HELIO HEALTH

Top 5 Takeaways

from the 2020 Compliance Congress for Specialty Products

On September 21st - 24th, 2020, Informa Connect-CBI hosted its 6th Annual Compliance Congress for Specialty Products. The Congress catered to the unique Legal and Compliance challenges for specialty pharmaceutical companies focused on rare, ultra-rare and orphan diseases. **Helio Health Group identified five key takeaways from the Congress that every Compliance Officer should be considering.**

Click on any takeaway to be taken directly to the appropriate section.

> **"You can corrupt a patient, too."**
>
> **- Gregg Shapiro,**
> *Assistant U.S. Attorney, Chief of Affirmative Civil Enforcement Unit - U.S. Attorney's Office, District of Massachusetts*

Patient support services continue to take a top spot on enforcement agencies' radars. Are you tuned in to the recent patient support settlements, DOJ announcements, and the multiple OIG Advisory Opinions in this space?

During COVID-19, **digital and virtual interactions with customers** have increased dramatically as have related risk considerations. Recently issued guidances by PhRMA, IFPMA, EFPIA, HHS, and FDA can help navigate through this unprecedented time.

Companies are developing **new and innovative strategies** to engage and influence the way HCPs interact with Electronic Health Records (EHR) platforms. These new strategies benefit the doctor and patient; however, be mindful of fraud and abuse laws, marketing and promotion regulation, product liability, device regulation, and patient privacy.

Pharmaceutical companies work with **Patient Advocacy Organizations (PAOs)** to increase patient engagement with the aim of producing and delivering better treatments. Legal and Compliance should be focused on appropriate funding, information sharing, and independence in this space.

Compliance is engaging with new **cross-matrix partners** to build a corporate shared identity and achieve diversity and inclusion goals. Is your Compliance network strategically expanding within the organization?

Now more than ever, novel business strategies require novel Compliance programs. Agile and purposeful Compliance strategies are needed to effectively evolve risk assessments, policies, training, monitoring, and data analyses. Make sure you're aiming not just to "flatten the curve," but, rather to get ahead of the curve.

Compliance Considerations in the Patient Support Space

In the specialty pharmaceutical space, patient support programs have become commonplace. The general belief is that these programs, when conducted appropriately, are beneficial and can provide patients with financial support to access drugs as well as provide effective disease education that may not otherwise be available. As companies continue to spend more dollars on driving awareness and utilization of these programs, regulators have taken notice.

An enforcement panel shared their focus on higher-priced drugs. There is nothing inherently wrong with having a higher priced product, but higher prices sometimes cause companies to "cross the line" (e.g., underpaying Medicaid rebates, kickbacks to doctors or patients, inappropriate payments to patient advocates).

Numerous enforcements related to pharmaceutical companies' arrangements with independent charity patient assistance programs (ICPAPs) have taught us to ensure that companies are not using ICPAPs as a way to sell its drugs. Companies should be sure to view any decisions on patient support programs through the lens of the multiple OIG Guidances and Advisory Opinions addressing such programs.

Services to help patients shouldn't become a form of promotion and should only be offered after a prescription decision has been made.

Pharmaceutical companies often engage vendors to facilitate distribution of company drugs in support of patient support programs. There are a number of best practices for monitoring and mitigating risk with such activities. First, companies should consider performing audits of vendors on a regular basis. Second, companies should make sure the vendor is not being used as a pass through to shield rebates to customers or physician practices. This could have anti-kickback statute (AKS), average selling price (ASP), and best price (BP) implications. Finally, companies should proactively mine their data (as referenced in the 2020 DOJ Guidance on Evaluation of Corporate Compliance Programs) to uncover potential policy violations, outliers and other red flags.

