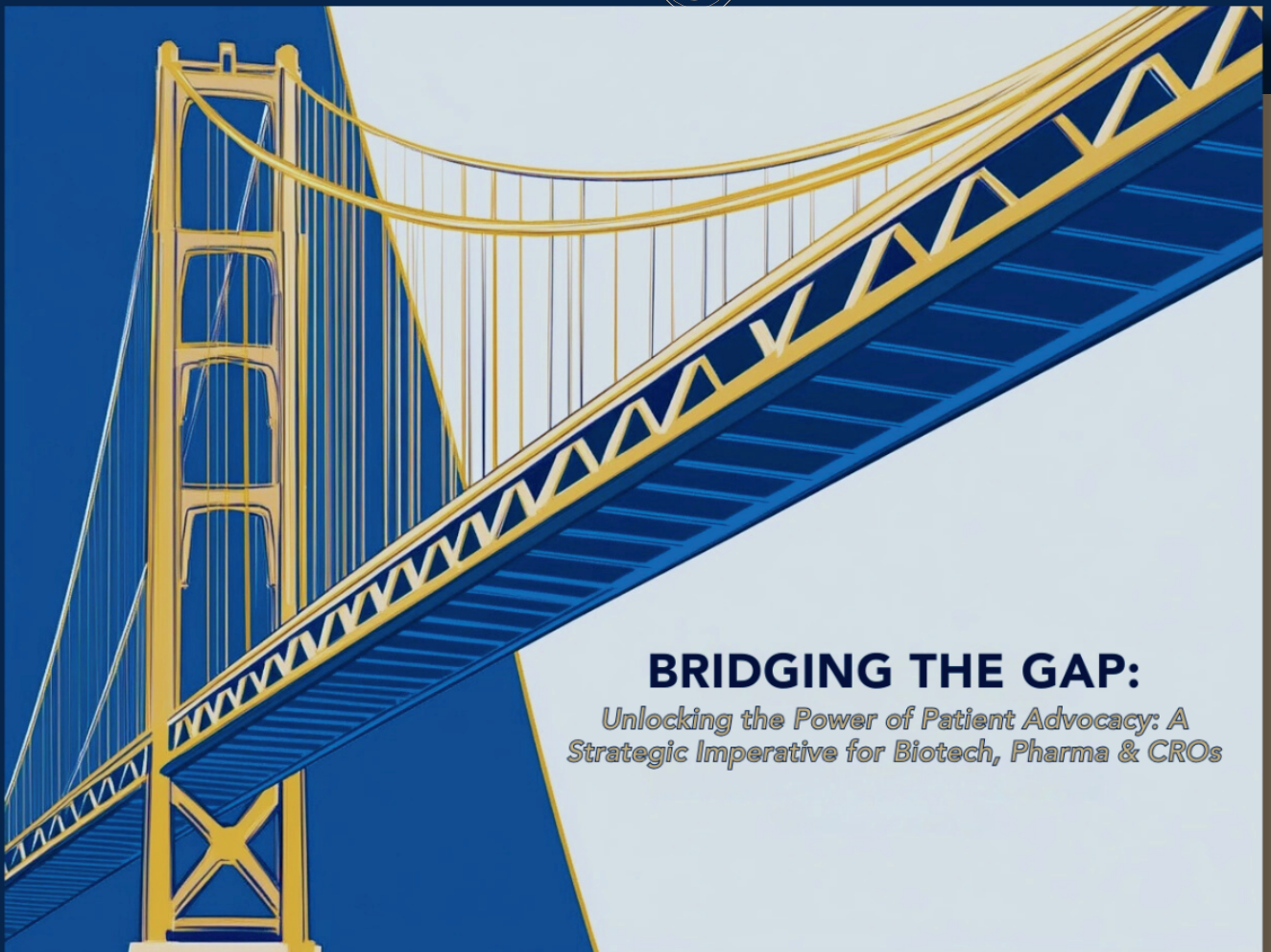
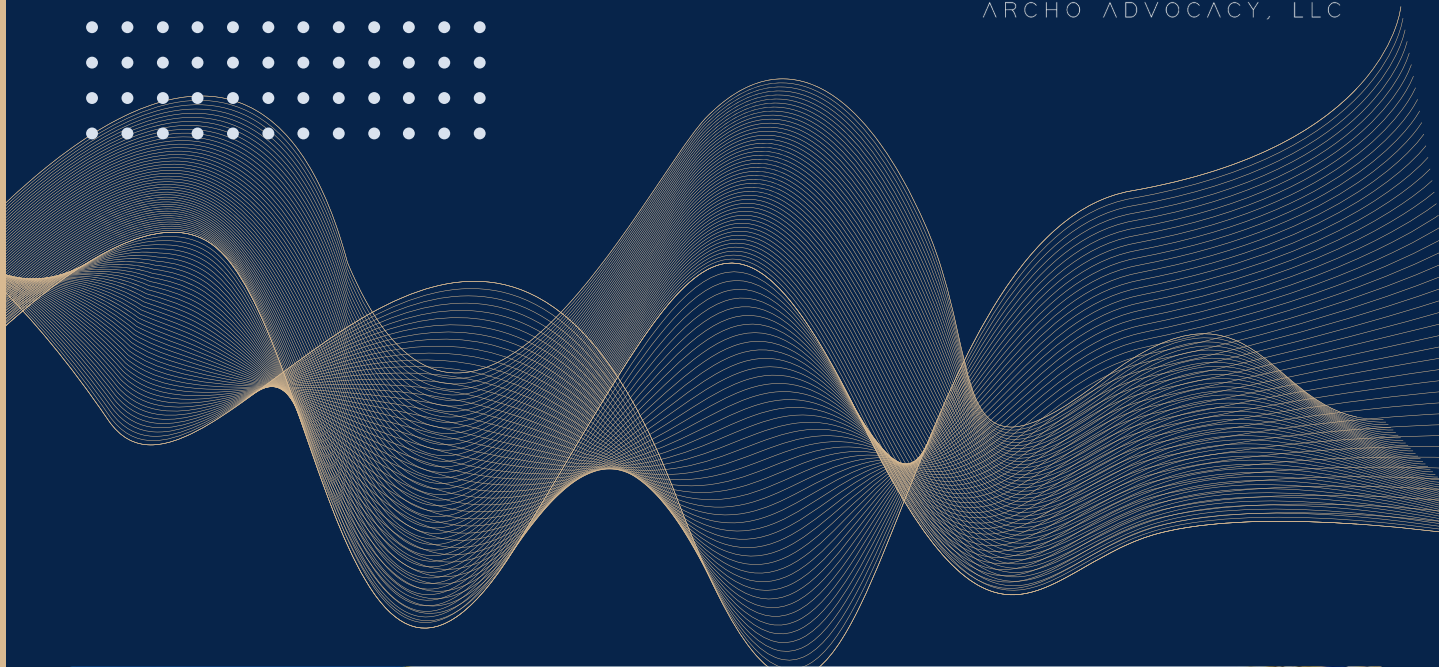




ARCHO ADVOCACY, LLC



BRIDGING THE GAP:

Unlocking the Power of Patient Advocacy: A Strategic Imperative for Biotech, Pharma & CROs

FROM THE AUTHOR

The complexity of the US Healthcare system has outpaced the knowledge of many of its own industry experts and healthcare professionals, leaving many patients in the dark. The PATIENT ADVOCACY function of a healthcare organization is the beacon of hope and the flashlight in the dark in more ways than leadership may understand.



Welcome to "Bridging the Gap: Unlocking the Power of Patient Advocacy." In today's healthcare environment, patient advocacy is not merely a compassionate effort but a vital strategic tool. This white paper sheds light on how advocacy functions within biotechnology and pharmaceutical companies can transform patient outcomes and drive sustainable success.

