Committee Report

CONSENT CALENDAR

March 21, 2019

HOUSE OF REPRESENTATIVES

REPORT OF COMMITTEE

The Committee on Commerce and Consumer Affairs to which was referred HB 695,

AN ACT relative to transparency of nonprofit patient advocacy organizations. Having considered the same, report the same with the following amendment, and the recommendation that the bill OUGHT TO PASS WITH AMENDMENT.

Rep. Joyce Weston

FOR THE COMMITTEE

Original: House Clerk
Cc: Committee Bill File

COMMITTEE REPORT

Committee:	**Commerce and Consumer Affairs**
Bill Number:	**HB 695**
Title:	**relative to transparency of nonprofit patient advocacy organizations.**
Date:	**March 21, 2019**
Consent Calendar:	**CONSENT**
Recommendation:	**OUGHT TO PASS WITH AMENDMENT 2019-0761h**

STATEMENT OF INTENT

This bill requires non-profit organizations that advocate on behalf of patients to disclose any payments, donations, or subsidies from pharmaceutical manufacturers, insurance carriers, or pharmaceutical benefit managers. This report, which must be posted on the nonprofit's web site, and if they don't maintain one, to the NH Insurance Department's web site, will provide transparency about the resources of the non-profit. If, however, the non-profit has a paid employee who is registered as a lobbyist in the state of NH, the organization shall be exempt from this section.

Vote 18-2.

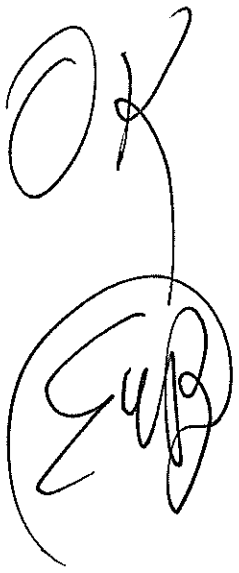
Rep. Joyce Weston
FOR THE COMMITTEE

Original: House Clerk
Cc: Committee Bill File

COMMITTEE REPORT

HB 695, Relative to transparency of nonprofit patient advocacy organizations. **OUT TO PASS WITH AMENDMENT.**

Rep. Joyce Weston for Commerce and Consumer Affairs. HB 695 requires non-profit organizations that advocate on behalf of patients to disclose any payments, donations, or subsidies from pharmaceutical manufacturers, insurance carriers, or PBMs (Pharmaceutical Benefit Managers). This report, which shall be posted on the non-profit's website or—should they not maintain a website—to the NHID, will provide transparency about the resources of the non-profit. If, however, the non-profit has a paid employee who is registered as a lobbyist in the state of NH, the organization shall be exempt from this section. **Vote 18–2.**



Rep. McBeath, Rock. 26
March 4, 2019
2019-0761h
01/10

Amendment to HB 695

Amend the bill by replacing all after the enacting clause with the following:

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.

Voting Sheets

HOUSE COMMITTEE ON COMMERCE AND CONSUMER AFFAIRS

EXECUTIVE SESSION on HB 695

BILL TITLE: relative to transparency of nonprofit patient advocacy organizations.

DATE: March 8, 2019

LOB ROOM: 302

MOTIONS: **OUGHT TO PASS WITH AMENDMENT**

Moved by Rep. Weston	Seconded by Rep. Williams	AM Vote: 20-0
Amendment # 2019-0761h		
Moved by Rep. Weston	Seconded by Rep. Williams	Vote: 18-2

CONSENT CALENDAR: YES

Statement of Intent: Refer to Committee Report

Respectfully submitted,

Rep Constance Van Houten, Acting Clerk

HOUSE COMMITTEE ON COMMERCE AND CONSUMER AFFAIRS

EXECUTIVE SESSION on HB 695

BILL TITLE: relative to transparency of nonprofit patient advocacy organizations.

DATE: 3-8-19

LOB ROOM: 302

MOTION: (Please check one box)

☑ OTP ☐ ITL ☐ Retain (1st year) ☑ Adoption of Amendment # 2019-0761h (*if offered*)

☐ Interim Study (2nd year)

Moved by Rep. Weston Seconded by Rep. Williams Vote: 20-0

MOTION: (Please check one box)

☐ OTP ☑ OTP/A ☐ ITL ☐ Retain (1st year) ☐ Adoption of Amendment # _____ (*if offered*)

☐ Interim Study (2nd year)

Moved by Rep. Weston Seconded by Rep. Williams Vote: 18-2

MOTION: (Please check one box)

☐ OTP ☐ OTP/A ☐ ITL ☐ Retain (1st year) ☐ Adoption of Amendment # _____ (*if offered*)

☐ Interim Study (2nd year)

Moved by Rep. _____ Seconded by Rep. _____ Vote: _____

MOTION: (Please check one box)

☐ OTP ☐ OTP/A ☐ ITL ☐ Retain (1st year) ☐ Adoption of Amendment # _____ (*if offered*)

☐ Interim Study (2nd year)

Moved by Rep. _____ Seconded by Rep. _____ Vote: _____

CONSENT CALENDAR: ✓ **YES** ____ **NO**

Minority Report? _____ Yes _____ No If yes, author, Rep: _____ Motion

Respectfully submitted: Constance Van Houten

Rep Rebecca McBeath, ~~Clerk~~

OFFICE OF THE HOUSE CLERK

1/14/2019 3:15:04 PM
Roll Call Committee Registers Report

2019 SESSION

Commerce and Consumer Affairs

Bill #: 695 Motion: adopt AM #: 2019-0761h Exec Session Date: 3/8/2019

Members	YEAS	Nays	NV
Butler, Edward A. Chairman	X		
Williams, Kermit R. Vice Chairman	X		
~~Gidge, Kenneth N.~~ Schultz	X		
Abel, Richard M.	X		
~~McBeath, Rebecca Susan Clerk~~ Rung	X		
Bartlett, Christy D.	X		
Herbert, Christopher J.	X		
Van Houten, Constance	X		
~~Fargo, Kristina M.~~ McConnell	X		
Indruk, Greg L.	X		
Muscatel, Garrett D.	X		
Weston, Joyce	X		
Hunt, John B.	X		
~~Sanborn, Laurie J.~~ BURNS	X		
Osborne, Jason M.	X		
Costable, Michael	X		
Plumer, John R.	X		
Barnes, Arthur E.	X		
Potucek, John M.	X		
~~Warden, Mark~~ Spilbane	X		
TOTAL VOTE: 20-0			

OFFICE OF THE HOUSE CLERK

1/14/2019 3:15:04 PM
Roll Call Committee Registers Report

2019 SESSION

Commerce and Consumer Affairs

2019-

Bill #: 695 Motion: OTPA AM #: 0761h Exec Session Date: 1/8/2019

Members	YEAS	Nays	NV
Butler, Edward A. Chairman	X		
Williams, Kermit R. Vice Chairman	X		
~~Gidge, Kenneth N.~~ Schultz	X		
Abel, Richard M.	X		
~~McBeath, Rebecca Susan Clerk~~ Rung	X		
Bartlett, Christy D.	X		
Herbert, Christopher J.	X		
Van Houten, Constance	X		
~~Fargo, Kristina M.~~ McConnell	X		
Indruk, Greg L.	X		
Muscatel, Garrett D.	X		
Weston, Joyce	X		
Hunt, John B.	X		
~~Sanborn, Laurie J.~~ BURNS	X		
Osborne, Jason M.		X	
Costable, Michael	X		
Plumer, John R.	X		
Barnes, Arthur E.	X		
Potucek, John M.		X	
~~Warden, Mark~~ Spilane	X		
TOTAL VOTE: 18-2			

Rep. McBeath, Rock. 26
March 4, 2019
2019-0761h
01/10

Amendment to HB 695

Amend the bill by replacing all after the enacting clause with the following:

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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.

2019-0761h

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.

2019-0761h

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.

Sub-Committee Minutes

HOUSE COMMITTEE ON COMMERCE AND CONSUMER AFFAIRS

SUBCOMMITTEE WORK SESSION on HB 695

BILL TITLE: relative to transparency of nonprofit patient advocacy organizations.

DATE: March 8, 2019

Subcommittee Members: Reps. Butler, Williams, McBeath, Gidge, Abel, Bartlett, Herbert, Van Houten, Fargo, Indruk, Muscatel, Weston, Hunt, Sanborn, J. Osborne, Costable, Plumer, Barnes, Potucek and Warden

Comments and Recommendations: To provide transparnecy, all in agreement after Holly clarified.

MOTIONS: **OUGHT TO PASS WITH AMENDMENT**

Moved by Rep. Weston	Seconded by Rep. Barnes	AM Vote: 6-0
Amendment # 2019-0761h		
Moved by Rep. Weston	Seconded by Rep. Potucek	Vote: 6-0

Respectfully submitted,

Rep. Edward Butler
Subcommittee Chairman

HOUSE COMMITTEE ON COMMERCE AND CONSUMER AFFAIRS

SUBCOMMITTEE WORK SESSION on HB 695

BILL TITLE: relative to transparency of nonprofit patient advocacy organizations.

