Pharma and Patient Advocacy Groups

Patient Centricity Finally Pays Off for Both

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“Patient Centricity” is finally paying off for drug companies in a BIG way, but it has nothing to do with designing clinical trials or marketing, both of which could claim to have been patient centric for many years.

The big patient-centricity payoff for pharma is its relationship with patient advocacy groups that are recruited to lobby Congress, local governments and the FDA to support industry-friendly legislation (or defeat anti-industry legislation) and influence the FDA drug approval process.

The Project on Government Oversight (POGO), for example, reports that at least 39 of 42 patient advocacy groups who participated in discussions with the FDA over agency review processes for prescription drugs received funding from pharmaceutical companies. Other studies have also shown that a majority of patient advocacy groups receive funding from the drug industry.

Pharma funding of patient advocacy groups is not new and I have written about this many times in the past dozen or more years.

Back in 2006, for example, I reported on the ties between the pharma industry and the Restless Leg Syndrome (RLS) Foundation. GSK and Boehringer Ingelheim—pharmaceutical companies that market treatments for RLS—were “Gold Level Sponsors” of the RLS Foundation.

Not only that, the first RLS Foundation Science Award went to Ronald L. Krall, MD, Senior VP of Worldwide Development at GSK! That was a first! Pipe money into a foundation and voilà! you (or a VP in your company) gets an award!

But what really gave away the secret that this organization was nothing more than an “astroturf” creation of GSK was that the color scheme of the Foundation’s website even matched that of the Requip.com website!

OK. That’s old news. But what is new is funding patient advocates to explicitly influence the FDA drug approval process. This was evident when in 2014 Sprout Pharmaceuticals, which at the time was seeking FDA approval for Addyi—a female sexual dysfunction drug—initiated a ground-breaking campaign called “Even the Score.”

The campaign included paying for a busload of women carrying gift bags, matching scarves, and large buttons with the “Even the Score” campaign slogan to testify at an October 27, 2014, FDA public hearing on Female Sexual Dysfunction. The majority of the patient panelists and those who spoke from the audience reported financial support from professional groups connected to pharmaceutical companies.

Now that the FDA is pro-actively inviting patients to testify at public hearings and even setting up a “Patient Engagement Advisory Committee,” the formerly meaningless “patient centricity” buzzword has taken on a new meaning for pharma marketers and PR specialists.

The following pages provide more details about the relationship between the pharmaceutical industry and patient advocates especially as it affects the drug approval process.

Continues...
The Yin Yang of Patient Advocate Groups and the Pharma Industry

[From www.pharmexec.com, April 3, 2017] FDA-industry user fee agreements in recent years have promoted "patient centricity" and strategies for giving the "patient voice" a more visible and articulate role in calculating the benefits as well as risks in drug testing and market approval. Patient groups now are more involved in agency deliberations over development strategies for specific drug classes and in vetting approval pathways for new medicines.

Greater patient involvement in regulatory processes, though, has boosted scrutiny of drug company financial support for independent patient organizations, raising questions about whether the views expressed by such groups fully reflect broader public needs and values. These concerns have been heightened by analyses documenting industry financial support of patient organizations.

More about those studies here...

Further Reading:

- The New, Patient-Centric FDA: A Double-edged Sword
- #Pharma's "Patient Centricity" Pays Off: Patient Groups Mum on Drug Costs

Mobile-Enabled Patient Focus Groups

[From www.pharmamarketingtalk.com] A conversation with WEGO Health CEO Jack Barrette and Fabio Gratton, co-founder and CEO of Vocalize, about Truvio, a new mobile-based market research tool that brings patient opinion leader insights to life with data visualizations and audio commentary.

Truvio is powered by the WEGO Health Activist Network of more than 65,000 opted-in and vetted consumer health influencers from more than 130 health conditions and topics.

Listen to this podcast here...
FDA May Establish "Office of Patient Affairs" to Capture Patient Perspectives

[From www.raps.org, March 15, 2017] As part of efforts to better capture patients’ perspectives, the US Food and Drug Administration (FDA) on Monday said it is considering establishing an "Office of Patient Affairs," to be tasked with supporting and coordinating patient engagement across the agency.

The office would likely host and maintain data management systems to incorporate and formalize knowledge shared with FDA by patient stakeholders and FDA’s relationships with patient communities, and the office would be part of efforts to develop a scalable and forward-looking platform for communicating with patient stakeholders, particularly online.

More here...

The New, Patient-Centric FDA: A Double-edged Sword

[From ht.ly, Sept 10, 2016] Here are some FDA actions that should warm the cockles of the heart of patient engagement advocates in the future, according to a report published by PricewaterhouseCoopers's Health Research Institute.