Here, you'll find insights into how advocacy is shifting from an auxiliary role to a central component of business strategy, providing underserved populations with access to the care they need. Through examples, data, and analysis, this paper highlights how advocacy teams work closely with patients, advocate organizations, and policymakers to develop solutions tailored to unique patient needs. We explore critical areas such as partnerships, policy support, health equity, and the ELAVAY benchmarking report, which provides a comprehensive look into advocacy performance across the healthcare sector.

As you navigate these pages, you will learn about the challenges and opportunities advocacy teams face, the importance of patient-centric care, and the long-term value of embedding advocacy into the core of healthcare organizations. Thank you for joining us on this journey towards a more inclusive, patient-centered healthcare system.

Sincerely,
Matt Toresco
Founder & CEO
Archo Advocacy, LLC

EXECUTIVE SUMMARY

In the competitive and complex U.S. healthcare landscape (and global for the matter), Patient Advocacy functions within biotechnology and pharmaceutical companies have continually battled through change to emerge as critical drivers of Patient care and commercial success. These functions are not merely cost centers; they are strategic assets that identify and engage underserved Patient populations—those who may be invisible to traditional marketing efforts due to barriers such as social determinants of health, lack of health literacy, or financial constraints. This white paper explores the strategic value of Patient Advocacy, the challenges these teams face, and the long-term benefits of integrating Patient-centered approaches into the core business strategies of biotechnology and pharmaceutical companies. The white paper will include commentary from Patient advocates, Professional Societies, and industry executives, as well as supportive data and analytics from Archo Advocacy’s **ELAVAY** report.

AN INTRODUCTION TO ELAVAY

Within this paper, you will see references to the **“ELAVAY: Patient Insights. Elevated Healthcare. Report”** completed by Archo Advocacy annually. **ELAVAY** provides feedback to the for-profit healthcare industry to understand the expectations of the Patients and advocates they serve through an annual assessment to benchmark organizations across the following sectors:

- Pharmaceutical & Biotechnology Organizations
- Medical Device Companies
- Genomics Laboratories
- Clinical Research Organizations
- Insurance Companies (Payers), Pharmacy Benefit Manageress (PBMs), & Specialty Pharmacy

The report measures many facets of Patient Advocacy interaction with nonprofit organizations such as Patient Advocacy Organizations, Professional Societies & Community-Based Organizations, including:

- Healthcare Companies Leading in Partnerships & Programs Support
- Healthcare Companies Leading in Federal & State Government Policy-Related Activities
- Corporate Image & Reputation
- Healthcare Companies Leading in Expanding Access & Education for Patient Treatment
- Healthcare Companies Leading in Patient Advocacy & Community-Based Organization Relationships



AN INTRODUCTION TO ELAVAY

- Healthcare Companies Leading in Diversity, Equity & Inclusion
- Healthcare Companies Leading in Health Equity & Social Determinants of Health

This benchmarking is crucial to these organizations as, legally, they cannot be tied to the organization's commercial success. They must be “non-promotional” and “unbranded” in their Advocacy efforts. Therefore, the **ELAVAY** Report serves as a success metric for these organizations across 23 therapeutic areas. The report also seeks to understand the issues that remain of high priority for these Patient-supporting organizations, including political matters, copay accumulators/maximizers, alternative funding programs, health literacy, and much more.

Archo's **ELAVAY: BIOADVOCATE BENCHMARK** has benchmarked the pharmaceutical and biotechnology industries. The **BIOADVOCATE BENCHMARK** data set represents the first time this critical information has been evaluated in a syndicated format and presented to the industry, offering unprecedented insights and shaping new standards in Patient Advocacy, including insights into the average budget, team size, organizational alignment, resources, and focus of industry Advocacy functions.

You can find more on the **ELAVAY** Report at <https://elavayreport.com> or the Archo Advocacy website at <https://archo.io>.

OUR OBJECTIVE OF THE WHITE PAPER

This paper delves into the intricate relationship between Patient Advocacy and commercial success, arguing that Patient Advocacy is not merely a moral imperative but a strategic asset with the potential to drive improved Patient outcomes and enhance commercial viability. Traditional commercial strategies, such as sales representatives educating physicians, often pay limited attention to specific Patient populations and issues restricting a Patient from receiving treatment once a prescription is written, resulting in unmet needs and untapped opportunities. By embracing Patient Advocacy, pharmaceutical companies can reach and serve these underserved populations, unlocking new avenues for innovation to advance Patient care..

Patient Advocacy goes beyond providing support and resources to individuals navigating complex healthcare systems. It involves actively listening to Patients' voices, understanding their unique challenges, and collaborating in drug development with Patient Advocacy Organizations to develop solutions that address their unmet needs. This Patient-

OUR OBJECTIVE OF THE WHITE PAPER

centered/Patient Advocacy-centered approach fosters trust and engagement, empowering Patients to participate actively in their healthcare journey.

From a commercial perspective, Patient Advocacy offers several strategic advantages. By understanding Patients' specific needs and preferences, pharmaceutical companies can tailor their products and services to better align with real-world experiences. This leads to improved Patient outcomes, increased satisfaction, and enhanced brand loyalty. Moreover, Patient Advocacy can help companies identify unmet medical needs, drive innovation, and develop novel therapies and treatments.

Patient Advocacy is a powerful strategic asset for market access. By highlighting the positive impact of their products on Patients' lives, pharmaceutical companies can build stronger emotional connections with Patient advocates, increasing brand awareness, improving reputation, and driving commercial success. Additionally, Patient Advocacy helps companies navigate the complex regulatory landscape, offering insights into policy decisions that affect Patient access to medicines or "assets." Working with Patient advocates through the drug development process allows companies to engage the Patient and gather insightful Patient feedback during the development process that will aid in the regulatory process. Engaging with Advocacy groups and policymakers allows companies to champion Patient-centered care and ensure Patients' voices are heard in healthcare decision-making.

Unfortunately, the full impact and breadth of Patient Advocacy's capabilities within pharmaceutical and biotechnology companies often go unnoticed. Based on Archo's primary engagement with Patient Advocacy teams, as of September 2024, over half of the top 50 pharmaceutical and biotechnology companies are changing and/or downsizing their Advocacy departments. Most executive leadership teams see Patient Advocacy as a "cost center," with funds being spent to "shape fog,"(nobody knows what they do, and they think it's easy and fake) as one executive described. They are unaware of the length and depth of engagement with Advocacy organizations that is expected and required by Patient Advocacy Organizations (PAOs). PAOs serve as necessary gatekeepers to their Patient community. They have represented the best interest of their Patients for decades and must defend the trust they've developed with the Patient community at all costs. Engaging and partnering with Advocacy organizations is a long-term and high-touch process that deserves the utmost respect. Successful Advocacy initiatives should be recognized as multi-year processes. Unfortunately, corporate executives, accountable to their shareholders, think in a quarterly and annual budgeting model. Therefore, when these organizations face headwinds, like today with the Inflation Reduction Act and Medicare Part D Drug Pricing



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Negotiations, Advocacy is one of the first functions to feel the squeeze. However, as we will explain, this short-sighted “win” for the bottom line can create long-term problems of distrust, abandonment, and the feeling of being manipulated within the Patient and Advocacy community. The IRA is noted by **ADAP Advocacy’s** leader, **Brandon Macsata**, as the perfect microcosm of the lack of understanding of leadership on the impact of advocacy. Brandon notes:

“I think a powerful real-world example of where industry failed to leverage Patient advocacy is the passage of the IRA. There weren't enough of our [advocacy] voices chiming into the debate about, rhetoric and talking points aside, how the IRA's "cost-shift" dynamics would actually hurt Patients; not help them. I still think industry leaders fail to recognize their failure in strategy over the IRA's passage. Patients don't care about "innovation" and frankly neither do lawmakers. Patients care about access and 'can get what I need' and there was an argument to be made during IRA's debate that the barriers removed by the new law would be quickly replaced by new, arguably more problematic, barriers to access to care care and treatment. That leads to angry Patients. Lawmakers listen to angry Patients.”