DATE: 3-8-19

Subcommittee Members: Reps. Butler, Williams, McBeath, Gidge, Abel, Bartlett, Herbert, Van Houten, Fargo, Indruk, Muscatel, Weston, Hunt, Sanborn, J. Osborne, Costable, Plumer, Barnes, Potucek and Warden

Comments and Recommendations:

To provide transparency - all in agreement after Holly clarified

MOTIONS: (OTP) OTP/A, ITL, Retained (1st Yr), Interim Study (2nd Yr)
(Please circle one)

Moved by Rep. Weston Seconded by Rep. Barnes AM Vote: ~~7-0~~ 6-0

Adoption of Amendment # 0761h

Moved by Rep. ~~Weston~~ Seconded by Rep. ~~Potucek~~ Vote: ~~6-0~~

_____ Amendment Adopted _____ Amendment Failed

MOTIONS: OTP, OTP/A, ITL, Retained (1st Yr), Interim Study (2nd Yr)
(Please circle one)

Moved by Rep. Weston Seconded by Rep. Potucek AM Vote: 6-0

Adoption of Amendment # _____

Moved by Rep. _____ Seconded by Rep. _____ Vote: ____

_____ Amendment Adopted _____ Amendment Failed

Respectfully submitted,

Rep. _____
Subcommittee Chairman/Clerk

Rep. McBeath, Rock. 26
March 4, 2019
2019-0761h
01/10

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Hearing Minutes

HOUSE COMMITTEE ON COMMERCE AND CONSUMER AFFAIRS

PUBLIC HEARING ON HB 695

BILL TITLE: **relative to transparency of nonprofit patient advocacy organizations.**

DATE: **March 5, 2019**

LOB ROOM: **302** **Time Public Hearing Called to Order: 12:25 PM**

Time Adjourned: 12:38 PM

Committee Members: **Reps. Butler, Williams, Abel, Herbert, Van Houten, Fargo, Indruk, Muscatel, Weston, Hunt and Potucek**

Bill Sponsors:
Rep. McBeath

TESTIMONY

* Use asterisk if written testimony and/or amendments are submitted.

***Rep. Rich Abel** - Introducing bill for sponsor Rep. Rebecca McBeath. Amendment after original replaces all of rest of bill to be more precise and expand definitions.

***Holly Stevens, New Futures** - Supports. She brought bill to sponsor. Pharmacy cost gave to lobbyists; saw ties between opiate manufacturers and Pharma and ties between advocacy and Pharma. Corporate donations and opiate friendly messaging private funding messaging - likely tie - bill ensures transparency between insurers, PBMs, manufacturers and advocacy organizations. Need to be aware of factors and motives. Amendment defines "patient advocacy organizations," excludes professional organizations. Exempts those wearing legislation badge per law. She has provided several written resources.

Q. Rep. Edward Butler - Requires patient advocacy committee in front of legislative committee or accepting donation to report with this commission?
A. Yes.
Q. No need to wear badge?
A. Yes, but can Google to see it.

Q. Rep. Kermit Williams - Do non-profit advocacy organizations usually report sources of funding?
A. Some, patient advocacy organizations are trusted sources and so info is important; only need to register and pay $6.

Q. Rep. Richard Abel - Other states have this?
A. Original bill from Nevada.

***Beverely Goodell, Lupus Foundation of New England** - Opposes. Small non-profit compiles government info. Bill would take away time - paperwork, posting on site, etc.

Q: Rep. Edward Butler - Funding from organization supporting particular drugs?
A: Yes, Always clearly states where from and where it's going. Often aligned with education.
Q: Is this posted?
A: Yes, logo is posted.

Q: Rep. Williams - Such requirements in other states?
A: They do some in MA and RI - event specific uses.
Q: Needs to be filed?
A: Public knowledge.

Sarah Lutat, Dismas Home of NH - Opposes. For previously incarcerated worker. What is purpose? Required to report to 990? Why these industries? They need resources, but don't influence. They have received resources.

Q: Rep. Edward Butler - Have supported other bills?
A: No.

Blue Sheet: Pro, 1; Con,0

Respectfully Submitted,

Constance Van Houten

Constance Van Houten, Acting Clerk

HOUSE COMMITTEE ON COMMERCE AND CONSUMER AFFAIRS

PUBLIC HEARING ON HB 695

BILL TITLE: relative to transparency of nonprofit patient advocacy organizations.

DATE: 3-5-19

ROOM: 302 **Time Public Hearing Called to Order:** 12:25

Time Adjourned: 12:38

(please circle if present)

Committee Members: Reps. Butler, Williams, McBeath, Gidge, Abel, Bartlett, Herbert, Van Houten, Fargo, Indruk, Muscatel, Weston, Hunt, Sanborn, J. Osborne, Costable, Plumer, Barnes, Potucek and Warden

Bill Sponsors:
Rep. McBeath

TESTIMONY

* Use asterisk if written testimony and/or amendments are submitted.

*(1) Rep. Rich Abel, for prime sponsor - amendment
*(2) Holly Stevens, New Futures - support
*(3) Beverly Goodell - Lupus Fundation of NE
(4) Sara Ludat, Dismas Home of NH

(1) 695

*(1) Rep. Rich Abel, for prime Sponsor McBeath
amendment - after original,
replaces all of rest of bill to
be more precise + expand
definitions

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*(2) Holly Stevens, New Futures - support
She brought bill to sponsor.
pharma cos. gave to lobbyists
saw ties betw. specific
manufactures + pharma
tie betw. advocacy +
pharma
corp donations + specific-friendly
messaging - likely tie
Bill ensures transparency betw.
insurers, PBMs, manufactures +
advocacy organizations
need - be aware of factors +
motives
amendment -
defines "patient advocacy organizations"
+ excludes professional
organizations
exempts those wearing leg.
badge per law

~~2011~~

She has provided several
written resources.

(2) 695

Q EB – requires patient advocacy committee in front of leg. committee & accepting donation to report w/ this commission?

A – yes

Q EB – no need to wean budget

A – yes, but can Google to see if

Q KW – DO nonprofit advocacy organizations usually report sources of funding?

A – some, patient advocacy org. are trusted sources and so info is important – only need to register + pay $6

Q RA other states have this?

A – original bill from Nevada

(3) Beverly Goodell – Lupus Fundation of NH (off) – Asthma Assoc
small nonprofit
compiles gov't info
bill would take away time – paperwork, posting on sites, etc.

Q EB – funding from org. supporting particular drugs?

A – yes, always clearly states where from + where go; often aligned w/ education

(3) 695

Q EB – 9us this posted?
A — yes, logo is posted
Q KW – such requirements in other states
A – ~~They~~ Do same in Mass & RI – event specific uses
Q ~~EH~~ – ~~xxx~~ Fed 990 needs to be filed?
A — public knowledge

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(4) Sara Lutat - Dismas Home of NH – opp. for previously incarcerated women
What is purpose? required to report on 990?
Why these industries? They need resources, but don't influence
They have received resources.

Q EB – have supported other bills?
A — no

SIGN UP SHEET

To Register Opinion If Not Speaking

Bill # HB 695 Date 3-5-19

Committee Commerce & CA

**** Please Print All Information ****

Name	Address	Phone	Representing	(check one) Pro	Con
Heidi Kroll	AHIP			X	

Testimony

Breathe
NEW HAMPSHIRE
Improving lung health since 1916

March 5, 2019

The Honorable Edward Butler, Chair
The Honorable Kermit Williams, Vice-Chair
House Commerce and Consumer Affairs Committee
Legislative Office Building - Room 302
107 North Main Street
Concord, NH 03301

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

Dear Chairman Butler, Vice-Chair Williams 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
President & CEO

145 Hollis St., Unit C | Manchester, NH 03101 | phone 603.669.2411 | fax 603.645.6220 | www.breathenh.org
Printed on 100% post-consumer recycled paper

ARS
AIDS Response Seacoast

COMPASSION | CARE | PREVENTION

March 5, 2019

The Honorable Edward Butler, Chair
The Honorable Kermit Williams, Vice-Chair
House Commerce and Consumer Affairs Committee
Room 302 LOB
107 North Main Street
Concord, NH 03301

Dear Chairman Butler, Vice-Chair Williams 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 Wagner
Executive Director
AIDS Response Seacoast

Asthma and Allergy Foundation of America®

NEW ENGLAND CHAPTER

March 5, 2019

Chairman Edward Butler
V Chairman Kermit Williams
Commerce and Consumer Affairs
LOB 302
107 North Main Street,
Concord, New Hampshire, 03301

Dear Committee Members,

Thank you for the opportunity to address the committee in opposition of HB695. My name is Robert Stoker with the Asthma and Allergy Foundation of America New England Chapter, we are a 501(c)(3) non-profit organization. Our mission is to advocate for all patients in the six New England States with Asthma and Allergic diseases. We do this through legislative initiatives, funding and administering studies on Asthma and Allergies. We also advise patients as to where they can go for medical treatment or receive funding to help with their healthcare needs. All of this is done with part-time employees and dedicated volunteers.

