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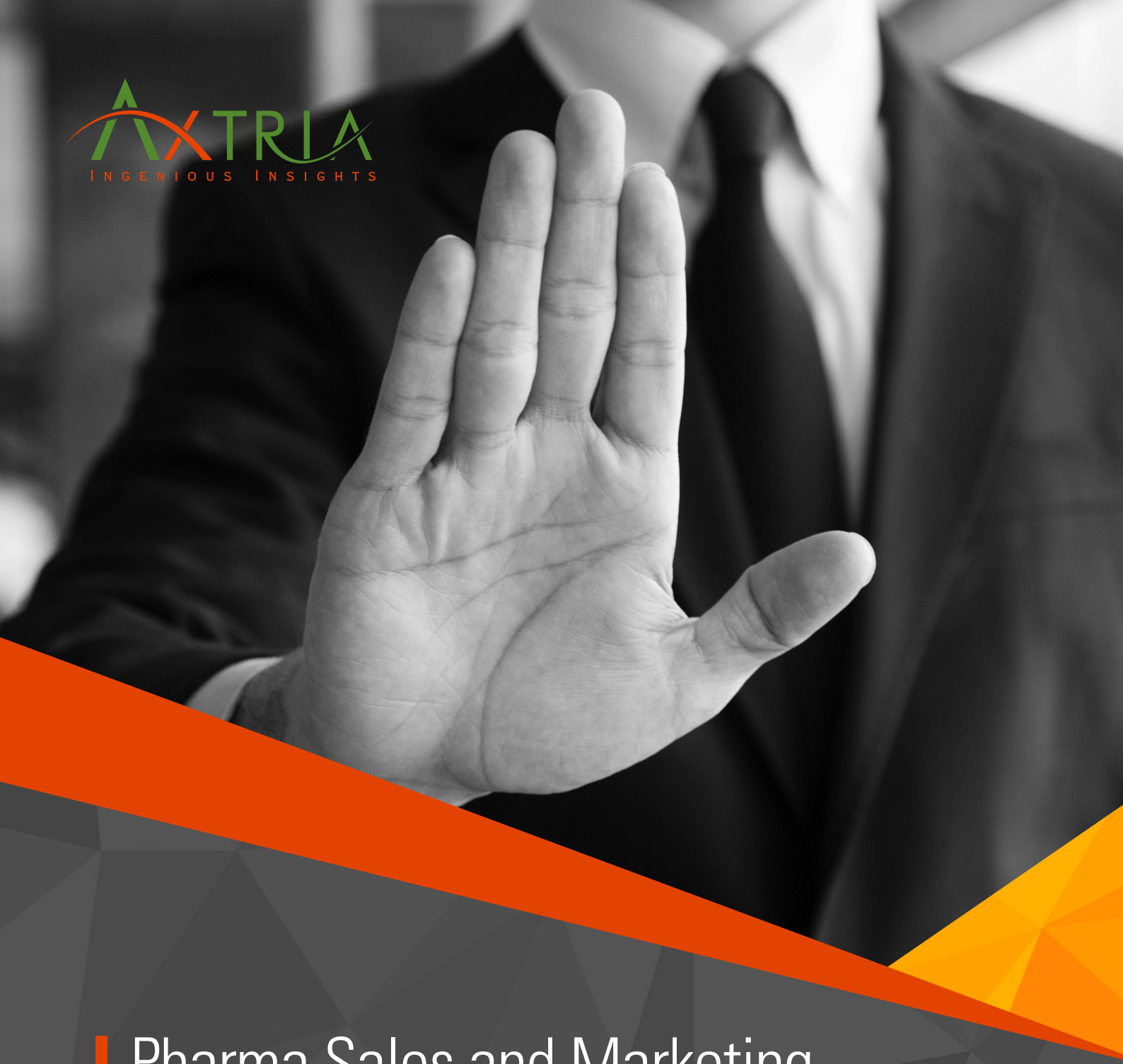

Pharma Sales and Marketing Restrictions – Has the Pendulum Swung Too Far?

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Pharma Sales and Marketing Restrictions – Has the Pendulum Swung Too Far?