In summary, this paper argues that Patient Advocacy is not just a moral obligation but a strategic asset with the potential to drive improved Patient outcomes and commercial success. By embracing Patient Advocacy, pharmaceutical companies can reach and serve underserved populations, foster trust and engagement with Patients, develop more effective products and services, and build stronger brands. In today's competitive healthcare environment, Patient Advocacy is no longer an option but an imperative for companies seeking sustainable growth and long-term success.

UNDERSTANDING THE CURRENT STATE OF PATIENT ADVOCACY IN INDUSTRY

Serving the Underserved

The Patient Advocacy landscape within biotechnology and pharmaceutical companies is profoundly transforming, and not in a positive way. In the past five years, the role and value of Advocacy have had to continually demonstrate their worth within organizations that often view these efforts through a short-term, commercial lens. Despite these issues, Advocacy functions have emerged as crucial players in bridging the gap between the healthcare system and the underserved and vulnerable Patient populations that traditional marketing efforts fail to reach. Underserved and vulnerable Patient populations are nearly 80% of Patients who share one or more of the following characteristics. They may:

- Have a high risk for multiple health problems and/or pre-existing conditions.
- Have limited options in life due to social restrictions (e.g., financial, educational, housing).



UNDERSTANDING THE CURRENT STATE OF PATIENT ADVOCACY IN INDUSTRY

- Display fear and distrust in accessing government programs or disclosing sensitive information about family members.
- Have a limited ability to understand or give informed consent without the assistance of language services
 - Consumers with limited English proficiency (LEP)
 - Consumers with cognitive impairments
- Have mobility impairments.
- Have a lack of access to transportation services.
- Have a lowered capacity to communicate effectively.
- Face any discrimination.
- Receive fewer health care services.
- Encounter barriers to accessing primary health care services (e.g., economic, cultural, and/or linguistic).
- They currently lack familiarity with the healthcare delivery system.
- Face a need for more readily available providers.[1]

With the sheer volume of Patients in the United States requiring medical assistance, the 80% of the Patient population with vulnerabilities or designated as underserved continues to grow. Some Patient Advocacy leaders have noted that “all Patients receiving treatment are underserved.” Much of this is due to the complexities of the healthcare industry, complexities in navigating hospitals and health systems, structural barriers to equity, innate biases by providers, and struggles in understanding insurance benefits and overcoming the plentiful hurdles placed in a Patient’s way as they attempt to get the care they need. As **John Hoffman**, the prior leader of the number one Patient advocacy team in the industry for 11 straight years at **Janssen (Johnson & Johnson Innovative Medicine)**, notes,

“These significant differences in access/outcomes that are created by the SDOH issues are further exacerbated by the adverse consequences of many of the utilization management practices that are put in place by the PBMs and health plans. Studies have shown that these practices (such as step therapy, non-medical switching, copay tiers, etc.) have a statistically significant, disproportionate adverse impact on underserved populations.” We must take decisive action.

Patient Centricity & The Patient Need for Advocacy

The transformation of industry Patient Advocacy functions is increasingly driven by the recognition of Patient-centricity’s crucial role in drug development and commercialization. As Patients become more informed and empowered, they seek greater involvement in their care decisions, a concept known as “shared decision-making.” This shift has led to the move

[1] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/006_Serving_Vulnerable_and_Underserved_Populations.pdf

UNDERSTANDING THE CURRENT STATE OF PATIENT ADVOCACY IN INDUSTRY

away from traditional, one-size-fits-all healthcare approaches, emphasizing a more personalized and Patient-focused model.

Advocacy functions are uniquely positioned to meet this need; they have the expertise and resources to understand the needs of Patients and their families and to advocate for their interests within the healthcare system. Patient Advocacy functions can also pull in their Government Affairs counterparts where necessary to engage the community. Patient Advocacy functions may work with policymakers, healthcare providers, and payers to ensure Patients can access the necessary treatments and services.

The transformation, positive or negative, of Patient Advocacy is still in its early stages, but it is already clear that this function will play a vital role in the future of healthcare. By bridging the gap between the healthcare system and the underserved Patient populations, Advocacy functions can help to ensure that all Patients have access to the treatments and services they need.

Here are some specific examples of how Advocacy functions have made a difference:

- In 2021, the Advocacy division of a major pharmaceutical company worked with policymakers to secure funding for a new program that provides financial assistance to Patients with rare diseases.
- In 2022, the Advocacy division of a biotechnology company launched a new initiative to educate and support Patients with chronic diseases.
- In 2023, the pharmaceutical company's Advocacy division partnered with a Patient organization to develop a new Patient-centered outcome measure for a new cancer treatment.

These are just a few examples of how Advocacy functions have worked to improve the lives of Patients and their families. As the healthcare landscape evolves, Advocacy functions must play an increasingly important role in ensuring that Patients have a voice and their needs are met. Unfortunately, many of these teams are facing uphill battles within their organization.

The Uphill Battle: Translating Advocacy's Value

Advocacy functions play a crucial role in improving the lives of Patients and their families within the ever-changing healthcare landscape. They act as Patient champions, ensuring their voices and needs are heard. However, many of these functions face significant challenges within their organizations.

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Firstly, Advocacy functions often need help to gain recognition and support from senior leadership within their associated companies. Healthcare organizations frequently focus on financial performance and operational efficiency, which can marginalize Advocacy efforts. This lack of recognition and support can make it easier for Advocacy functions to secure the resources they need to be effective, such as funding, staffing, and technology.

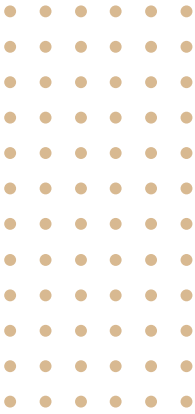
Secondly, Advocacy functions may need more support from other departments or even face “Silos” and “Turf Wars” within their organization. For example, clinical teams may be reluctant to share Patient information with Advocacy functions, citing privacy concerns. Financial departments may hesitate to approve funding for Advocacy initiatives, arguing that they are not directly related to Patient care. Marketing teams may be unable to engage with Patient Advocacy functions due to compliance concerns around branded vs. unbranded communications to Patients and Patient advocates. These challenges can make it difficult for Advocacy functions to build collaborative relationships with other departments and to achieve their goals.

Thirdly, Advocacy functions often need more resources at their disposal. They may have small budgets, limited staffing, and need access to technology and data. This can make it challenging for Advocacy functions to conduct research, track Patient outcomes, and measure the impact of their efforts. The latest data from Archo’s **ELAVAY: BIOADVOCATE BENCHMARK** study showed pharmaceutical Patient Advocacy teams' budgets to be between 0.01% and 0.08% of annual corporate revenue. These are menial budgets and staff allotments for critical work. Without adequate resources, Advocacy functions may struggle to make a meaningful difference in the lives of Patients and their families.