The general rule for patient support services have not changed; services to help patients shouldn't become a form of promotion and should only be offered after a prescription decision has been made. However, there is an absence of guidance in certain rare disease situations such as diagnostic testing. Some companies have launched free genetic testing programs with the belief that in order to evaluate the right patient for the right therapy, such testing is needed. Inherent risk is present because often these tests are part of the diagnostic journey and are employed by an HCP for a patient before a prescribing decision is made. Also, the provision of the free service may implicate the anti-kickback statute and other related laws. Companies are trying to mitigate these risks by ensuring the tests are narrowly tailored, programs are targeted to the right HCP specialty who would be diagnosing the disease on-label, programs are not being promoted by the sales organization, controls are being added to ensure no spillover, and bills are sent directly to the pharmaceutical company.

In January 2020, OIG issued an Advisory Opinion on lodging and other patient expenses. OIG is concerned that manufacturers that provide travel and lodging for patients who are prescribed their drugs could use the travel and lodging to generate business for themselves by steering patients to their drugs over competing drugs, which could be less expensive but equally effective, and that this could result in inappropriately increased costs to the Federal health care programs. The Advisory Opinion was issued in response to a company's specific arrangement. The conclusion, based solely on the facts and circumstances of the one company's specific arrangement, was that OIG will not proceed against the company with respect to any action that is taken in good faith reliance upon the advisory opinion. Overall, other companies have taken a very cautious approach with their arrangements because the advisory opinion is so narrowly focused to one company's program. The positive news is that with this opinion, the government showed that it recognizes innovative therapies and that manufacturers should be able to help patients access them by providing tailored, appropriate support.

In August 2020, the California Department of Insurance announced a settlement agreement to resolve a lawsuit alleging AbbVie violated the California Insurance Fraud Prevention Act by providing kickbacks to healthcare providers relating to the sale of its drug Humira. The allegation covered meals, gifts, management practice software, support services, etc. and claimed these were kickbacks. While the claim was ultimately settled for $24 million, the positive news is that the settlement did not dismantle nurse ambassador programs and that there is a path forward for companies to appropriately conduct such programs.

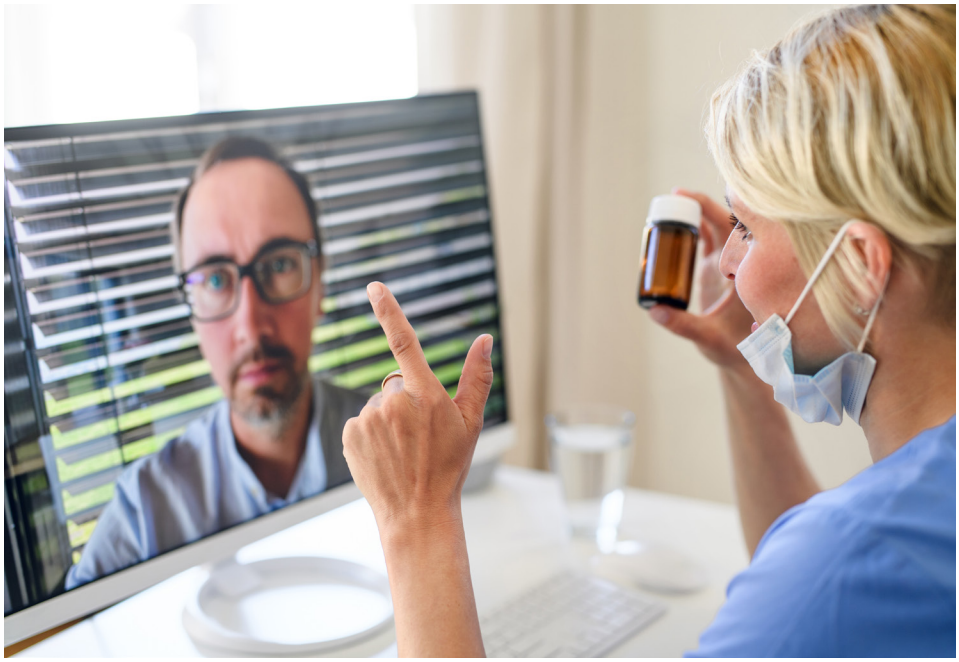
Challenges, Risks, and Lessons Learned from the COVID-19 Pandemic

In response to the COVID-19 pandemic, pharma digital and virtual interactions with customers have increased dramatically. Companies are developing new and effective ways to engage with HCPs, payors, patients, and caregivers. There are a number of unique considerations and new learnings from working during the global pandemic.