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Increasing Sales and Marketing Restrictions

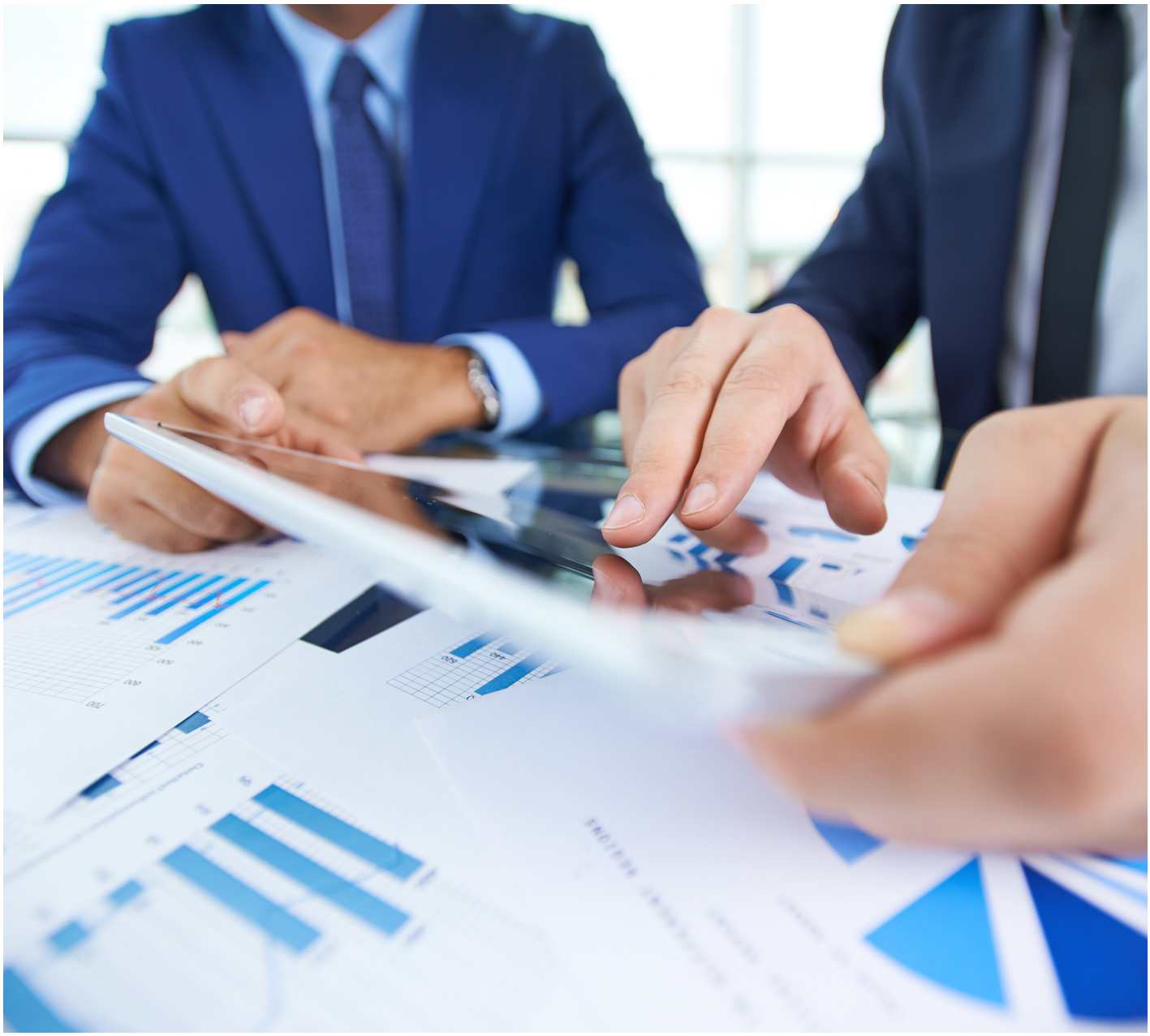
Recent years have seen increasing calls for and evidence of greater restrictions on pharma sales and marketing practices. A non-exhaustive list illustrates what one could say is an increasingly hostile environment facing pharma companies in the US, not to mention what is globally happening. Sales rep access restrictions to physicians are higher now than ever before, requiring a significant change (as noted in previous white papers published here) in how pharma companies conduct sales force strategy and operations.[1] Calls have also been made to extend sales rep access restrictions and put in place more rigorous policies governing pharma and medical device company relationships with physicians and staff at academic medical centers (AMCs).[2] An association exists representing the interests of medical students, which among many initiatives, is to strengthen conflict of interest policies at AMCs.[3] Empirical evidence has been provided that shows increasing managed control is associated with greater sales