Long-term Value vs. Short-term Budgets

Senior executives in biotechnology and pharmaceutical organizations often focus on quarterly and annual financial results, viewing Patient Advocacy as a cost center rather than a strategic investment. However, when Advocacy is done well, it improves Patient outcomes, enhances corporate reputation and brand awareness, and, ultimately, increases Patient access and treatment. Advocacy efforts are critical in expanding the market by identifying Patients who would otherwise remain untreated due to various barriers. However, Advocacy in the Patient community takes time with often difficult ROI analyses due to the long-term implications of their potential success in patient-focused efforts.

Building lasting relationships requires trust at the foundation, a potential financial investment, time, and a commitment to working together side-by-side to benefit Patients.



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This, unfortunately, separates Advocacy from the commercial business as Advocacy actions must be allowed to work in two to five-year engagements. With all eyes in the industry focused on quarterly and annual budgets, Advocacy is at odds with the conventional budgeting and accounting processes. The long-term impact of Advocacy requires the appropriate time and resources to have the opportunity to have an effect, but it runs counter to the conventional industry culture.

To survive and thrive, Advocacy functions must align with the long-term corporate goals and speak the language of the commercial business. Advocacy functions should maintain strategic plans, report tactical execution/wins in the community, and leverage key performance indicators like the ELAVAY report to adjust on the fly. Only with effective partnerships with senior executives and ensuring biopharmaceutical executives get their “hands dirty” alongside the Advocacy division will senior leadership genuinely understand the impact of Advocacy efforts in full.

Internal Organizational Issues Have Consequences for Bystanders

The Patient Advocacy Organizations, Professional Societies, and Community-Based Organizations supported by these teams also face these challenges indirectly. According to the ELAVAY report, Patient Advocacy within biotechnology and pharmaceutical organizations is undergoing a “relaunch.” Many Advocacy teams in pharmaceutical and biotechnology companies need to demonstrate the value of their Advocacy efforts to executive leadership, especially in a landscape where support for these activities has yet to keep pace with growing interest and need. In response, many organizations have relocated their teams within the organization (e.g., from the Corporate Communications division to the Medical/R&D division) or changed the leadership reporting structure of the Advocacy division. New leadership often needs an understanding of the value of Patient Advocacy and the historical work done to build trust and partnerships with the Patient community. The data reveals significant gaps between the interest in Advocacy initiatives and the level of support they receive, underscoring a critical opportunity for companies to enhance their efforts in this area.

ELAVAY INSIGHTS: PATIENT CARE GAPS & NEEDS IDENTIFIED IN THE PATIENT COMMUNITY

Identifying Gaps in Patient Care: Insights from ELAVAY

Each year, ELAVAY engages with Patient Advocacy Organizations, Professional Societies (organizations that represent medical professionals, such as the American Society of Clinical Oncology or ASCO), and Community-Based Organizations that work alongside healthcare companies to serve the needs of Patients. The 2024 ELAVAY report notes some of the

ELAVAY INSIGHTS: PATIENT CARE GAPS & NEEDS IDENTIFIED IN THE PATIENT COMMUNITY

following vital gaps that Patient-serving organizations recognize as significant needs in the Patient community:

- **Disease Education & Awareness Campaigns** – These campaigns help to educate the general population about various diseases and how Patients can access treatments for these conditions. Nonprofit organizations request further support in developing and distributing materials to the Patient community. This work with industry ensures that those needing care know possible treatment options. Additionally, it aims to help those who may not be aware of a specific medical condition understand the symptoms they are experiencing and what these may be signaling.
- **Sharing of Scientific Information** – Facilitating the exchange of scientific advancements between healthcare organizations and Patient groups is crucial. When industry and specific Patient Advocacy Organizations (PAOs) conduct clinical trials or establish disease state registries, scientific leaders in industry and the nonprofit sector need to engage in detailed discussions about developing innovative treatments. This allows for conversations about new treatment evaluation methods, gathering input from Patient communities, and more.
- **Coalition Support** – An organized group of Patient Advocacy Organizations formed to address specific Patient issues, such as prior authorization reform. Nonprofit organizations are dedicated to assisting the Patients within their reach and implementing strategies on their behalf. However, these organizations may not be aware of other groups within their disease state running programs in different ways that could benefit the Patient population more. The involvement of a third party, like an industry Patient Advocacy division, in understanding the landscape of nonprofit organizations working for Patients and bringing them together around a joint mission can be precious to the Patient community.
- **Support of Conferences & Symposia** – With COVID-19 in the past, Patient organizations are looking to unite Patients, allowing them to socialize, establish a support network, and find solutions to everyday challenges. The Patient Advocacy functions within the industry can be highly beneficial in assisting advocates in planning and organizing conferences and symposia, developing agendas, identifying and recruiting speakers, engaging with the Patient community, and more.

ELAVAY INSIGHTS: PATIENT CARE GAPS & NEEDS IDENTIFIED IN THE PATIENT COMMUNITY

following vital gaps that Patient-serving organizations recognize as significant needs in the Patient community:

- **Patient-Centric Insights & Collaboration** – Ensuring everything in the healthcare industry is evaluated through the eyes of actual Patients, including clinical trials, clinical endpoints, Patient-reported outcomes, feedback on Patient education materials, and much more. Patient Advocacy functions must serve as the lead point of contact with the Patient community, built on the foundation of trust.
- **Policy Discourse Opportunities** – Patient Advocacy Organizations, Professional Societies, and Community-Based Organizations often lack awareness of healthcare policy changes at the federal and state levels due to their primary focus on serving the Patient community. The Patient Advocacy functions can lead in engaging Patient support organizations to educate them on developing policies, gather their input and opinions, and guide appropriate feedback or comments on the legislation. This will help represent the Patient's voice in upcoming legislative actions.
- **Payer Engagement Support/Drug Access Awareness & Education** – Patients, advocates, and Advocacy groups actively work with payers and Pharmacy Benefit Managers (PBMs) to ensure access to essential medications for their communities. Advocacy groups also educate Patients about the full range of treatments for specific medical conditions. This involvement empowers Patients to participate in shared decision-making with their healthcare providers and to navigate and overcome obstacles imposed by insurers and PBMs. Advocacy groups collaborate with organizations to develop educational programs, ensuring Patients are well-informed and supported in their healthcare journey.
- **Addressing Social Determinants of Health Issues Inhibiting Appropriate Patient Care** – Issues include the need for social support networks, increased individual education and health literacy, systemic barriers to equity, and transportation challenges. Patient advocacy functions should look beyond the commercial point of sale to identify all the obstacles that prevent patients from maximizing their care. This starts with understanding the availability of and access to appropriate care and practitioners. It also involves defining the hurdles that patients must overcome to access specific treatments that fit their budget and other aspects of their lives. This is a growing area that requires our focus.



ELAVAY INSIGHTS: PATIENT CARE GAPS & NEEDS IDENTIFIED IN THE PATIENT COMMUNITY

- **Continuity of Patient Care Throughout the Health System** – The individual Patient journey is arduous, fraught with hurdles to overcome, hoops to jump through and giants to battle. Unfortunately, this journey can often be fragmented as Patients seek care from multiple clinicians within a care system. Due to healthcare workforce staffing challenges, the physician referral network can be disjointed, with limited support staff. This often leaves the Patient alone to battle the challenges of keeping up with appointments, understanding insurance requirements to access healthcare specialists, and fighting to gain access to vital medications and services. Patient Advocacy functions can come alongside the Advocacy community to develop educational materials to help equip Patients on their care journey with support tools that allow them to be more knowledgeable about what to expect and how to overcome common challenges.
- **Communication Gaps & Cultural Sensitivity** – Patient Advocacy Organizations, Professional Societies, and Community-Based Organizations collaborate closely with pharmaceutical and biotech Patient Advocacy functions to gain insights into the communication gaps and cultural barriers present within the Patient community. By identifying these barriers, they can develop targeted programs to maximize Patient awareness and education regarding disease screening opportunities and available treatment options. These collaborative efforts involve creating informative materials, outreach initiatives, and support networks to ensure Patients have access to the resources and information they need to make informed decisions about their healthcare. The organizations aim to empower Patients, improve healthcare outcomes, and foster a more supportive and informed Patient community through these initiatives.
- **Technology Gaps** – With the rise of digital tools and social media, Patients can now access essential resources and education about their medical conditions online. However, not all Patients have the necessary tools or internet access to benefit from these resources. To address this issue, industry Advocacy functions, Patient Advocacy Organizations, Professional Societies, and Community-Based Organizations can collaborate to understand local barriers to accessing digital tools, create online support networks, and develop new technology solutions to empower Patients in managing their healthcare. They can also partner with local and state agencies to address gaps in internet access, smartphone ownership, and technology education, ensuring that all Patients have equal access to digital tools to improve their healthcare outcomes.