We can accomplish all this with an approximate budget of $100,000-$120,000 per year. Our operating expenses are paid for through primarily private donations as well as the occasional corporate contribution. AAFNE's single biggest donor is MSIC- Mass. credit union share insurance corporation, followed by Mass General, and then Mass General Children's Hospital, New England Society of Allergy and CVS Healthcare. At no time, to my knowledge, in the last 7 years have we ever accepted a corporate donation that required anything of us (AAFA-NE) other than to help design and implement a public health study.

As a 501(c)(3) organization we are forced to file a 990 tax return every year which shows our monetary activity. I can assure you that based on the cost of a CPA to do our taxes, we have nothing to hide. In fact, in 35 years in Healthcare and 7 years on the board at AAFA-NE I've never seen a more legitimate organization. Since we don't rely on a $2 million budget supplied by government or other sources to deal solely with New Hampshire we don't have any of the political pressure that may occur with other non-profits.

The additional burden (time and money) to comply with HB 695 will take away from our primary goal of advocacy, education, research and helping patients navigate the healthcare system. Based on the increased costs and duplication of information that's already available, AAFA New England **cannot** endorse HB695.

Thank you,

Robert Stoker
Board of Directors

Asthma and Allergy Foundation of America-New England Chapter25 Braintree Hill Office Park, Suite 200, Braintree, MA 02184-8796

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,

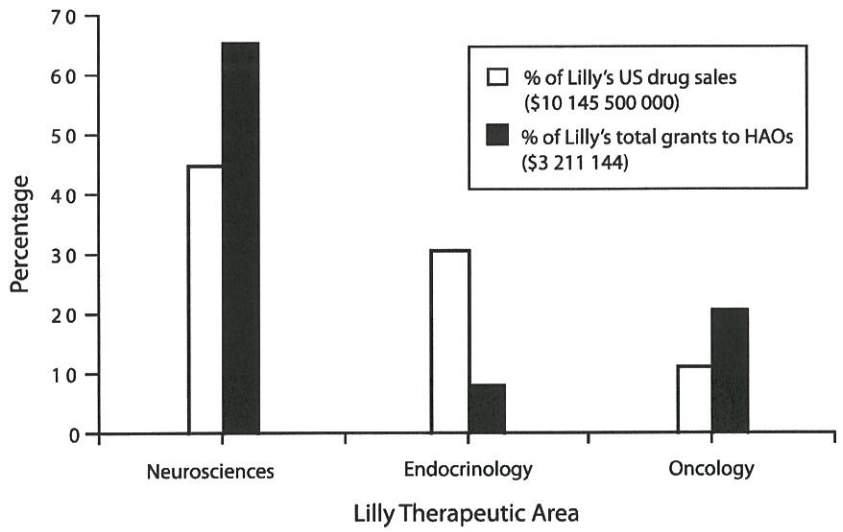

FIGURE 1—Lilly and Company's US sales and grants to US health advocacy organizations (HAOs), by therapeutic area, 2007.

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.■

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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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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

Part 1 of 3

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Updated — December 15, 2016 at 9:07 am ET

POLITICS OF PAIN: DRUGMAKERS FOUGHT STATE OPIOID LIMITS AMID CRISIS

Jennifer Weiss-Burke, executive director of a youth recovery center in Albuquerque, N.M., stands by one of the rooms at the recovery center named after her son, Cameron Weiss. He died of a heroin overdose in 2011. Weiss-Burke said her teenage son's descent into drug addiction started with an opioid prescription a doctor wrote for him for a wrestling injury. AP Photo/Mary Hudetz

Makers of prescription painkillers tried to kill state measures aimed at stemming the tide of opioid drugs

Liz Essley Whyte
State Politics Reporter

Geoff Mulvihill

Ben Wieder

This story was co-published with **The Associated Press**.

Editor's note: *This is the first installment of an ongoing series. The next stories explore how a loose coalition of drugmakers and industry-backed nonprofits shaped the federal response to the opioid crisis and how drugmakers are pushing a profitable, yet unproven, remedy.*

The makers of prescription painkillers have adopted a 50-state strategy that includes hundreds of lobbyists and millions in campaign contributions to help kill or weaken measures aimed at stemming the tide of prescription opioids, the drugs at the heart of a crisis that has cost 165,000 Americans their lives and pushed countless more to crippling addiction.

The drugmakers vow they're combating the addiction epidemic, but **The Associated Press**and the **Center for Public Integrity**found that they often employ a statehouse playbook of delay and defend that includes funding advocacy groups that use the veneer of independence to fight limits on the drugs, such as OxyContin, Vicodin and fentanyl, the narcotic linked to Prince's death.

The mother of Cameron Weiss was no match for the industry's high-powered lobbyists when she plunged into the corridors of New Mexico's Legislature, crusading for a measure she fervently believed would have saved her son's life.

It was a heroin overdose that eventually killed Cameron, not long before he would have turned 19. But his slippery descent to death started a few years earlier, when a hospital sent him home with a bottle of Percocet after he broke his collarbone in wrestling practice.

Jennifer Weiss-Burke pushed for a bill limiting initial prescriptions of opioid painkillers for acute pain to seven days. The bill exempted people with chronic pain, but opponents still fought back, with lobbyists for the pharmaceutical industry quietly mobilizing in increased numbers to quash the measure.

They didn't speak up in legislative hearings. "They were going individually talking to senators and representatives one-on-one," Weiss-Burke said.

Unknowingly, she had taken on a political powerhouse that spent more than $880 million nationwide on lobbying and campaign contributions from 2006 through 2015 — more than 200 times what those advocating for stricter policies spent and more than eight times what the formidable gun lobby recorded for similar activities during that same period.

The pharmaceutical companies and allied groups have a number of legislative interests in addition to opioids that account for a portion of their political activity, but their steady presence in state capitals means they're poised to jump in quickly on any debate that affects them.

Collectively, the AP and the Center for Public Integrity found, the drugmakers and allied advocacy groups employed an annual average of 1,350 lobbyists in legislative hubs from 2006 through 2015, when opioids' addictive nature came under increasing scrutiny.

"The opioid lobby has been doing everything it can to preserve the status quo of aggressive prescribing," said Dr. Andrew Kolodny, founder of **Physicians for Responsible Opioid Prescribing**and an outspoken advocate for opioid reform. "They are reaping enormous profits from aggressive prescribing."

About this project

This two-part investigation by the Center for Public Integrity and **The Associated Press**examines the politics behind the nation's opioid addiction epidemic.

AP reporters **Geoff Mulvihill**and **Matthew Perrone**and Center for Public Integrity reporters Liz Essley Whyte and Ben Wieder collaborated on the project for seven months.

Wieder collected and analyzed campaign finance and lobbying data covering 2006 through 2015 from the **National Institute on Money in State Politics**, **Center for Responsive Politics**, Federal Election Commission, the U.S. House of Representatives Office of the Clerk and the IRS.

Mulvihill, Perrone and Whyte reviewed hundreds of documents and interviewed more than 150 officials, experts, advocates and others to gain insights into how the political process influenced the response to the opioid epidemic.

Taken together, this information provides a unique national lookat how drugmakers and their allies often sought to delay stepsintended to combat opioid abuse while pushing their own priorities with lawmakers and regulators. The findings were provided in advance to news outlets around the country to help reporters prepare stories for their local audiences and augment their ongoing reporting about the nation's opioid crisis.

The drug companies say they are committed to solving the problems linked to their painkillers. Major opioid-makers have launched initiatives to, among other things, encourage more cautious prescribing, allow states to share databases of prescriptions and help stop drug dealers from obtaining pills.

And the industry and its allies have not been alone in fighting restrictions on opioids. Powerful doctors' groups are part of the fight in several states, arguing that lawmakers should not tell them how to practice medicine.

While drug regulation is usually handled at the federal level — where the makers of painkillers also have pushed back against attempts to impose restrictions — ordinary citizens struggling with the opioid crisis in their neighborhoods have looked to their state capitals for solutions.

Hundreds of opioid-related bills have been introduced at the state level just in the last several years. The few groups pleading for tighter prescription restrictions are mostly fledgling mom-and-pop organizations formed by families of young people killed by opioids. Together, they spent about $4 million nationwide at the state and federal level on political contributions and lobbying from 2006 through 2015 and employed an average of eight state lobbyists each year.

Prescription opioids are the synthetic cousins of heroin and morphine, prescribed to relieve pain. Sales of the drugs have boomed — quadrupling from 1999 to 2010 — and overdose deaths rose just as fast, totaling 165,000 this millennium. Last year, 227 million opioid prescriptions were doled out in the U.S., enough to hand a bottle of pills to nine out of every 10 American adults.

The drugmakers' revenues are robust, too: **Purdue Pharma**, the maker of OxyContin and one of the largest opioid producers by sales, pulled in an estimated $2.4 billion from opioids last year alone, according to estimates from health care information company **IMS Health**.

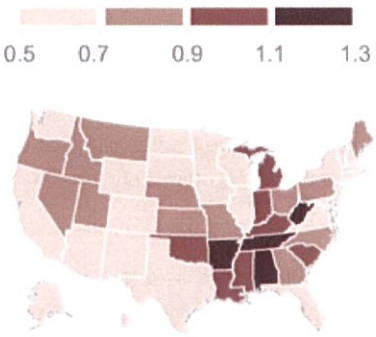
That's even after executives pleaded guilty to misleading the public about OxyContin's risk of addiction in 2007 and the company agreed to pay more than $600 million in fines.