Virtual HCP availability has been less than ideal. Often the only chance that companies have for true interaction with HCPs is through Medical Affairs. Hence, we are seeing an **increased reliance on MSLs**. Companies must take caution to ensure these interactions do not morph into off-label promotion.

Many companies are looking to **increase the utilization of digital apps**. Specialty products require strict adherence to drug regimens to provide positive outcomes. However, most patients do not want daily reminders of their health condition. The challenge for pharmaceutical companies is to communicate and interact with the right amount of balance. Companies should continue to explore ways to integrate the HCP into the process but not lose sight of fraud and abuse laws. Additionally, organizations should make certain that a digital app doesn't rise to the level of a medical device (unless that is the company's desired outcome).

Electronic materials that were approved for sales representatives to discuss in-person (and not left behind with the HCP) are now being shown electronically. Although most likely without malicious intent, HCPs now have the ability to take screen shots of the material during a virtual interaction. Companies must ensure that materials are being used as intended. Additionally, sales representatives may email or text such materials to an HCP to review as it may be easier to facilitate dialogue. Companies must consider whether this sharing violates the intended use of the material. Decisions such as these are critical as post-pandemic pharmaceutical sales representatives will most likely have a hybrid role with both virtual and in-person HCP engagement.



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Meals with HCPs continue to be a lively topic of conversation amongst Compliance professionals. It appears that most companies and regulators agree that meals should not be sent to doctors' homes, however there is a lack of consensus on how to best handle many other HCP meal situations arising as a result of the pandemic.

Zoom meetings and constant telehealth interactions have fatigued physicians. Pharmaceutical companies are faced with **new challenges of how to engage a doctor** to attend a detail or virtual speaker program after a long day of screen interactions. Compliance questions arise around how to treat a meal sent to an office when the HCP does not show up. There are other tactical questions Compliance Officers are grappling with including how to appropriately handle cross-matrix interactions with an HCP when it may not be practical to have separate meetings for each company matrix representative (e.g. sales representative, MSL, and field reimbursement specialist) or should HCP fair market value rates be reassessed for the new look, feel, and effort to conduct virtual programs.

The golden rule in addressing the aforementioned situations is to always ask if the Company is engaging in an activity for the right reasons and in line with the principles of the PhRMA Code and other relevant regulations and guidances. Compliance professionals should leverage published resources to think through these challenges (e.g. guidances issued by PhRMA, EFPIA, and IFPMA on virtual meals; FDA policy on drug sample distribution amid COVID-19; HHS telehealth rules, etc.). It is recommended that pharmaceutical companies appropriately benchmark with peer companies, update risk assessments, and document decisions made along with the rationale. **Remember that enforcement agencies don't take time off.**

Innovative Strategies and Technologies at Specialty Pharmaceutical Companies

Pharmaceutical companies are developing novel strategies to reach patients and HCPs. As the industry has become more patient-centric, data savvy, and digitally advanced, there has been an increase in collaboration between pharmaceutical companies and Electronic Health Records (EHR) vendors. In addition to digital apps, pharmaceutical companies are playing a bigger role in the development of EHR platforms.

To date, the focus of enforcement agencies in this space has been limited to EHR vendors. Despite this, the prevailing thought is that it is just a matter of time before regulators focus on pharmaceutical company involvement with EHR vendors and platforms. Legal and Compliance departments should be considering various facets as they collaborate with business partners on EHR engagements.