- Between 2017 and 2021, the agency expects to hire additional staff focused on engaging with patients and facilitating the development as well as use of patient-focused drug development methods.
- In 2018, FDA is expected to provide draft guidance describing approaches to collecting patient and caregiver input.
- In 2019, the agency plans to issue draft guidance describing how companies can collect information from patients, and how that information can be used in the drug development and regulatory decision-making process.
- Another draft guidance describing how meaningful patient perspectives and information can be collected in clinical trials is expected in 2020.
- And finally, a draft guidance on patient-reported outcome measures to replace the one released in 2009 is set to be available come 2021.

While FDA is dabbling with patient engagement strategies, on the flip side, patient advocacy groups are also getting involved in the regulatory space (read, for example, "How a #pharma Funded 'Grassroots' Patient Advocacy Campaign Changed FDA's Approval Process").

"While patient input is unlikely to improve the approval chances of a drug lacking solid efficacy and safety data, regulators may be more willing to work with companies that are developing a product in close concert with engaged or especially ill patient populations," advised PricewaterhouseCoopers.

More here...
How Patient Advocates Make Money from Pharma with Help from Agents

[From www.fastcompany.com, February 21, 2017]

Leanna Mullen has Gaucher's disease, a rare genetic disorder that is associated with a variety of debilitating symptoms, from lung disease to arthritis. Mullen, a New Jersey-based television producer in her late twenties, has built up a vast network in the patient advocacy community and has used her media platform to raise awareness of her disease. Several months ago, she was contacted by a research firm called BrandTrust regarding a survey into the mental health of patients with Gaucher's. She was told that the information would be delivered to a pharmaceutical company, but she declined to disclose the company to me after signing a non-disclosure agreement.

If Mullen could recruit a diverse set of patients to participate in the research, she would be paid about 80% of a $10,000 fee. "I had the connections, and was able to recruit almost my entire demographic within two or three days," she says. Mullen was able to reach out directly to patients in closed Facebook groups and private forums, which would have been off-limits to recruiters.

Mullen says she did not disclose in every discussion that she would be paid, as she figured that it would be obvious. "They're aware that there's usually some sort of headhunter," she says. Also, she figured that the risk would be low, as it was a survey rather than a clinical trial.

Bioethicists such as New York University's Arthur Caplan have some concerns... Caplan suggests that guidelines should be formulated to clarify how patients should disclose conflicts of interest, if they're getting paid. That's particularly important if they're being asked to recruit for a potentially risky clinical study.

More here...

Further Reading:

- **Transparency is Good in Theory, But Not in Practice**
- **Novartis Respects the Patient Perspective and Pays for It Too! But Is It Absolutely Transparent?**
- **Pharma-Patient Collaboration: Activist Survey is a "Wake Up Call"**
- What do you think? **Should Pharma Hire Online "Patient Opinion Leaders"?**
#Pharma Turning Patients With Rare Diseases Into D.C. Lobbyists

[From www.thedailybeast.com, April 10, 2017] The pharmaceutical industry is teaming up with advocacy groups that are training and even paying for patients who need their medicines to promote their causes in Washington.

Dr. Ezekiel Emanuel, a bioethicist who has studied the issue, said he questions whether patient advocacy groups truly are "white knights defending the good fight." He said research suggests that the conflicts of interest that occur when drug companies train and finance patient groups are "pretty rampant."

Emanuel co-authored a March study that found 83 percent of the 104 largest patient advocacy groups take money from the drug, medical device, and biotech industries (read "83% of Patient-Advocacy Organizations Receive Substantial Financial Support from the Drug Industry But Few Disclose How Much"). Smaller organizations are even more likely to be disproportionately dependent on industry funding for their operating budgets, he said.

The patient-lobbying conference, organized by the EveryLife Foundation for Rare Diseases, underlines how the financial interests of manufacturers and the medical needs of patients are intertwined.

When [patients are] deployed to pay visits to politicians, they add a human face to lobbying efforts around proposed legislation that affects pharma. Legislation like the Cures Act might increase spending on drug development or grease the pathway of drugs to market and with fewer regulations.

Before going to Capitol Hill, the patients and their families underwent a day of training, learning how to tell their stories. If at a loss for what to talk about, they were provided talking points on what EveryLife staffers called potential "asks."

The group's president, Dr. Emil Kakkis, is a drug industry executive. He said the foundation doesn't "tell patients what to do on the Hill. They are given options."

During one session called "Tricks of the Trade: Preparing for a Successful Meeting," Soapbox Consulting chief executive Christopher Kush walked the audience through logistics for the next day.