The politics of pain

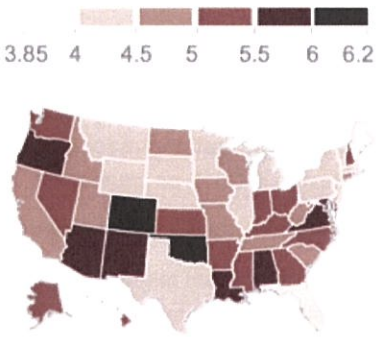
States nationwide are grappling with a devastating opioid crisis. Yet attempts at regulating pain medications have faced resistance from a powerful pro-drug political machine, the Center for Public Integrity and the AP found.

THE OPIOID PROBLEM

The rate of opioid prescriptions per adult was higher in the southeast. (*2014 data*)

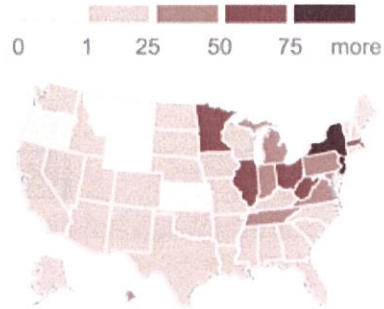


Nonmedical use of pain relievers in 2013 - 2014 among adults. *(percentages)*

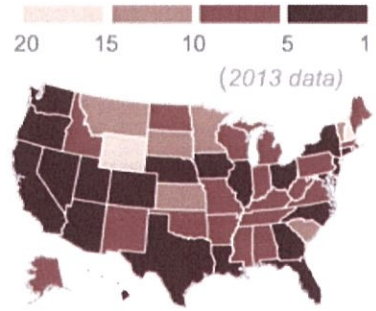


LEGISLATION AND LOBBYING

Number of state bills mentioning opioids. (*2013-16)*



Number of state legislators for each pro-opioid lobbyist.



POLITICAL SPENDING

Opioid manufacturers and their allies have contributed roughly $80 million to state and federal candidates and have spent about $746 million on state and federal lobbying since 2006. How the spending breaks down:

to State	to Federal	for State/Federal candidates	
$109 mil.	$716 mil.	45% Dems	54% Reps

SOURCES: Substance Abuse and Mental Health Services Administration; IMS Health; National Institute on Money in State Politics; Quorum; Federal Election Commission AP

Opioids can be dangerous even for people who follow doctors' orders, though they also help millions of people manage pain associated with cancer, injuries, surgeries and end-of-life care.

The industry group **Pharmaceutical Research and Manufacturers of America**issued a statement saying, "We and our members stand with patients, providers, law enforcement, policymakers and others in calling for and supporting national policies and action to address opioid abuse."

And Purdue said: "Purdue does not oppose — either directly or indirectly — policies that improve the way opioids are prescribed, including when those policies may result in decreased opioid use."

One of the chief solutions the drugmakers actively promote now are new formulations that make their products harder to crush or dissolve, thwarting abusers who want to snort or inject painkillers. But the new versions also extend the life of their profits with fresh patents, and some experts question their overall effectiveness.

A focus on pain treatment

An analysis of state records collected by the **National Institute on Money in State Politics**provides a snapshot of the drugmakers' battles to limit opioids. For instance, they show that pharmaceutical companies and their allies ramped up their lobbying and campaign contributions in New Mexico in 2012 as lawmakers considered — and ultimately killed — the bill backed by Cameron Weiss' mother.

But one of the drug companies' most powerful engines of political might isn't part of the public record — a largely unknown network of opioid-friendly nonprofits they help fund and meet with monthly known as the Pain Care Forum, formed more than a decade ago.

Combined, its participants contributed more than $24 million to 7,100 candidates for state-level offices from 2006 through 2015, with the largest amounts going to governors and the lawmakers who control legislative agendas, such as house speakers, senate presidents and health committee chairs.

Related Articles

POLITICS OF PAIN

Drugmakers fought domino effect of Washington opioid limits

READ

They've gotten involved in nitty-gritty fights even beyond legislatures. After Washington state leaders drafted the nation's first set of medical guidelines urging doctors not to prescribe high doses of opioids in 2007, the Pain Care Forum hired a public relations firm to convince the state medical board that the guidelines would hurt patients with chronic pain.

A sizable slice of the drugmakers' battles are carried out by pharma-funded advocates spreading opioid-friendly narratives — with their links to drug companies going unmentioned — or by persuading pharma-friendly lawmakers to introduce legislation drafted by the industry.

Two years ago, it was a major patient organization receiving grants from the opioid industry, the **American Cancer Society's Cancer Action Network**, that led the fight against a measure in Tennessee aimed at reducing the number of babies born addicted to narcotics.

And in Maine last year, drugmakers persuaded a state representative to successfully push a bill — drafted by the industry — requiring insurers to cover so-called abuse-deterrent painkillers, the new forms of opioids that are harder to abuse.

Legislatures have begun considering limits on the length of first-time opioid prescriptions. But the new laws and proposals in states including Connecticut and Massachusetts carve out a common exception: They do not apply to chronic pain patients. Drugmaker-funded pain groups, which can mobilize patients to appear at legislative hearings, advocate for the exceptions.

Many patients vouch that opioids have given them a better quality of life.

"There's such a hysteria going on" about those who have died from overdoses, said Barby Ingle, president of the **International Pain Foundation**, which receives pharmaceutical company funding. "There are millions who are living a better life who are on the medications long term."

That's contrary to what researchers are increasingly saying, however. Studies have shown weak or no evidence that opioids are effective ways to treat routine chronic pain. And one 2015 study from a hospital system in Pennsylvania found about 40 percent of chronic non-cancer pain patients receiving opioids had some signs of addiction and 4 percent had serious problems.

"You can create an awful lot of harm with seven days of opioid therapy," said Dr. **David Juurlink**, a toxicology expert at the University of Toronto. "You can send people down the pathway to addiction ... when they never would have been sent there otherwise."

A surprising opponent

Letting advocacy groups do the talking can be an especially effective tactic in state legislatures, where many lawmakers serve only part time and juggle complicated issues.

Lawmakers in Massachusetts, for example, said they didn't hear directly from pharmaceutical lobbyists when they took up opioid prescribing issues this year. But they did hear from a patient advocate with ongoing back pain who works with and volunteers for groups that receive some of their funding from pharmaceutical companies. She also brought in patients to meet with them.

"A lot of times those legislators, they don't have the ability to really thoroughly look into who these organizations are and who's funding them," said **Edward Walker**of the University of California Los Angeles, who studies grassroots groups.

Nonprofit advocacy groups led the countercharge in Tennessee in 2014 when Republican state Rep. **Ryan Williams**began work to stanch the flow of prescription painkillers, alarmed by a rapidly rising number of drug-addicted babies, who suffer from withdrawal in their first weeks of life and complications long after they leave the hospital.

More than 900 babies had been born addicted in Tennessee the year before, many of them hooked on the prescription opioids their mothers had taken. That number had climbed steadily since 2001, when there were fewer than 100.