Despite facing various internal organizational challenges, Patient Advocacy functions are crucial for ensuring that Patients have a voice and their needs are met. There are clear



ELAVAY INSIGHTS: PATIENT CARE GAPS & NEEDS IDENTIFIED IN THE PATIENT COMMUNITY

examples of the impact of organizational Patient Advocacy teams, along with supportive data that highlight the importance of this role in the healthcare ecosystem. By addressing these challenges, Advocacy functions can continue to improve the lives of Patients and their families and positively impact the healthcare system. We need Patient education and empowerment to bring about the necessary Patient-focused healthcare revolution in the United States. Patient Advocacy functions must have the appropriate resources, budget, and tools to lead the nonprofit Patient community forward.

BEYOND THE FISHBOWL: THE STRATEGIC VALUE OF PATIENT ADVOCACY

Commercial Focus vs. Advocacy Focus

Patient Advocacy is vital for bridging the gap between the Patient community and the organization's commercial efforts in today's healthcare market. Advocacy is critical to pushing the organization beyond established Patient pools to identify and engage those who struggle to access care. Barriers such as poverty, inadequate housing, lack of transportation, and low health literacy hinder Patients' ability to navigate the healthcare system and obtain necessary treatments. Financial constraints, including the high cost of care and medications, worsen the issue.

Patient Advocacy initiatives employ strategic approaches to address these challenges to reach underserved populations. These include forming partnerships with community organizations, faith-based groups, and social services. Providing educational resources to enhance health literacy empowers Patients to make informed decisions about their health. Moreover, Advocacy efforts are crucial in advancing policies that address social determinants of health and foster equitable access to care.

Current Patients who understand how to navigate the healthcare system can be seen as part of the "commercial fishbowl"—individuals already within the reach of healthcare providers and commercial sales teams. However, Patient Advocacy functions enable healthcare organizations to extend their focus beyond these existing Patients, targeting those who are most vulnerable and often overlooked. These individuals are outside the "fishbowl" and thus beyond the commercial reach of the organization. Healthcare entities can drive educational efforts more profoundly into the general population by collaborating with Patient Advocacy and Community-Based Organizations. This promotes health equity and enhances the overall well-being of communities. As an example, Patient Advocacy



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Organizations in the Prostate Cancer space work with Community-Based Organizations and houses of worship to educate the community about health insurance, access to said insurance, prostate cancer screenings for men, why to be screened, where to be screened, and more. It is this “boots on the ground” advocacy that drives true change in the community while addressing barriers at the individual patient level.

Such initiatives serve a dual purpose. They ensure that those who have not yet sought or received the care they need are brought into the healthcare system, effectively “adding fish to the fishbowl.” This, in turn, supports the commercial organization by expanding its potential Patient base while upholding its commitment to social responsibility.

Advocacy as a Business Driver

Advocacy teams can have immense value in many domains of the pharmaceutical world.

These domains include:

- Approval/Indication and Labeling
- Product Coverage & Utilization Management
- Drug Coding & Provider Reimbursement where appropriate
- Economics & Affordability
- Patient-Focused Medicine Development
 - Clinical Trial Awareness & Enrollment
 - Clinical Trial Protocol Development, Inclusion & Exclusion Criteria, Primary Endpoints, Patient Reported Outcomes & more.
- Site of Care for Treatment & The Availability of Sites of Care
- Social Factors Inhibiting Patients from Accessing Care & Health Disparities

Patients, healthcare providers, employers, and other Advocacy organizations must actively participate and involve themselves to impact access to healthcare services positively. This collaboration ensures that all Patients achieve the most favorable overall health outcomes.

Advocacy In Product Development

Patient Advocacy engagement is crucial in product development for pharmaceutical and biotechnology companies. The term “Patient-Focused Medicine Development (PFMD)” or “Patient-Focused Drug Development (PFDD)” began under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). Initially, the FDA’s PFDD initiative referred to a series of disease-specific meetings hosted by the FDA.[1] This concept emphasizes involving Patients to ensure treatments align better with their needs, preferences, and lifestyles. It builds on the more significant movement toward Patient-centered care, which gained traction in the early 21st century as the healthcare industry shifted toward more

[1] <https://nationalhealthcouncil.org/additional-resources/Patient-focused-medical-product-case-examples/>

BEYOND THE FISHBOWL: THE STRATEGIC VALUE OF PATIENT ADVOCACY

personalized approaches to medicine. PFDD aims to improve treatment outcomes, reduce inefficiencies, and ensure that medical innovations are more tailored to Patients' diverse needs. Advocacy teams are crucial to engaging with Patient Advocacy Organizations and Professional Societies to gather Patient perspectives and ensure medical, regulatory, and compliance teams know the Patients' needs. In the 2024 edition of the ELAVAY report, 74% of Patient Advocacy Organizations request engagement with them and the patients they represent at phase 0 or 1 of clinical development, ensuring that the patient voice is included early and often. Engaging Patients early allow pharmaceutical and biotechnology companies to understand the following:

- **Patient Perspectives:** Patients have first-hand experience with the diseases or conditions the products treat. Their insights and perspectives can help companies better understand Patients' unmet needs and develop therapies that more effectively address them. As one patient advocate recently shared, a pharmaceutical company wanted to streamline its product manufacturing and move to a one-size bottle for all its medications. However, the oncology medication in question was a single monthly prescription with one pill in a large bottle. The lack of Patient engagement and perspectives brought about much angst and trouble for Patients who needed help opening their medication, capturing it without capturing the desiccant also in the bottle, and a host of other issues with the side effects of the drug itself. All problems could have been solved/addressed early with Patient insights or perspectives into manufacturing and packaging.
- **Improved Outcomes:** Engaging with Patient advocates can improve clinical trial outcomes. Patients can provide valuable feedback on the design and execution of clinical trials, ensuring that they are Patient-centered and meet the needs of the Patient population.
- **Regulatory Support:** Regulatory agencies, such as the FDA in the United States or the MHRA in the UK, emphasize increasing Patient engagement in the drug development process. Companies that actively engage with Patients and incorporate their perspectives into their product development plans will likely gain regulatory support and approval.



