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ARTICLE

**THE CALL FOR
DISRUPTION IN
A HIGHLY
REGULATED
INDUSTRY**

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An infusion that saves the lives of patients suffering from a rare disease, an electronic cigarette, a child nutrition formula, hair straighteners, insecticides for crops and household sanitizers... There is a universe of products our bodies absorb in a wide variety of ways, and all are subject to more stringent regulations than other kinds of products. In most of the Western world, these regulations establish how an item is labeled, applied, packaged, sold, distributed and promoted... if the product in question is even allowed. In Brazil, the agencies, foundations and offices in charge of these regulations are housed within the Ministry of Health.

“Despite the limitations regulatory agencies have imposed, we have seen how associations have become empowered, helped by the ubiquitous involvement of macro- and micro-influencers, as well as the inescapable world of social media”

Between 2014/2015 and 2019/2020, Brazil had five ministers of Health and three national presidents. Although the political ideologies of each leader have swung from left to right, the actions each has taken—and, especially, those taken by the technical personnel in the Ministry, its agencies and subordinate bodies—continue to be

extremely important for companies regulated by the country’s health structures.

Despite the limitations regulatory agencies have imposed over the past five years, we have seen how associations (including patient, medical and consumer, among others) have become empowered, helped by the ubiquitous involvement of macro- and micro-influencers, as well as the inescapable world of social media. Thinking of political mobilization through the lens of social media was a novelty in 2011, when the Arab Spring changed North Africa’s status quo by organizing gatherings via Twitter (something that led to Egyptian President Hosni Mubarak blocking internet access in the country).¹ Since then, LLYC’s Center for Ideas, Analysis and Trends² described the power of grassroots campaigns and astroturfing to mobilize public opinion in 2016³ and 2017.⁴

“The number of influential political stakeholders and active interest groups is increasing. It is no wonder that, once many people gain access to decisionmakers, the press and social media, messages are diluted, lost or forgotten. Thus, third-party mobilization is a frequent practice among lobbyists, who use it to endow projects with more representation and legitimacy, as well as gain more attention for certain matters within the political and media agendas.”⁵

The same general concepts apply to mobilizations led by a cause’s ambassadors, i.e., its advocates. Besides, lobbying is still somehow taboo among Latin societies (unlike in Anglo-Saxon societies and in the countries that have worked to regulate the practice—such as Chile— where it has a profound influence). However, the evolution of the matter can be seen when comparing the most emblematic cases and the corporate profiles that have marked and mobilized grassroots campaigns over the past five years.

¹ <https://oglobo.globo.com/mundo/sem-internet-celular-egipcios-tem-que-driblar-manobra-de-ditador-para-protestar-2830631>

² <https://ideasbr.llorenteycuena.com/>

³ https://ideas.llorenteycuena.com/wp-content/uploads/sites/5/2016/12/161216_DI_artigo_Grassroots_BR.pdf

⁴ https://ideas.llorenteycuena.com/wp-content/uploads/sites/5/2017/06/170601_DI_Articulo_Grassroots_PT.pdf

⁵ Ref. Ideas 2017

A NEW SETTING

In this context, sharing economy companies like Uber and Airbnb have paved the way for the use of big data to acquire in-depth knowledge of and influence in (and through) their communities of interest. In turn, there is another sector—both traditional and innovative—exploring a road that, through advocacy actions, leads to a common and essential goal: Social license to operate, sell and market products.

These are the pharmaceutical industry clusters spearheading the development of disruptive and highly specialized therapies, including gene-therapies, to treat diseases or ultra-segmented groups, which are, as a result, as costly as they are effective.

After observing the Brazilian scenario and facing the growing demand for grassroots action, we have noticed a higher success rate in the pharmaceutical industry—or at least one less questionable in public opinion—than other sectors (telecommunications, finance, defense, aerospace and food, for instance). Positive

regulatory response, even with restrictions, is considered essential for this success.

In the case of Brazil, this procedure entails drug registration with ANVISA⁶ and its inclusion in the public (SUS)⁷ or private health system (ANS)⁸ for sale and distribution.

If volatility, uncertainty, complexity and ambiguity are features of a world where success, or even the sole existence of a business (from a legal standpoint) increasingly depends on communication, aka the ability to engage, what challenges is the pharmaceutical industry successfully addressing that could serve as a benchmark for other sectors?