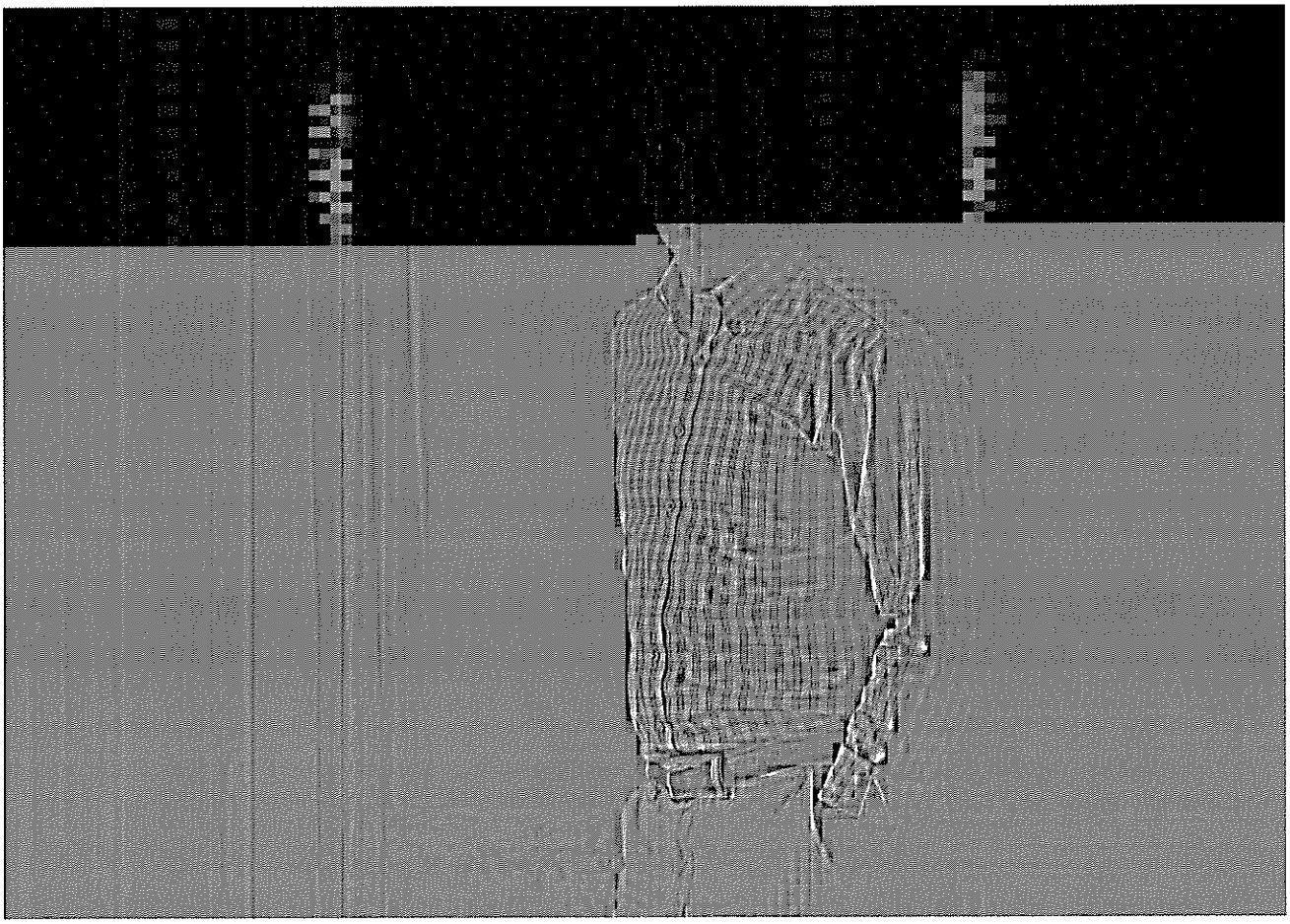
Whitney Moore and her husband adopted two girls born addicted to prescription opioids and other drugs in eastern Tennessee, and she still remembers her older daughter's cries in the hospital, "the most high-pitched scream you've ever heard in your life"— a common symptom in babies in the throes of withdrawal.

Doctors gave Moore's infant daughter morphine to ease her seizures, vomiting and diarrhea, and she stayed in a neonatal intensive care unit more than a month. Now 3 years old, she still suffers from gastrointestinal problems and remains sensitive to loud noises.

When Williams was mulling potential legislation, doctors told him that part of Tennessee's problem was a 2001 law — similar to measures on the books in more than a dozen states — that made it difficult to discipline doctors for dispensing opioids and allowed clinicians to refuse to prescribe powerful narcotics only if they steered patients to an opioid-friendly doctor.

The result, according to the experts Williams worked with, was a rash of prescribing, even for pregnant women. In 2014, Tennessee ranked third in the country for per-capita opioid prescriptions, with roughly 1.3 prescriptions doled out for every person in the state, according to an analysis of prescription data from IMS Health.

Williams' mission to repeal the law failed that year, and he was shocked by the group that came out in opposition — the American Cancer Society Cancer Action Network, the advocacy arm of one of the country's biggest and best-known charities.



Republican State Rep. Ryan Williams introduced a bill to put limits on opioid prescriptions in Tennessee, concerned about pregnant mothers getting hooked on opioids and passing the addiction on to their babies. Williams' mission failed that year, but his bill succeeded the next year. (AP Photo/Mark Zaleski)

Two Cancer Society lobbyists worked against the bill, even though prescribing painkillers for cancer patients is a widely accepted medical practice that would have remained legal.

"We injected ourselves into the debate because we did not want cancer patients to not be able to have access to their medication," said Theodore Morrison, a lobbyist working for the network that year.

The society's annual ranks of about 200 lobbyists around the country have taken similar positions elsewhere, defending rules that some argue encourage extensive prescriptions and opposing opioid measures even if the proposed legislation specifically exempted cancer patients.

The Cancer Action Network listed four major opioid makers that provided funding of at least $100,000 in 2015, in addition to five that contributed at least $25,000. Companies that donate such sums get **one-on-one meetings**with the group's leaders and other chances to discuss policy.

The network said only 6 percent of its funding last year came from drugmakers and that its ties to drug companies do not influence the positions it takes. "ACS CAN's only constituents are cancer patients, survivors, and their loved ones nationwide," spokesman Dave Woodmansee said.

The network said it advocates for certain measures despite exemptions for cancer because some patients continue to experience pain even after their cancer is gone.

ACS CAN teamed up with another group to defend the Tennessee painkiller law — the Academy of Integrative Pain Management, an association of doctors, chiropractors, acupuncturists and others who treat pain, until recently known as the **American Academy of Pain Management**. The group promotes access to pain drugs as well as non-pharmaceutical treatments such as acupuncture.

Seven of the academy's nine corporate council members **listed online**are opioid makers. The other two are **AstraZeneca**, which has invested heavily in a drug to treat opioid-induced constipation, and Medtronic, which makes implantable devices that deliver pain medicine.

The academy's executive director, Bob Twillman, said his organization receives 15 percent of its funding from pharmaceutical companies, not including revenue from advertisements in its publications. Its **state advocacy project**is 100 percent funded by drugmakers and their allies, but he said that does not mean it is beholden to pharmaceutical interests.

"We don't always do the things they want us to do," he said. "Most of the time we're saying, 'Gosh, yes, there should be some limits on opioid prescribing, reasonable limits,' but I don't think they would be in favor of that."

Both the academy and the cancer group have been active across the country, making the case that lawmakers should balance efforts to address the opioid crisis with the needs of chronic pain patients. Between them, they have contacted legislators and other officials about opioid-related measures in at least 18 states.

In Massachusetts this year, they helped persuade lawmakers to soften strict proposals that would have limited first-time opioid prescriptions to three days' worth. They also have weighed in on how often doctors should be required to check prescription-monitoring databases, which can help crack down on prescription-shopping with multiple doctors.

The academy reported on its website that, since 2013, its state advocacy network had provided "extensive comments" on clinician guidelines in New Mexico, Pennsylvania, Indiana and elsewhere; issued action alerts resulting in more than 300 emails and phone calls to more than 80 legislators in 2014 alone; and held teleconferences with more than 100 advocates.

Purdue, which gives to both the academy and the cancer network, said it contributes to a range of advocacy groups, including some with differing views on opioid policy. "It is imperative that we have legitimate policy debates without trying to silence those with whom we disagree. That's the American political system at work," the company said in a statement.

As for Williams, he tried again last year to repeal Tennessee's intractable pain law — and won unanimous approval in both houses. The extra year had given Williams and his co-sponsor time to help educate their fellow lawmakers, he said, even though the Cancer Society still opposed the repeal.

Lobbyists 'were killing it'

The tried-and-true tactics of lobbying and campaign contributions remain a major plank of the pharmaceutical playbook. In 2014 alone, for instance, participants in the Pain Care Forum spent at least $14 million nationwide on state-level lobbying.

Two years earlier — facing the threat of limits on opioid-prescribing — forum members had upped their number of lobbyists in New Mexico, which is second only to West Virginia in per-capita deaths primarily due to prescription and illegal opioid drugs, according to the most recent federal data available.

After Cameron Weiss's death from a heroin overdose in 2011, his mother pushed for a bill in New Mexico limiting initial prescriptions of opioid painkillers for acute pain to seven days. The bill exempted people with chronic pain, but opponents still fought back, with lobbyists for the pharmaceutical industry quietly mobilizing in increased numbers to quash the measure.
(Jennifer Weiss-Burke via AP)

The aim of the bill Jennifer Weiss-Burke backed was to limit initial prescriptions of opioids for acute pain to seven days to make addictions less likely and produce fewer leftover pills that could be peddled illegally.

After her son had left the hospital with his first bottle of Percocet in 2009 at the age of 16, the Albuquerque teen had suffered two more injuries and gotten two more prescriptions. He also took pills he found at his grandparents' house. Less than a year later, he started smoking heroin, which costs less than black-market prescription drugs.

He repeatedly went into rehab, and just as repeatedly relapsed. In August 2011, his mother found him at home, dead.

Weiss-Burke said she didn't realize how dangerous prescription pills could be until her son already had moved on to heroin, a tortuous progression mirrored by the downward spirals of tens of thousands of other people across the country.

Heeding concerns from the state medical society, the bill's sponsors amended it to allow the boards overseeing doctors and other prescribers to set their own limits. Still, the bill died in the House Judiciary Committee.

"The lobbyists behind the scenes were killing it," said Bernadette Sanchez, the Democratic state senator who sponsored the measure.

Lobbyists for three Pain Care Forum members declined to comment, saying they were not authorized to speak about their clients' work.

Forum participants had 15 lobbyists registered in New Mexico that year, up from nine the previous year. One was reported to be working out of the office of a high-ranking lawmaker; another was a former lawmaker himself.

Pfizer said that its two lobbyists in Santa Fe — up from one — reflected a change in firms, not an addition, and that the company did not lobby on opioid restrictions.