BEYOND THE FISHBOWL: THE STRATEGIC VALUE OF PATIENT ADVOCACY

- **Market Access & Reimbursement:** Patient Advocacy groups can be critical in market access and reimbursement decisions. They can help companies navigate the complex healthcare landscape, advocate for the value of new therapies, and ensure that Patients have access to the treatments they need. Engaging with Patient advocates can aid the organization in identifying potential blind spots, such as coding and reimbursement for product administration, and even assistance in formulary discussions with payers and PBMs.
- **Reputation & Trust:** Partnering with Patient Advocacy groups can enhance a company's reputation and build trust with Patients, healthcare professionals, and the general public. Companies that commit to Patient engagement are seen as more Patient-centric and socially responsible.
- **Ethical & Regulatory Considerations:** Engaging with Patient advocates is a moral imperative. Patients have a right to be involved in decisions that impact their health and well-being. By engaging with Patients, companies can ensure that their products are developed with their best interests. In June 2024, the FDA presented draft guidance to require the submission of a Diversity Action Plan (DAP) to ensure clinical trials represent appropriate and diverse populations. Pulling through the diverse Patient population into a clinical trial requires engagement by Patient Advocacy functions with the Patient community and nonprofits to aid in educating on the trial design and availability of the clinical trial.[1]

By actively engaging with Patient advocates, pharmaceutical and biotechnology companies can improve the quality of their products, accelerate development timelines, enhance regulatory and market access success for launch, and build stronger relationships with Patients and their communities. Their actions also have a financial impact on the bottom line of the organization through clinical trials. Engaging Patients and Patient Advocacy Organizations through PFDD ensures in greater clinical trial success. As noted in a recent publication,

“For example, a study from the Economist Intelligence Unit (EIU)², the research and analysis arm of The Economist Group, a sister company of The Economist magazine, found that drugs developed using Patient-centric designs were more likely to be launched than drugs developed without such a focus, with a percentage point difference of nearly 20% (87%) from the control group (68%). The same study found that Patient-centric trials took less time to recruit 100 participants (four months), compared to the control group (seven months). While the reasons for the time reduction were unclear, the study concluded that the nature of a Patient-centric approach implies “more effective mechanisms of engaging Patients.”

[1] <https://www.fda.gov/news-events/press-announcements/fda-guidance-provides-new-details-diversity-action-plans-required-certain-clinical-studies>



BEYOND THE FISHBOWL: THE STRATEGIC VALUE OF PATIENT ADVOCACY

A second study conducted by the Tufts Center for the Study of Drug Development (CSDD) and the Clinical Trials Transformation Initiative (CTTI), a public-private partnership of the FDA and Duke University to develop and drive practices to increase the quality and efficiency of clinical trials, developed a method for projecting the financial value of Patient engagement. The study found that a \$100,000 investment in a Patient-centric initiative during the design of a study for a typical oncology development program entering a Phase 2 or 3 clinical trial could yield an ENPV (expected net present value) of 500 times that amount — the equivalent of accelerating a pre-Phase 2 product launch by 30 months and a pre-Phase 3 project launch by 18 months.”[1]

EVOLVING THE PARADIGM OF ADVOCACY: FROM COSTLY BURDEN TO ORGANIZATIONAL IMPERATIVE

Enhancing the Strategic Alignment of Patient Advocacy Functions

One key challenge facing Patient Advocacy functions is their positioning within corporate structures. These teams are often housed under departments such as corporate communications or medical affairs with distinct strategic objectives. This misalignment can dilute the effectiveness of Advocacy efforts and limit their capacity to deliver Patient-centered outcomes.

Several factors contribute to this misalignment. First, Patient Advocacy is a relatively new function, and many organizations are still exploring how to integrate it into their corporate framework. Additionally, Patient Advocacy requires specialized skills that differ from those in marketing or sales. As a result, finding executives with the appropriate experience and qualifications to lead these functions can take time and effort.

The misalignment of Patient Advocacy functions can have significant consequences. It may result in a lack of understanding and support from other departments, hindering the division’s ability to secure necessary resources. Furthermore, conflicting priorities between Patient Advocacy and other corporate functions may arise. For instance, a corporate communications department might prioritize brand promotion over Patient Advocacy, making it difficult for the Advocacy team to fulfill its mission effectively.

Companies must adopt a more strategic approach to Patient Advocacy to address these challenges. Patient Advocacy functions must establish clear reporting structures and ensure that Advocacy functions receive the necessary resources and support to succeed. Patient Advocacy must be aligned with the company’s overall mission and values, positioning it as a core business function rather than an auxiliary effort.

[1] [1] <https://www.fda.gov/news-events/press-announcements/fda-guidance-provides-new-details-diversity-action-plans-required-certain-clinical-studies>



EVOLVING THE PARADIGM OF ADVOCACY: FROM COSTLY BURDEN TO ORGANIZATIONAL IMPERATIVE

Key Steps to Strengthen Alignment of Patient Advocacy Functions

To maximize the effectiveness of Patient Advocacy efforts, companies must prioritize integrating these functions into their broader organizational framework. This involves creating a clear reporting structure that ensures Advocacy teams have direct access to senior leadership, providing the necessary resources for success, and aligning Advocacy initiatives with the company's core mission and values. Additionally, fostering a culture that champions Patient Advocacy across all departments and measuring the impact of these efforts are critical steps in ensuring meaningful, Patient-centered outcomes. By adopting these strategies, organizations can strengthen their Advocacy functions and drive lasting improvements in Patient care:

- **Create A Clear Reporting Structure.** Patient Advocacy functions should report directly to the CEO or another senior executive to ensure they have a voice in critical decision-making processes.
- **Provide Adequate Resources.** These functions need appropriate staffing, budget, and access to data for effective operation and meaningful outcomes. The annual program budget should also be evaluated quarterly (not to be decreased as has been the historical norm but rather to be increased) to ensure that the Advocacy division is supporting the appropriate Patient Advocacy and Community-Based Organizations with the proper resources to have the desired impact in the Patient community at community events, live meetings, conferences, and symposia.
- **Align With the Company's Mission and Values.** Patient Advocacy should be fundamental to the company's broader objectives, strengthening its dedication to Patient-centered care. Suppose the company is dedicated to an ESG strategy (Environment, Social & Governance). In that case, Advocacy must be viewed as the social impact the organization must have for its desired social outcomes.
- **Foster A Strong Patient Advocacy Culture.** Cultivating a corporate culture that values Patient Advocacy encourages employees across departments to champion Patient needs. Ensuring all teams and team members are focused on how they can impact Patients' lives daily will provide Advocacy and authentic "Patient-centricity" are central components of the organization's culture.
- **Measure The Impact of Advocacy Efforts.** Implementing metrics to assess the success of Patient Advocacy initiatives will help demonstrate their value and inform future strategies. Resources like the "ELAVAY: Patient Insights. Elevated Healthcare." report



EVOLVING THE PARADIGM OF ADVOCACY: FROM COSTLY BURDEN TO ORGANIZATIONAL IMPERATIVE

and the ELAVAY: BIOADVOCATE BENCHMARK serve as critical syndicated research studies to provide the organization with the insights necessary to understand how they can maximize their Patient Advocacy impact while ensuring appropriate team resourcing and budgeting in alignment with industry norms. ELAVAY allows organizations to understand what “best-in-class” looks like in Patient Advocacy and guides strategic decision-making in the future.

By implementing these steps, companies can enhance the alignment of their Patient Advocacy functions and empower them to make a meaningful impact on Patients' lives.

Executive Clarity: The Strategic Importance of Patient Advocacy

At the executive level, more understanding of the strategic importance of Patient Advocacy is often needed. This misunderstanding can have severe consequences for the company, as underfunded and undervalued Advocacy functions are limited in improving Patient outcomes and contributing to the company's long-term success.

There are several reasons for this need for more understanding. First, many executives are not directly involved in Patient care, so they may need firsthand knowledge of Patients' challenges. Second, the value of Patient Advocacy is often difficult to measure, as it is seldom directly tied to financial outcomes. Third, Patient Advocacy is frequently seen as a "soft" issue and, therefore, not as important as other business priorities.