“There will always be a group of people who may not be connected, but who share a series of common causes and needs that may match the interests of a sector, company, institution, etc. If a need is identified and stakeholders and leaders are discovered, pooled together, organized and prepared, new social change will take place.”⁹

⁶ The National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, ANVISA) is in charge of the regulation, registration and marketing of drugs, food, cosmetics, agrochemicals and other items in Brazil.

⁷ The Single Health System (*Sistema Único de Saúde*, SUS) guarantees comprehensive, universal and equal access for the Brazilian population, ranging from simple outpatient care to more complex procedures. The SUS was modeled after the British public health system, and it currently covers about 74% of the Brazilian population.

⁸ The National Supplementary Health Agency (*Agência Nacional de Saúde Suplementar*, ANS) is the regulatory agency linked to the Ministry of Health, in charge of health plans in Brazil. This agency also defines what drugs and equipment will be provided by health plans, in addition to overseeing services and values.

⁹ Ref. Ideas 2016.

CHALLENGE 1: LISTENING TO AND UNDERSTANDING COMMUNITIES

The first challenge for evolution, since the time when Uber allowed users to request a car and send an email to the mayor demanding friendlier regulations,¹⁰ arises from government and law-maker responses to the use of personal information obtained by apps and tools that gather, store and resend big data.

The Brazilian General Data Protection Act and its European counterpart GDPR are creating legal barriers that hinder the thorough and extremely segmented knowledge of communities, their motivations and the less-apparent flows of change.

Apart from the legal aspect, which still forms the basis of discussions on how to enforce regulations in practice, these laws are a symptom of a broader awareness across different sectors of society regarding the collection and use of personal data for political or commercial purposes. In our hyper-transparent world, there have already been signs of people rejecting certain social media and brands.

It is also worth noting that, in the face of this challenge, cutting-edge pharmaceutical companies' success comes from before the use of big data, stemming instead from the identification of a common message between industry and society.

This consideration lies within the strategic thinking of the business itself or, at least, of those who use the latent need to develop the responding product as a basis. The pharmaceutical industry, of course, benefits from the fact that the physiological need for health, more time and quality of life are at the top of Maslow's hierarchy.

However, any sector can start with generic needs, like more freedom (of election) or more ability to socialize (connectivity), to reach both niches and patients suffering from rare diseases,

but are capable of supporting a storyline that goes from local to universal.

Organized and Hyperconnected Communities

A good example is the community around spinal muscular atrophy, a serious and rare disease considered to be the leading genetic cause of death in infants and children up to two years old.

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Even before the first drug for the disease was approved, the local community was following its development and communicating the need to make it available in Brazil. After its approval in the United States, the community grew even closer and, together, they were able to promote collective funding campaigns to directly import the drug, with massive participation from local authorities and celebrities. As a group, they fought for its registration and, later, inclusion in the Brazilian public health system.

This process is considered a benchmark in the sector, hitting various records. For example, it organized two public consultations that, combined, gathered almost 90,000 contributions in 30 days. It also achieved one of the shortest periods between sanitary registration and inclusion.

¹⁰ <https://techcrunch.com/2015/07/16/uber-launches-de-blasios-uber-feature-in-nyc-with-25-minute-wait-times/>

Certainly, the drug license holder’s commitment to ensuring the community’s access to the medication—given that it was sustainable for the health systems—was a crucial factor, one constantly mentioned in all communications between the company and its many stakeholders.

In that sense, the industry’s role—or even a possible new role for the use of big data—is less related to using information to guide the story and more related to analyzing data flows to understand the loops and asymmetries in information, then act specifically as a specialist and propose other spokespeople who fit the storyline.

CHALLENGE 2: PROTAGONISM

This response by the industry leads to the **second challenge**: Protagonism. Traditional grassroots campaigns or pre-Brexit political campaigns always engineered digital campaigns for a candidate or corporation with a clear selfish interest (winning an election or making profit), even though they could also result in potential benefits for the community.

An email could be sent to regulators through the corporate platform, or a campaign committee could send posters or stickers to voters’ homes or cars.

Brexit and the elections of leaders (such as Donald Trump in the United States and Jair Bolsonaro in Brazil, despite both questionably lacking transparency) have clarified the fact that distrust has grown widespread among both voters and consumers regarding a system that requires large capital investments. The question is now, “What do they want in exchange for so much money spent on that campaign?”

In the case of the 2018 election campaign in Brazil, this was reflected by statements claiming “I am Bolsonaro’s *caixa 2*”¹¹ on T-shirts or signs voters made to support their candidate.