Still, the majority of the judiciary committee received drug industry contributions in 2012. Overall that year, drug companies and their employees contributed nearly $40,000 to New Mexico campaigns — roughly 70 percent more than in previous years with no governor's race on the ballot.

In New Mexico alone, opioid makers spent $32,000 lobbying in 2012 — more than double their outlay the year before.

Restrictions like the ones considered in New Mexico did not become law anywhere until this year, after the U.S. Centers for Disease Control and Prevention **called for even tighter restrictions**. In 2016, they have been adopted in Connecticut, Maine, Massachusetts, New York and Rhode Island, all with exceptions for patients with chronic pain.

The next frontier

Now, pharmaceutical companies are directing their lobbying efforts to their new legislative frontier in the states — medicines known as abuse-deterrent formulations. These drugs ultimately are more lucrative, since they're protected by patent and do not yet have generic competitors. They cost insurers more than generic opioids without the tamper-resistant technology.

Skeptics warn that they carry the same risks of addiction as other opioid versions, and the U.S. Food and Drug Administration noted that they don't prevent the most common form of abuse — swallowing pills whole.

"This is a way that the pharmaceutical industry can evade responsibility, get new patents and continue to pump pills into the system," said Dr. **Anna Lembke**, chief of addiction medicine at the Stanford University School of Medicine and author of a book on the opioid epidemic.

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Pro-painkiller echo chamber shaped policy amid drug epidemic

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Pharma lobbying held deep influence over opioid policies

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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,

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Disorders, Medical Disciplines) or H (Medical Research). The $7.5 million cutoff was selected to ensure a sufficiently sizable sample of large organizations. This query returned 756 organizations, which included patient-advocacy organizations as well as other nonprofit organizations — such as hospitals and professional societies — that engaged in health-related activities. We excluded organizations that were not patient-advocacy organizations, as well as regional organizations (e.g., local chapters of national organizations) and internationally focused organizations, leaving 104 organizations for the final analysis. For a list of all organizations included in the study as well as detailed inclusion and exclusion criteria, see the Supplementary Appendix, available with the full text of this article at NEJM.org.

DATA COLLECTION

From January through June 2016, we reviewed the Form 990 tax records, annual reports, and websites of each organization included in the study. Data collection followed a standardized process for each organization. (For details, see the Supplementary Appendix.) We began by visiting the website of the organization and downloading the most current annual report and Form 990 available. Tax forms were reviewed to confirm the annual revenue of the organization in order to calculate the percentage of its annual revenue made up of industry donations. Annual reports were reviewed in four steps. First, we determined whether the annual report included a list of donors and, when donor lists were available, whether they included the amounts or uses of individual donations. Second, if an organization reported receiving donations from drug, device, or biotechnology companies, we recorded the names of the donors and, if available, the amounts and uses of the donations. Third, we searched the annual report for the names and employment information of the board members of the organization. Fourth, if any board members were employed by a drug, device, or biotechnology company, we recorded their names, employers, and positions on the board.

Websites were reviewed with the use of the same four-step process. In addition, we searched websites for conflict-of-interest policies or policies on accepting corporate donations and recorded the entire text of such policies when available.

STATISTICAL ANALYSIS

Descriptive statistics and frequencies were calculated with the use of Microsoft Excel. When patient-advocacy organizations reported the amounts of individual donations that they received, we summed donations from drug, device, and biotechnology companies to calculate the total revenue that each organization received from industry donations. Revenue from industry donations was then divided by the annual revenue of the organization to calculate the percentage of its revenue accounted for by industry donations. When organizations reported donation amounts using ranges (e.g., $100,000 to $249,999) rather than exact figures, we calculated the maximum and minimum values of industry donations. Maximum values were calculated under the assumption that all donations fell at the upper bound of reported ranges; minimum values were calculated under the assumption that all donations fell at the lower bound of reported ranges. Maximum and minimum donation values were then divided by the annual revenue of the organization to determine the maximum and minimum percentage of annual revenue from industry donations.

RESULTS

CHARACTERISTICS OF THE ORGANIZATIONS

Our analysis included 104 patient-advocacy organizations. More than a third of these organizations (37%) focused on a variety of cancer; more than half had annual revenues of $7.5 million to $24.9 million. For more on the characteristics of the organizations, see Table 1.

DISCLOSURE PRACTICES

Overall, 91 of the 104 patient-advocacy organizations (88%) published a list of donors either on the website of the organization or in the annual report (Table 2). Two of the 91 organizations stated explicitly that published donor lists included all corporate donors.

Of the 104 organizations, 57% published the amounts of received donations. Only 5% published the exact amounts of received donations, whereas 52% published donation amounts in

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Table 1. Characteristics of Patient-Advocacy Organizations.

Characteristic	Organizations (N = 104)
	no. (%)
Disease area	
Cancer	38 (37)
Neurologic	13 (12)
HIV–AIDS	7 (7)
Musculoskeletal	6 (6)
Heart or lung	5 (5)
Vision	4 (4)
Kidney	3 (3)
Diabetes	2 (2)
Mental health	2 (2)
Lupus	2 (2)
Other disease or condition*	11 (11)
General†	11 (11)
Annual revenue, in millions of $‡	
7.5–24.9	60 (58)
25.0–49.9	18 (17)
50.0–74.9	5 (5)
75.0–99.9	5 (5)
100.0–124.9	2 (2)
125.0–149.9	4 (4)
150.0–174.9	1 (1)
175.0–199.9	2 (2)
200.0–224.9	1 (1)
225.0–249.9	0
≥250.0	6 (6)

* These organizations are active in a single disease area that is not captured by the categories in the table. Examples include the American Liver Foundation, Alpha-1 Foundation, and Crohn's and Colitis Foundation of America.

† These organizations claim to serve a broad group of patients rather than patients in a particular disease area. Examples include Community Health Charities, National Organization for Rare Disorders, and Patient Advocate Foundation.

‡ Annual revenues are reported on the basis of the most recent Form 990 tax records made available by the organization at the time of data collection.

ranges. The difference between the upper and lower bounds of reported ranges varied considerably, from less than $250 to more than $1 million. Nearly two thirds (31 of 54) of the organizations that published donations using ranges included an unbounded upper range (e.g., >$1 million). Of the 104 organizations, 18 specified the total amount of industry or corporate donations that they received; 10 provided information about how individual donations were used.

Almost all the organizations (97%) published the names of board members. A total of 74% of the 104 organizations provided board members' employment information.

FINANCIAL SUPPORT

Overall, 86 of the 104 patient-advocacy organizations (83%) reported receiving financial support from industry. Of the 18 organizations that did not report receiving industry support, 13 provided no donor information. Only 1 of the 104 organizations explicitly indicated that it does not accept industry support.

Given that donation amounts were typically reported in ranges, it is impossible in most cases to provide precise estimates of the amount of industry support that patient-advocacy organizations received. Of the 59 organizations that published the amounts of donations, 23 (39%) reported receiving at least $1 million annually from industry donations; 13 (22%) reported receiving less than $1 million; and 23 (39%) reported information that did not allow a determination of whether industry donations were less than $1 million or at least $1 million (Table 3). There are two reasons for this ambiguity. For some organizations, the minimum value of the reported donations was less than $1 million and the maximum value was more than $1 million. Other organizations did not definitively report industry donations of at least $1 million but reported donations using unbounded upper ranges, thus making it impossible to cap the maximum value of the reported donations. With respect to the percentage of annual revenue, 11 of the 59 organizations (19%) that reported donation amounts reported receiving at least 10% of annual revenue from industry donations; 20 (34%) reported receiving less than 10% of annual revenue from industry donations; and 28 (47%) reported information that did not allow a determination of whether industry donations accounted for less than 10% or at least 10% of annual revenue.

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Table 2. **Information Disclosed by Patient-Advocacy Organizations on Websites or in Annual Reports.**

Information Disclosed	Website (N=104)	Annual Report (N=104)	Website or Annual Report (N=104)
	number of organizations (percent)		
Financial support			
Names of donors	60 (58)	67 (64)	91 (88)
Amount of individual donations	23 (22)	48 (46)	59 (57)
Range	19 (18)	47 (45)	54 (52)
Exact figure	4 (4)	1 (1)	5 (5)
Uses of individual donations	9 (9)	4 (4)	10 (10)
Total revenue received from industry or corporate donations*	8 (8)	12 (12)	18 (17)
Board membership			
Names of board members	101 (97)	84 (81)	101 (97)
Board members' employment information	76 (73)	35 (34)	77 (74)

* The organization made an explicit statement indicating the total amount of revenue that it received from drug, device, or biotechnology companies or from all corporate donors.

BOARD MEMBERSHIP

Of the 104 patient-advocacy organizations, 37 (36%) reported at least one current drug, device, or biotechnology company executive on the governing board. In addition, 4 organizations reported at least one former industry executive on the board. A total of 12 of the 104 organizations (12%) reported that a current drug, device, or biotechnology executive held a leadership position on the board, such as chair or vice-chair, with 1 additional organization reporting a former industry executive in a board leadership position. Roughly one quarter of patient-advocacy organizations (26%) provided no employment information for board members.