However, there is a growing body of evidence that Patient Advocacy is essential for the success of any healthcare company. Studies have shown that Patient Advocacy can improve Patient outcomes, increase Patient satisfaction, and reduce costs.[1][2] In addition, Patient Advocacy can help companies build stronger relationships with Patients and their families and improve the company's reputation.

Given the strategic importance of Patient Advocacy, executives must clearly understand it. This understanding should be reflected in the company's mission, vision, and values. In addition, executives should provide Advocacy functions with the resources and support they need to be successful.

By investing in Patient Advocacy, executives can help ensure that their companies meet the needs of Patients and their families and that they are well-positioned for long-term success. Here are some specific ways that executives can demonstrate their commitment to Patient Advocacy:

[1] <https://chcao.org/special-report-2023/>

[2] <https://nationalhealthcouncil.org/additional-resources/patient-focused-medical-product-case-examples/>

EVOLVING THE PARADIGM OF ADVOCACY: FROM COSTLY BURDEN TO ORGANIZATIONAL IMPERATIVE

- Make Patient Advocacy a priority in the company's mission, vision, and values.
- Allocate sufficient resources to Advocacy functions.
- Provide Advocacy functions with the support they need to be successful.
- Regularly review the performance of Advocacy functions and adjust as needed.
- Communicate the importance of Patient Advocacy to employees and stakeholders.

By taking these steps, executives can help to create a culture of Patient Advocacy within their companies and ensure that Patient Advocacy is a crucial part of the company's long-term success.

Recommendations for Companies

To successfully navigate the challenges and opportunities of the relaunch of Patient Advocacy, biotechnology, and pharmaceutical companies should consider the following recommendations:

- **Establish a Clear Vision and Mission:** Companies must develop a clear vision and mission for Patient Advocacy efforts. This will help ensure all stakeholders are aligned and resources are used effectively.
- **Build a Strong Advocacy Team:** Companies need to invest in building a strong Advocacy team with the necessary skills and experience. This team should be responsible for developing and implementing the company's Patient Advocacy strategy.
- **Create a Culture of Patient Advocacy:** Companies must create a culture of Patient Advocacy throughout the organization. This means ensuring that all employees are aware of the importance of Patient Advocacy and that they are empowered to advocate for the needs of Patients.
- **Partner with Patient Organizations:** Companies should partner with Patient organizations to leverage their expertise and networks. These partnerships can help to ensure that Patient Advocacy efforts are effective and sustainable.
- **Measure and Communicate Impact:** Companies need to develop metrics to measure the impact of their Patient Advocacy efforts. This data can be used to secure the necessary resources and support from senior management. Reports like the **"ELAVAY: Patient Insights. Elevated Healthcare"** report and the **ELAVAY: BIOADVOCATE BENCHMARK** is critical to understanding how "best-in-class" teams operate, budgetary requirements, team size, and the overall effectiveness of the Patient Advocacy functions through the eyes of their customers.

THE PATH FORWARD: A CALL TO ACTION

Partnership with Archo Advocacy

The partnership between Advocacy leaders and Archo Advocacy (the team behind the ELAVAY study) presents a transformative opportunity to elevate the impact and recognition of Patient Advocacy within corporate strategies. Archo Advocacy's expertise bridges the gap between Patient needs and corporate goals, ensuring that Advocacy efforts align seamlessly with the company's long-term success.

Here's how this partnership can drive meaningful change:

- **Demonstrating Commercial Impact:** Archo Advocacy possesses the tools and insights to quantify the commercial impact of Patient Advocacy. By measuring metrics such as Patient engagement, treatment adherence, and healthcare outcomes, they can illustrate the tangible benefits that Advocacy efforts bring to the company. This data-driven approach allows Advocacy leaders to present a compelling case for increased investment and support.
- **Aligning Patient Needs with Corporate Goals:** Aligning Patient needs with corporate goals is crucial for the sustainability and success of Advocacy initiatives. Archo Advocacy works closely with Advocacy leaders to identify shared values and objectives. By integrating Patient perspectives into corporate decision-making, companies can develop products, services, and policies that genuinely address unmet medical needs. This alignment fosters a shared purpose and drives innovation.
- **Addressing Social Determinants of Health (SDOH):** Social determinants of health play a significant role in Patient outcomes. Archo Advocacy recognizes the need to address these factors in comprehensive Advocacy efforts. They collaborate with Advocacy leaders to develop interventions and programs that tackle SDOH, such as access to healthcare, education, housing, and employment. By addressing these underlying issues, Advocacy initiatives can have a broader impact on Patient well-being and overall health outcomes.
- **Recognizing Advocacy as Integral to Long-Term Success:** The partnership with Archo Advocacy empowers Advocacy leaders to demonstrate the strategic value of their work. By providing evidence of the commercial impact and alignment with corporate goals, Advocacy efforts gain recognition as integral to the company's long-term success. This recognition leads to increased resources, dedicated teams, and a seat at the decision-making table, ensuring that the Patient's voice is heard and valued throughout the organization.

Overall, the partnership with Archo Advocacy transforms Advocacy efforts from isolated initiatives into core components of corporate strategy. It empowers Advocacy leaders to drive positive change, improve Patient outcomes, and ultimately contribute to the company's long-term success.



THE PATH FORWARD: A CALL TO ACTION

Engaging Local Communities to Drive Effective Solutions to Address Social Determinants of Health (SDOH):

To maximize the impact of Patient Advocacy, companies must prioritize engaging with communities, particularly those affected by social determinants of health. This strategic approach aligns with many organizations' broader environmental, social, and governance (ESG) strategies and can improve Patient outcomes and healthcare equity. Advocacy engagement in the local community can:

- **Understanding Social Determinants of Health:** Social determinants of health, such as income, education, housing, and access to healthcare, can significantly impact a person's health and well-being. By understanding the unique challenges faced by communities affected by these factors, companies can tailor their Patient Advocacy programs to address their specific needs.
- **Building Trust and Collaboration:** Engaging with communities requires building trust and collaboration. Companies should involve community leaders, healthcare providers, and Patients in the planning and implementing Patient Advocacy initiatives. This inclusive approach ensures that programs are culturally sensitive, relevant, and sustainable.
- **Empowering Patient Advocates:** Companies should invest in empowering Patient advocates within affected communities. These advocates can provide valuable insights into their peers' challenges and needs, advocate for policy changes, and educate others about the importance of Patient Advocacy.
- **Leveraging Technology and Data:** Technology and data can play a vital role in engaging communities and delivering Patient Advocacy services. Telehealth platforms can provide remote access to healthcare professionals, and data analytics can help identify care gaps and effectively target interventions.
- **Measuring Impact and Iterating:** Measuring the impact of Patient Advocacy programs is crucial to demonstrating their value and securing continued support. Companies should establish clear metrics, such as improved health outcomes, increased access to care, and reduced healthcare costs. Regular monitoring and evaluation allow for iterative improvements, ensuring that programs remain effective and responsive to changing needs.

By engaging with communities and addressing the social determinants of health, companies can improve Patient outcomes and contribute to a more equitable and sustainable healthcare system. This strategic approach aligns with the broader ESG goals of many organizations and showcases their commitment to responsible corporate citizenship.

CONCLUSION:

Patient advocacy has become essential for enhancing patient outcomes and driving commercial success in the rapidly evolving and complex healthcare landscape. This white paper highlights the strategic value of patient advocacy functions within biotechnology and pharmaceutical companies. It demonstrates how these teams extend beyond traditional roles to act as vital connectors between patients and the healthcare system.