Compliance needs to be aware of the risks associated with EHR engagements by pharmaceutical companies. Understanding if an arrangement provides something of value to the HCP or patient that could be considered an inducement to prescribe a particular drug may run afoul of fraud and abuse laws. Compliance should be asking questions to see if any part of the EHR solution makes it a medical device and subject to regulation by FDA. Deciphering if the solution is being used for marketing or clinical purposes will help determine what regulations might be applicable. With these EHR solutions it is imperative to understand who has access to a patient's health information (PHI), how is it being used, and how it is protected. Finally, it is important to understand what happens if something goes wrong with the EHR tactic. Knowing who may be liable – the pharmaceutical company, the EHR vendor, or the prescribing physician – may help with strategy, implementation, and execution decisions.

Notable EHR Litigation and Settlements

- eClinicalWorks ***$155M***
- Greenway Health ***$57M***
- Practice Fusion/Allscripts ***$145M***
- Community Health Systems/ Medhost ***Ongoing***

Companies are developing new and creative strategies to engage and influence the way HCPs interact with their EHR platforms.

- Patient lists to identify patients who have gaps in care
- Favorites, pick lists, and formulatory indicators to make it easy for HCPs to prescribe preferred brand at time of Rx
- HCP electronic prior authorizations to assist with insurance barriers
- Alerts/reminders to assist in the evaluation and diagnosis of a patient
- Clinical guidelines and order sets to facilitate evidence-based treatment pathways
- Patient education and engagement tools to drive adherence to a patient's medication regimen

Increasing Involvement with Patient Advocacy Organizations

Patient Advocacy Organizations (PAOs) provide services to patients and caregivers as well as lobby for increased research dollars and policy changes. Pharmaceutical companies often provide significant funding to PAOs to help advance the PAO's goals, but this may also create a conflict of interest. Companies should develop an advocacy approach that is thoughtful and measured about funding and about what information is shared with PAOs.

FUNDING

What are the Risks of Pharma Companies Funding PAOs?

- Lack of independence
- Inappropriate interference
- Intended scientific exchange becoming promotional in nature

What are some Mitigation Strategies?

- It is ideal to not be the only company contributing to a PAO. If company is the sole source (common in rare diseases), make sure to balance preserving independence (e.g. no company employees on the PAO Board of Directors, no company employees performing administrative tasks for PAO, etc.).
- Review funding to a PAO holistically across the company (ie., medical, sales, exhibits, etc.).
- Ensure no inappropriate interference.
- Set criteria for which PAOs the company will provide funding (e.g., does PAO have a credible Board of Directors, strong set of operating principles, etc.).

INFORMATION SHARING

What Information is Desired by Advocacy Organizations?

- Information about the work a company is doing in a particular disease state
- Status of research projects
- Publications or presentations
- Real World Data learnings
- Supply and access
- Affordability