CONFLICT-OF-INTEREST POLICIES

Of the 104 patient-advocacy organizations, 27 published any policy pertaining to conflicts of interest on the website of the organization. We analyzed the content of these policies and found that 12 organizations had a policy that addressed institutional conflicts of interest — that is, conflicts of interest arising from the relationships between the organization and the corporate donors or other partners. Other conflict-of-interest policies dealt only with the individual

Table 3. **Annual Revenue from Reported Industry Donations across Patient-Advocacy Organizations That Disclosed Donation Amounts.**

Annual Revenue from Industry Donations	Organizations (N=59)
	no. (%)
In total dollars	
≥$1 million*	23 (39)
<$1 million†	13 (22)
Unclear‡	23 (39)
As percentage of annual revenue	
≥10%*	11 (19)
<10%†	20 (34)
Unclear‡	28 (47)

* Shown are organizations that received at least $1 million (or 10% of annual revenue) on the basis of the minimum value of industry donations.
† Shown are organizations that received less than $1 million (or 10% of annual revenue) on the basis of the maximum value of industry donations. Included are two organizations — Child Mind Institute and Children's Cancer Recovery Foundation — that reported no donations from industry.
‡ Shown are organizations with a minimum value of industry donations of less than $1 million (or 10% of annual revenue) and a maximum value of industry donations of at least $1 million (or 10% of annual revenue) and organizations that did not definitively report industry donations of at least $1 million (or 10% of annual revenue) but reported donations using unbounded ranges.

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conduct of the employees and board members of the organization.

DISCUSSION

This study shows that among 104 of the largest U.S.-based patient-advocacy organizations, at least 83% received financial support from drug, device, and biotechnology companies, and at least 39% have a current or former industry executive on the governing board. Our results raise four points worth highlighting.

First, industry financial support of patient-advocacy organizations is widespread, with at least 83% of reviewed organizations receiving financial support from drug, device, and biotechnology companies. By comparison, a recent study showed that 41% of physicians across all specialties received industry payments in 2013–2014.[19] Moreover, although there is considerable variation in the levels of declared industry support across patient-advocacy organizations, we found that the support was often substantial, with at least 39% of the organizations that disclosed donation amounts receiving at least $1 million annually from industry.

Second, although existing studies of the relationships between patient-advocacy organizations and industry have focused almost exclusively on financial support from industry, it is important to recognize that conflicts of interest can also arise as a result of the competing interests of board members and senior officials. We found that ties between patient-advocacy organizations and industry are reflected in the governance structures of many organizations: at least 39% of patient-advocacy organizations have a current or former industry executive on the board, and at least 12% have a current or former industry executive in a leadership position on the board.

Third, current disclosure practices of patient-advocacy organizations are limited. Although we can conclude that industry support for such organizations is common, the full scope of this support and the severity of conflicts of interest remain difficult to determine given the disclosures of the organizations. Many of the organizations (88%) published the names of donors in the annual report or on the website of the organization. Although these donor lists are necessary for determining the existence of conflicts of interest, they are insufficient for assessing the severity of such conflicts, which requires knowing — at a minimum — the amounts of donations and the uses to which donations were put. We found that full disclosure of this information was rare. Over half (57%) of the 104 organizations disclosed the amounts of the donations that they received. However, disclosure of donation amounts was typically done with the use of broad ranges rather than exact figures. Disclosure of donation uses was rarer, with only 10% of patient-advocacy organizations providing such information.

Fourth, we found little evidence of self-regulation of conflicts of interest among patient-advocacy organizations. Only 12% of such organizations have published policies in place for managing institutional conflicts of interest. Having conflict-of-interest policies in place does not ensure that they will be followed, nor does it eliminate conflicts of interest. However, sound, publicly accessible policies are generally thought to reduce the likelihood of harm resulting from conflicts of interest while fostering public trust.[13]

Our study has several limitations. First, because we relied on publicly disclosed data, we cannot determine the extent to which patient-advocacy organizations received unreported or underreported industry donations. Consequently, our findings are likely to underestimate the full scope of industry support for patient-advocacy organizations. Second, companies can channel donations to patient-advocacy organizations through nonprofit entities that they control or substantially fund but that are not readily identifiable with those companies. Any donations of this type are not captured by our findings. Third, we studied high-revenue patient-advocacy organizations and are thus unable to draw conclusions about the reporting practices and industry ties of smaller organizations with annual revenues of less than $7.5 million. Larger organizations are likely to have more resources to devote to tracking donations and maintaining up-to-date websites and annual reports. Thus, our findings may overestimate the extent to which patient-advocacy organizations disclose industry support.

Taken together, the ubiquity of industry support for patient-advocacy organizations, the variation in levels of support, and the limitations of

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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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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

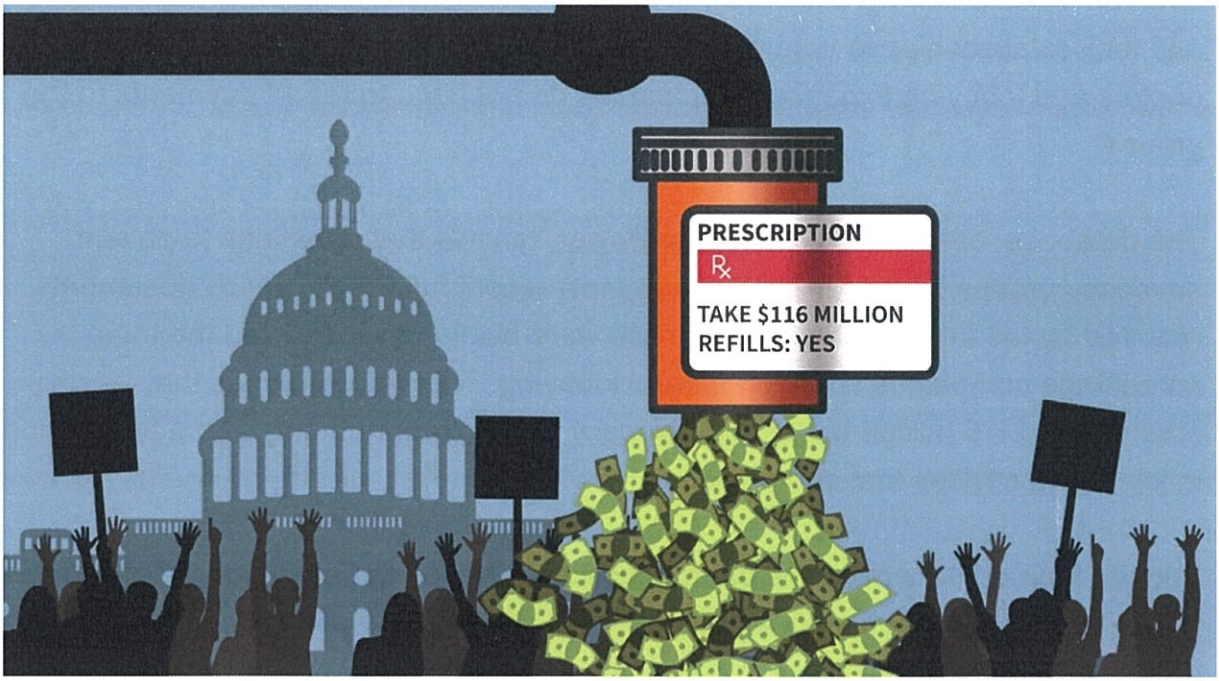
It is my hope that following everything you hear from the various patient groups and stakeholders that this committee will recommend legislation, as 28 other states have, to reign in PBMs' influence on drug prices, keep patients at the center of healthcare decision-making, and significantly reduce healthcare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



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.

How Many Patient Groups Received Pharmaceutical Funding?

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

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.

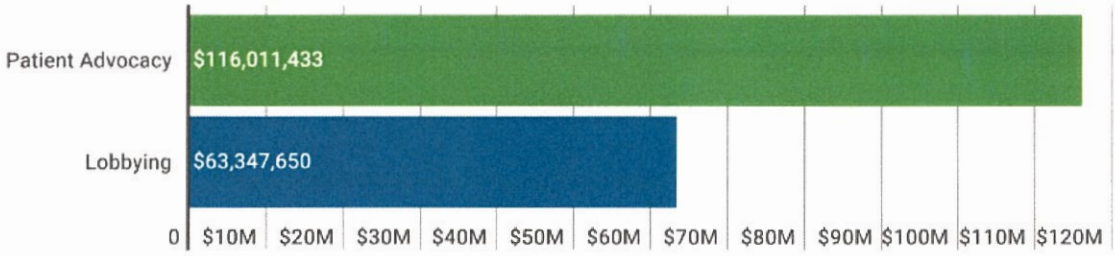
A coalition of patient groups, Patients for Biologics Safety & Access, opposes the automatic substitution of a cheaper biosimilar when doctors prescribe a biologic. In 2015, members of that coalition, including the Crohn's & Colitis Foundation, the Arthritis Foundation and the Lupus Foundation of America, 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.

