are offered to the senate):

___ - amendment # _____ ___ - amendment # _____

___ - amendment # _____ ___ - amendment # _____

Post Floor Action: (if applicable) {Clerk's Office}

___ Committee of Conference Report (if signed off by all members. Include any new language proposed by the committee of conference):

___ Enrolled Bill Amendment(s)

___ Governor's Veto Message

All available versions of the bill: {Clerk's Office}

___ as amended by the senate ___ as amended by the house

___ final version

Completed Committee Report File Delivered to the Senate Clerk's Office By:

_____ _____

Committee Aide **Date**

Senate Clerk's Office AK