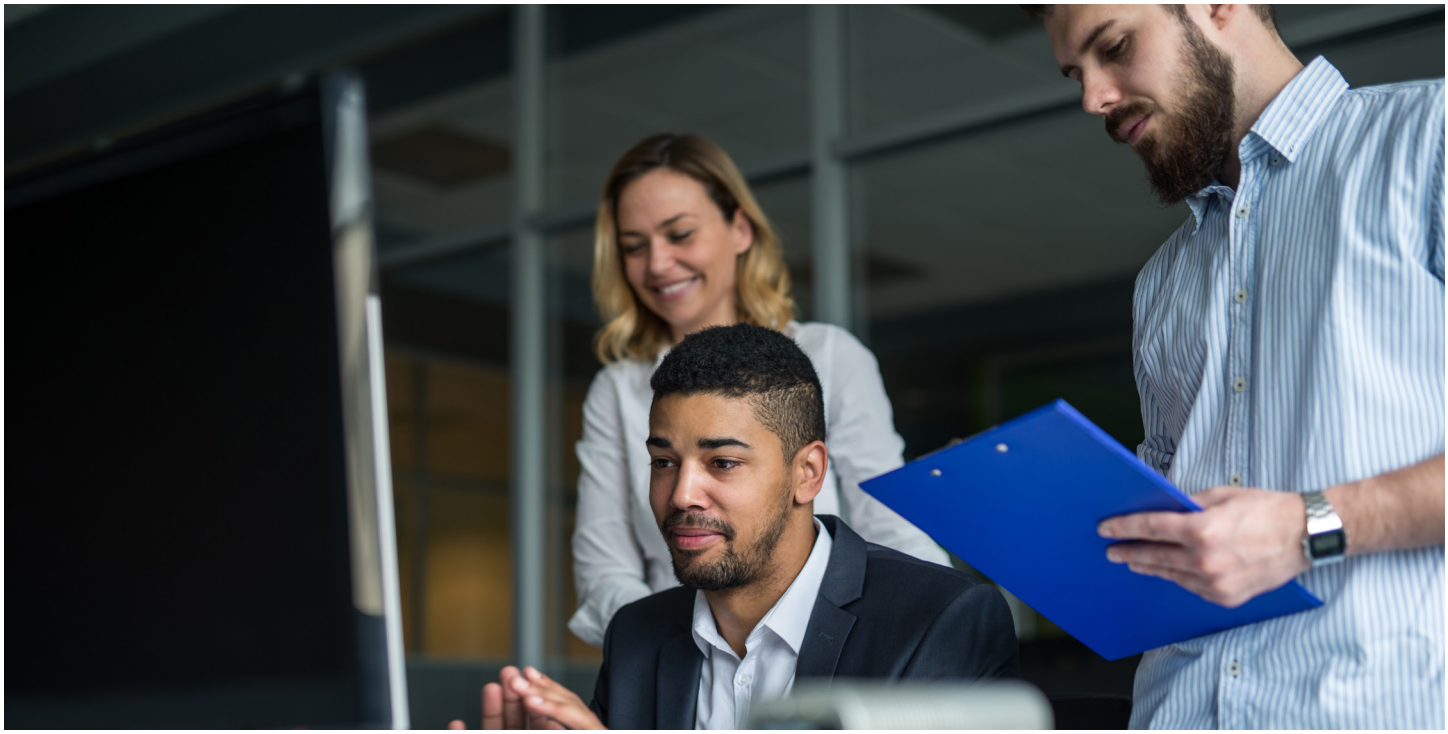
What are the Risks?

- Pre-approval promotion
- Information not going through MLR review
- Are the right people sharing the right information (i.e., advocacy or sales)?

What are some Mitigation Strategies?

- Being clear on who can share information
- Approved Q&A docs
- Being clear on how thought leaders are defined in this space
- Taking points to help company representatives verbalize what they are allowed to share and why

Finally, some PAOs are beginning to lead community-hosted forums in lieu of advisory boards. There is a sense of ad board fatigue with patients as each company is doing its own ad boards. This is especially true in the rare disease space where there is often a limited number of patients or families in the space to participate in such engagements. Among others, the European Rare Disease Organization began hosting its own forums and inviting multiple companies to attend. It will be interesting to see if this becomes a trend in the patient advocacy space going forward.



Compliance's Emerging Business Partners

Compliance partnerships with business colleagues have evolved. Human Resources and Corporate Communications are becoming increasingly important internal partners to Compliance in helping to shape the culture of the organization. These are colleagues Compliance didn't necessarily count in its immediate matrix a few years ago.

Human Resources and Corporate Communications can help Compliance build a corporate shared identity which is becoming increasingly difficult in the remote work environment.

Recent high-profile events such as the passing of Justice Ruth Bader Ginsburg have many calling for more effective diversity and inclusion initiatives. Compliance should be a leading voice on diversity and inclusion within the company and should be partnering across the organization to achieve desired goals. Specifically, companies should be reviewing who gets into its clinical trials, assessing its clinical protocols to make sure ethnic groups are appropriately represented, and ensuring diversity of thought in the workplace by challenging its hiring practices.

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