Sending political information over WhatsApp, despite suspicions that they had access to a professional structure and sponsors, was successful precisely thanks to the feeling of closeness with the supposed sender, who forwarded it to their direct contacts on a shared social network.

¹¹ During the 2018 presidential election, there were suspicions that companies were receiving funds in exchange for WhatsApp messages with information against Bolsonaro’s main rival. To fight these accusations, voters defended Bolsonaro on social media and through public demonstrations, as if only they were responsible for sending these messages—that is, as if they were working for free for their candidate’s campaign. Thus, the voters themselves would be the “*caixa 2*,” an expression referring to undeclared financial resources.



Although there are effective short-term solutions to dealing with the challenge of protagonism—such as falsely unbranded campaigns, data base tampering or use of robots as disseminators in the virtual environment—these are not only ethically condemnable, but they also pose a permanent risk for reputation and business. Furthermore, they could even be subject to legal penalties.

Thus, in the analyzed Brazilian cases, the solution adopted by the pharmaceutical industry by way of advocacy is far more sustainable.

Similarly, in terms of response to regulatory restrictions on direct communications, the solutions that established horizontal communication channels with their stakeholders (patient associations, medical societies, academia, class associations) have been most successful, acting only in educational, transparent and collaborative capacities. They have done so even when they could take a naturally prominent position, such as in press relations (grass-tops) or in the case of other influencers.

When appropriately executed, disease awareness campaigns, developed transparently by patient associations and sponsored by companies (whether from the health sector or not), are considered extremely useful for increasing knowledge and understanding of pathologies. They provide an excellent way to help spread relevant content and knowledge without the industry being centerstage.

For instance, the multiple sclerosis-focused NGO *Amigos Múltiplos pela Esclerose Múltipla (AME)* has organized an event called “Bike for a cause: Multiple Sclerosis” for the past five years. This event, which started small, now takes place in 18 Brazilian cities and had 3,500 participants this year.

It is worth noting that, to conquer this space, organizations must go beyond financial support. It is paramount to produce relevant content, have access to the media and build connections among patients and communities. These play a key role in the same area of interest, so are therefore key supports for actions of

common interest. As a result, the event became recognized for its relevance among different stakeholders, gaining support from companies in different fields and from various technical backgrounds, ultimately endowing this specific community with a stronger voice.

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CHALLENGE 3: FAKE NEWS

More than acting as a campaign catalyst or spokesperson, playing an educational role—again, whether as a specialist or by identifying, empowering and giving visibility to other specialists—allowed the analyzed pharmaceutical companies to overcome the **third challenge** looming in today’s world: Fake news.¹²

One example of the harm fake news has caused, both in society and among corporations, is the flare-up of diseases that appeared to be under control. In Brazil, a good example of this is the currently worsening measles outbreak and damage caused to vaccine companies as a result of the anti-vaxxer movement.

¹² Referring to the phenomenon, the word of the year, etc. <https://www.telegraph.co.uk/news/2019/08/18/pm-say-social-media-firms-must-share-responsibility-rising-spread/>

This is precisely one of the sectors where the pharmaceutical industry cannot yet be considered successful in terms of its communication strategy, despite the Ministry of Health's proactive measures. For example, the entity created a WhatsApp number for the population to ask questions about these news pieces and find out about joint actions between the **industry and medical societies**, hoping to raise awareness on misleading information.

Part of the reluctance is the difficulty of finding a prominent figure or training specialists outside their sphere of direct influence, or that of the government's. This highlights how disruptive it is for this sector—just like for most corporations—to follow the path of joining vertical knowledge and horizontal communication. It is a road some companies—though only a few, and usually small—have been proving, at least for the time being, leads to success.

And it is a road that is disruptive by nature.

As with any financial investment, past return does not guarantee future return. Identifying these challenges and analyzing the pharmaceutical industry's responses mark an evolution in the

process, highlighting trends for those sectors still learning to survive and create business opportunities in a VUCA world.

At the end of the day, we are all part of this scenario, alternately playing the roles of subject and object.

For companies in highly regulated industries and that increasingly depend on the approval and support of citizen-activists to successfully carry out their activities, the choice of role is between telling their own story and only passively responding, being dragged to the center of a conversation they really should be leading.

For the companies and sectors that choose to pave the way and contribute to the storylines that will have an impact on their businesses, this road's nature is per se disruptive. This means there will be new challenges lying ahead, for which we must find new solutions.

On the other hand, it also means the lessons learned about the importance of being transparent, investing in information and giving up the spotlight are part of a legacy that may lead us safely into the future.

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