The attendees were given a mobile app, which shows each advocate's prearranged meeting list. Checking a map, Kush looked at the audience and said: "If you see a little dot where you live, you may have a new member of Congress - or a green check on your state, that means you have a new senator."

Emanuel said he believes that patient advocacy groups should openly state their potential conflicts while participating in regulatory meetings. In addition, Emanuel said, drug and device manufacturers should annually report how much they pay patient advocacy groups just as they do with physicians and teaching hospitals.

More here...
93% of Patient Advocacy Groups Included in FDA Funding Discussions Receive $ from Pharma

[From theintercept.com, April 10, 2017] "Patient advocacy" groups have a unique power on Capitol Hill. They claim to represent the true voice of constituents, untainted by special interest bias. Politicians and the Food and Drug Administration use their endorsements as reflective of genuine public support.

But a new study shows that nearly all of these patient advocacy groups are captured by the drug industry.

The Project on Government Oversight (POGO) reports that at least 39 of 42 patient advocacy groups who participated in discussions with the FDA over agency review processes for prescription drugs received funding from pharmaceutical companies.

More here...

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More Than Two-thirds of Patient Advocacy Groups Receive Industry Funding

<table>
<thead>
<tr>
<th>Source of Revenue</th>
<th>Proportion of Organizational Revenue, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0%</td>
</tr>
<tr>
<td>Donations from individuals (n = 277)</td>
<td>17 (6.1)</td>
</tr>
<tr>
<td>Donations or grants from for-profit companies (n = 276)</td>
<td>94 (34.1)</td>
</tr>
<tr>
<td>Fundraising events (n = 275)</td>
<td>69 (25.1)</td>
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<td>Membership dues (n = 273)</td>
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<tr>
<td>Investment income (n = 274)</td>
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<td>Foundations (n = 275)</td>
<td>151 (54.9)</td>
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<tr>
<td>Government grants (n = 276)</td>
<td>215 (77.9)</td>
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<tr>
<td>Proceeds from marketed products or services (eg, food, clothing) (n = 273)</td>
<td>185 (67.8)</td>
</tr>
<tr>
<td>Other industry revenue sources (n = 268)</td>
<td>232 (86.6)</td>
</tr>
</tbody>
</table>

[From www.statnews.com, January 17, 2017] 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.

More study details here...
Pharma's Rep Among Patient Groups Sinks to Near Historical Lows

[From www.statnews.com, March 21, 2017] For all the criticism that drug makers have endured in recent years, a new survey finds that they are faring worse than ever. Just 38 percent of patient groups thought the pharmaceutical industry had an "excellent" or "good" reputation last year, down from almost 45 percent in 2015 (read "Pharma's Rep Among Patient Groups at 4-Year High"), according to PatientView, a research firm that canvassed more than 1,400 patient groups from 105 countries.

More details here...

Further Reading:

- Can You Trust Patient Rankings of #Pharma Corporate Reputation?
- Americans Hate the #Pharma Industry Almost as Much as They Hate U.S. Gov't!
- Italian edition: Corporate Reputation of Pharma in 2015 - the views of 67 Italian patient groups
- 83% of Patient-Advocacy Organizations Receive Substantial Financial Support from the Drug Industry But Few Disclose How Much
Patient Advocate Backlash Against TV Drug Ads

[From www.mmm-online.com, March 29, 2017] For all the talk about digital migration and channel agnosticism, pharma companies remain huge fans of direct-to-consumer television ads. In 2016, pharma spent $4.06 billion on TV buys, up 4% from $3.91 billion in 2015, according to Kantar Media.

So, pharma loves TV and TV loves pharma - or, to be more specific, its endearing generosity. But in the past 18 months or so, there has been an increasing sense that the rest of us may not be quite as sold on the marriage.

The first vocal pushback arrived in October 2015 when members of the MS community expressed some less-than-appreciative thoughts about the images and patient depictions in a Biogen TV spot for Tecfidera (read "More DTC Ad Backlash. This Time from Patient Bloggers!").

Bristol-Myers Squibb found itself on the receiving end of a similar response when its own series of ads for Opdivo made promises that, patients and caregivers alike proclaimed, the drug could not keep (read "Opdivo TV Ads "Educate" Patients About the Positive, Not the Negative Trial Data").

More here...

Patients have sounded their opinions loud and clear, in social media and elsewhere. Whether pharma’s many DTC-on-TV boosters have heard them remains very much open to debate.

Further Reading:

- Big Pharma Spending on TV Ads Like a Drunken Sailor
- Who Said DTC Ads Are Not Effective? Those "Knotty" Linzess Ads Increased Sales by 30% Claims Ironwood Executive