Key Takeaways

- **Strategic Asset, Not A Cost Center:** Patient Advocacy functions have demonstrated their ability to identify and engage underserved populations, ensuring that these individuals receive the care and support they need. Far from merely cost centers, these functions are strategic assets that contribute to identifying unmet needs, product development, and market access strategies.
- **The Role of Data:** The **ELAVAY** report is a critical benchmarking tool, providing insights into the performance and impact of Advocacy efforts across various healthcare sectors. This data-driven approach is essential in an environment where Patient Advocacy must remain “non-promotional” and “unbranded” while aligning with corporate goals.
- **Patient-Centricity as a Competitive Advantage:** Embracing Patient Advocacy allows companies to foster trust and engagement with Patients, empowering them to participate actively in their healthcare journey. By understanding and addressing the specific needs of Patient populations, companies can tailor their products and services to improve Patient outcomes, enhance brand loyalty, and drive innovation.
- **Navigating Internal and External Challenges:** Despite the apparent value of Patient Advocacy, many functions face internal challenges, including limited recognition and support from senior leadership, resource constraints, and organizational silos. Externally, the evolving healthcare landscape and regulatory environment pose additional hurdles. Advocacy functions must navigate these challenges while maintaining their focus on long-term Patient outcomes.
- **Long-Term Value over Short-Term Gains:** The white paper underscores the importance of recognizing Patient Advocacy as a long-term investment rather than a short-term budgetary concern. Advocacy efforts require time, resources, and sustained engagement to build trust and deliver meaningful impact. Companies that understand this long-term value are better positioned for sustainable growth and success.



CONCLUSION:

- **Addressing Social Determinants of Health:** Advocacy functions are crucial in addressing social determinants of health, key factors influencing Patient access and outcomes. Advocacy teams can drive more equitable healthcare delivery by engaging with local communities and focusing on issues such as health literacy, transportation, and socioeconomic barriers.

Final Call to Action:

To fully realize Patient Advocacy's potential, biopharmaceutical companies, and Clinical Research Organizations must integrate these efforts into their core business strategies. This involves a commitment from senior leadership to provide adequate resources, establish clear reporting structures, and foster a culture that values Patient Advocacy as integral to the organization's mission and values.

- **Partnership with Archo Advocacy:** Companies are encouraged to leverage the expertise of organizations like Archo Advocacy to align Patient needs with corporate goals, measure the commercial impact of Advocacy efforts, and develop comprehensive strategies that address social determinants of health. By doing so, they can transform Advocacy efforts from isolated initiatives into core components of corporate strategy, driving positive change and improving Patient outcomes.
- **Engaging Local Communities:** Companies must prioritize community engagement to effectively tackle social determinants of health. By building trust and collaborating with community leaders, healthcare providers, and Patients, Advocacy initiatives can be tailored to meet the unique needs of underserved populations, ensuring that healthcare equity is a reality, not just an aspiration.
- **Executive Clarity and Support:** For Patient Advocacy to reach its full potential, executives must recognize its strategic importance and commit to its integration into the company's long-term objectives. By prioritizing Patient Advocacy, providing necessary resources, and regularly measuring impact, companies can ensure that their Advocacy efforts align with their overall mission and contribute to sustainable success.

Patient Advocacy is no longer a peripheral activity but a strategic asset in the healthcare industry. By embracing a Patient-centered approach, companies can drive commercial success while improving Patient outcomes and fostering trust within the communities they serve. Integrating Patient Advocacy into core business strategies is a moral imperative and a pathway to long-term viability in an increasingly Patient-centric healthcare market.

Patient Advocacy will become even more crucial as the industry continues to evolve. Companies

CONCLUSION:

that recognize and invest in this vital function will enhance their competitive edge and contribute to a more equitable and effective healthcare system for all. The journey towards Patient-centered healthcare is a shared responsibility, and it begins with the strategic elevation of Patient Advocacy within every organization.

ABOUT ARCHO ADVOCACY:

At its core, Archo is committed to amplifying the Patient's voice and driving meaningful change in healthcare. By advocating for today's Patient advocates and delivering robust data and analytics, Archo bridges critical gaps within the healthcare system. Our platform provides a comprehensive resource and support suite, empowering Patients and healthcare organizations to foster Patient-centered care.

Through training, market research (**ELAVAY**), and Advocacy initiatives, Archo educates the industry on the undeniable value of Patient-directed care. We offer strategic, data-driven guidance on effective strategies to engage the Patient community better. Together with industry partners, Archo addresses the most pressing challenges in Patient care, ensuring that Patients remain at the heart of every healthcare decision.

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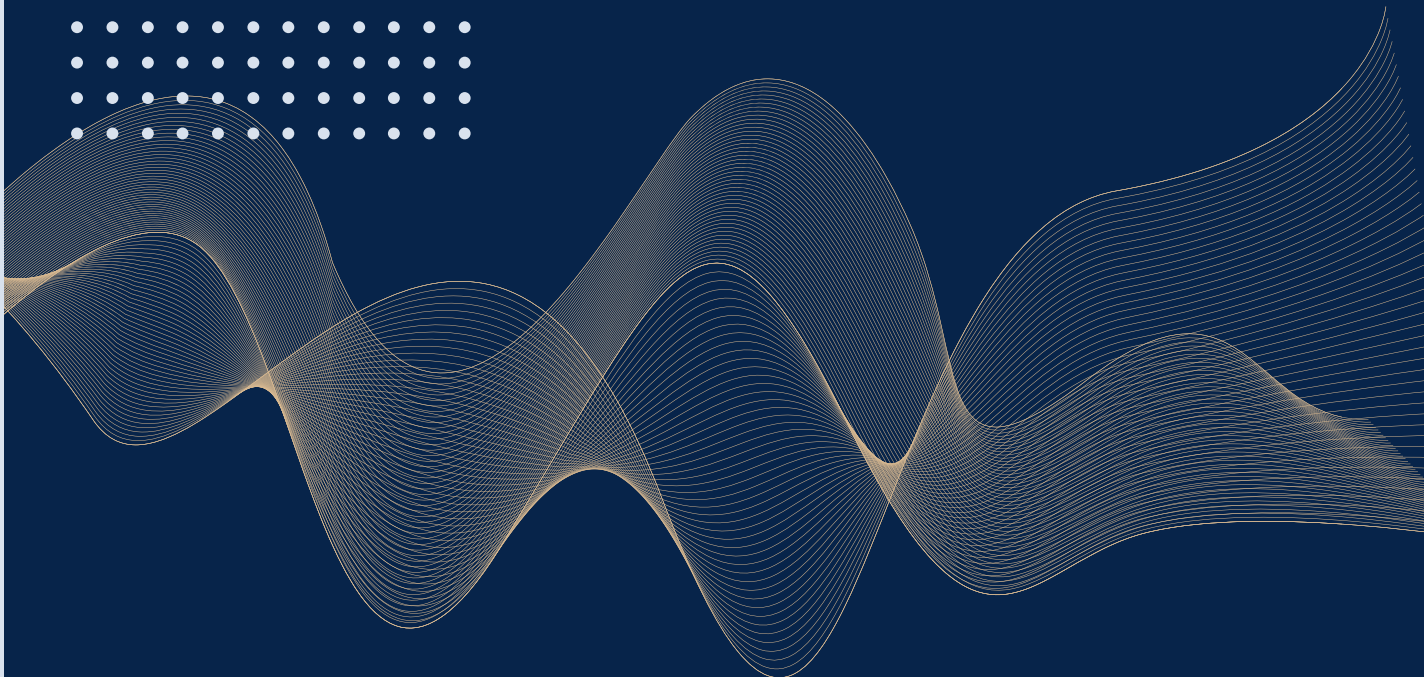


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