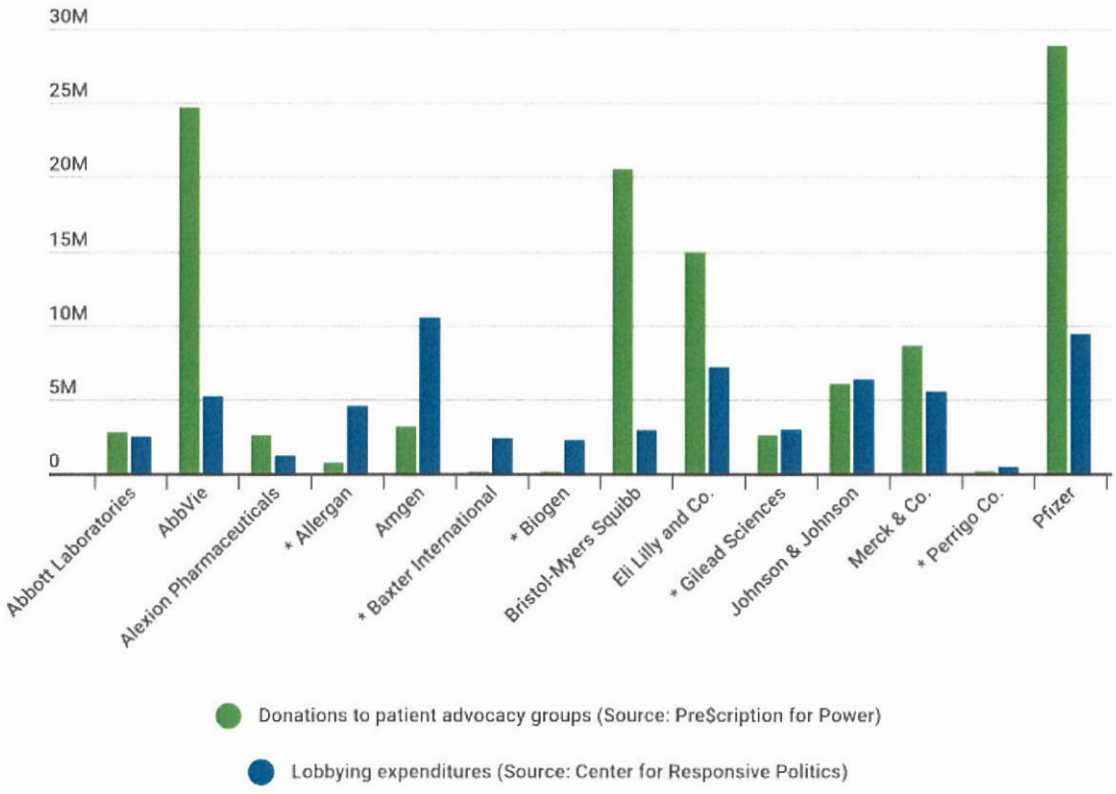
The Arthritis Foundation did not deny receiving the money but said the foundation represents patients, not sponsors. It is "optimistic" about biosimilars' ability to help patients and save them money, said Anna Hyde, vice president of advocacy and access. "The Foundation supports the Food and Drug Administration's 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.





**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."

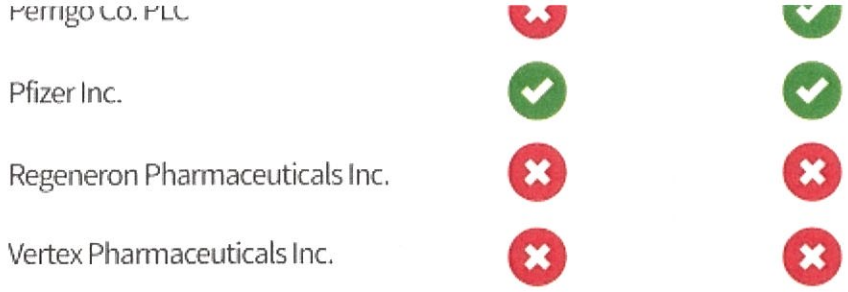
Soon after, breast cancer patients started visiting the Hill more frequently. Patients with other diseases followed. Over time, patients' voices became a potent force, often with industry support.

> *"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



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.

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March 5, 2019

The Honorable Edward Butler, Chair
House Commerce and Consumer Affairs Committee
Legislative Office Building Room 302
Concord, NH 03301

Re: New Futures' support of HB 695

Dear Chairman Butler 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 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. 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 its 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

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.

Rx WHEN YOU LIMIT DRUG THERAPIES, YOU THREATEN LIVES.

Every patient is different. A drug therapy that works for one may not work for another. That's why for more than a decade, Medicare beneficiaries have had access to cutting-edge FDA-approved therapies included in the "six protected classes" to treat their cancer, organ transplants, epilepsy, HIV/AIDS and mental illness. Our patients know this policy works and it saves lives. But a proposal from the administration could interfere with what doctors think is the best course of treatment for their patients and if finalized, could delay patients' access to lifesaving innovative therapies. It's wrong and it will put patients' lives at risk.

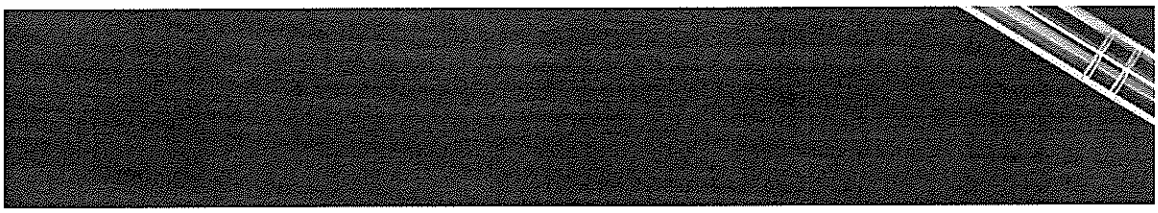
USE AS DIRECTED.

Tell Secretary Azar and Congress: Protect patients' lives and stop the proposed changes to Medicare Part D's Six Protected Classes. Don't delay access to lifesaving medicines for patients living with cancer, organ transplants, epilepsy, HIV/AIDS or mental illness.

- Addario Lung Cancer Medical Institute
- Advocates for Responsible Care
- Alliance for Patient Access
- American Autoimmune Related Diseases Association
- American Brain Coalition
- American Cancer Society Cancer Action Network
- American Heart Association
- American Kidney Fund
- American Lung Association
- American Medical Association
- American Society of Clinical Oncology
- American Society of Consultant Pharmacists
- Bladder Cancer Advocacy Network
- Bonnie J. Addario Lung Cancer Foundation
- Cancer*Care*
- Cancer Support Community
- Center for Health Law and Policy Innovation
- Colorectal Cancer Alliance
- COPD Foundation
- Deadliest Cancers Coalition
- Disability Rights Legal Center
- Epilepsy Foundation
- Esophageal Cancer Action Network, Inc.
- Fight Colorectal Cancer
- FORCE: Facing Our Risk of Cancer Empowered
- Global Healthy Living Foundation
- Global Liver Institute
- ICAN, International Cancer Advocacy Network
- International Myeloma Foundation
- Long Term Care Community Coalition
- Lung Cancer Alliance
- LUNGevity Foundation
- Lupus and Allied Diseases Association, Inc.
- Lupus Foundation of America
- MAPRx Coalition
- Men's Health Network
- Mental Health America
- Metastatic Breast Cancer Alliance
- Metastatic Breast Cancer Network
- METAvivor Research and Support
- Movement Disorders Policy Coalition
- NASTAD
- National Alliance on Mental Illness
- National Blood Clot Alliance
- National Brain Tumor Society
- National Coalition for Cancer Survivorship
- National Comprehensive Cancer Network
- National Council for Behavioral Health
- National Health Council
- National Hemophilia Foundation
- National Infusion Center Association
- National Kidney Foundation
- National Organization for Rare Disorders
- National Patient Advocate Foundation
- Susan G. Komen
- The AIDS Institute
- Tuberous Sclerosis Alliance

SIGNATURE: *Paid for by American Cancer Society Cancer Action Network*

Make your voice heard at **fightcancer.org/sixprotectedclasses**



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."

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Bill as Introduced

HB 695 - AS INTRODUCED

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

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 and carriers. 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.

19-0735
01/04

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. On or before January 1 of each year, a nonprofit organization which is tax exempt pursuant to section 501(c)(3) of the Internal Revenue Code that advocates on behalf of patients or funds medical research in New Hampshire and has received a payment, donation, subsidy or anything else of value from a pharmaceutical manufacture, health insurance carrier, or pharmacy benefit manager, or a trade or advocacy group for pharmaceutical manufactures, health insurance carrier, or pharmacy benefit managers during the immediately preceding calendar year shall compile a report which includes:

(a) 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;

(b) 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; and

(c) A disclosure that the nonprofit organization has received a payment, donation, subsidy, or other contribution from a pharmaceutical manufacture, health insurance carrier, pharmacy benefit manager, or group when testifying, lobbying, or otherwise engaging with a member of the New Hampshire house of representatives or senate.

II. The nonprofit organization shall post the report on the Internet website that is maintained by the nonprofit organization and accessible to 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 complied pursuant to paragraph I to the insurance commissioner.

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