rep access restrictions, likely due to growing consolidation of providers and payers, and the desire of health plans to force greater lower-cost generic drug utilization.[4] Physician groups have developed to call for actions against biopharma industry practices.[5] Recent calls have been made to ban digital marketing communications from pharma companies to physicians[6], and similarly eliminating DTC advertising.[7] Financial disclosures by medical product manufacturers are now required, from the Physician Payments Sunshine Act (PPSA) under section 6002 of the Affordable Care Act (ACA) of 2010, regarding any transfers of value made to physicians or teaching hospitals, with such information compiled and made public.[8] The pricing practices of pharma companies have also been severely criticized as noted in previous white papers published here. The recent presidential election cycle was not very kind to the pharma industry, to put it mildly, with the risk of either price controls or direct federal government negotiation of drug prices a greater reality than ever before.[9] Criticizing pharmaceutical marketing to doctors has even made the popular media.[10] And this brief review just scratches the surface of the explosion of articles published in the medical and health policy academic journal literature in recent years criticizing pharma industry actions and alleged negative effects on the healthcare system. Admittedly from yours truly, criticisms of the industry are now at a breadth and depth not seen in my pharma professional career since the mid-1990s. Very few voices or examples, as compared to those from industry critics over the past 10 years, can be seen in the literature that challenge the prevailing narrative and ask prudent questions about the unintended effects from policies critics would like to see imposed on the industry.[11-20]

What Should be the Response from Industry?

The main question is how will the biopharma industry *strategically* respond to criticisms of its practices and proposed policies from such advocates intended to curb undesirable drug company activities and/or outcomes? Admittedly, individual company actions at times has been their own worst enemy, and would seem to provide plenty of reasons to justify the words of industry critics. However, when compared to the vast improvements in societal well-being from pharma innovation seen over the years, and novel therapies coming out of R&D pipelines over an array of specialty medicines,[21] such criticisms deserve to be placed in a more balanced perspective. Moreover, the cost to bring such novel innovative therapies to society is not getting any cheaper.[22] The demands placed on pharma companies to deliver new drugs to treat ever-more difficult diseases are increasing. This trend is happening at a time when enacting restrictive policies previously discussed will make it even more challenging for companies to achieve health outcome and cost effectiveness goals demanded by society. Optimal regulation is about weighing the marginal benefit and marginal cost of policy actions. Attempts to eliminate "undesirable" outcomes by enacting highly restrictive policies of pharma practices will likely produce results where the marginal costs greatly exceed the marginal benefits, thus being suboptimal for society. This is not to condone bad industry/company actions, but simply a recognition that effective regulation is a balancing act. Does the pharma industry really deserve its continual low public reputation as measured by Gallup over the years, given the medicines and health outcomes it has produced, where only the oil/gas industry and federal government have consistently scored lower?[23]

So the question is simply this - has the pendulum swung too far in the opposite direction, with critics proposing policies that may very well stifle the very environment needed by companies to meet the demands and expectations of society? One consistent challenger over the years to the current anti-industry narrative says "yes".[20] However, words alone from the industry will not suffice in addressing critics. What the industry needs now more than ever is *empirical evidence* that connects existing or intended increasingly restrictive policies to changes in a set of publicly desirable performance measures, e.g., increases in R&D investment and the number of new novel therapies launched, improvements in health outcomes and reductions in total treatment cost, improvements in individual quality of life metrics, reductions in societal medical spending, and increases in worker productivity. The good news for the



industry is the growing availability of data needed to measure and assess analytically these relationships. The opportunity is here for individual companies and industry trade associations to step forward and begin to challenge the current narrative. It is very likely that in this process of analytical assessment, improvements in pharma practices will be uncovered for the betterment of individual companies and more importantly the patients their drugs serve. However, it is also equally very likely empirical evidence will uncover many policies advocated by critics that go too far from an optimal regulatory standpoint that work against the interests of patients and society.

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