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The Evidence Supporting Sales Rep Access Restrictions to Physicians – "Where's the Beef?"

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Objectives

The last 10-15 years have seen an explosion of articles in major health policy and medical journals advocating severely restricting or banning biopharmaceutical sales rep access to physicians in all settings.[1-9] With very few exceptions, the prevailing narrative these articles describe and policies recommend have gone unchallenged. This article looks at three important questions related to this narrative trend:

1. "Where's the beef?" supporting this narrative?
2. How does implementing this narrative into policy potentially affect pharma companies and patients through the lens of another viewpoint not commonly seen in the literature?
3. What should biopharmaceutical companies do in response to this increasing narrative trend of restricting access of sales reps to physicians?

"Where's the Beef?" Behind the Current Narrative

Critics of pharmaceutical detailing contend such activity is "persuasive" in intent,[10] thus producing negative outcomes for physicians, patients, and the healthcare system requiring restricting and/or banning sales rep access to physicians. Recent examples of the literature reveal inconclusive or non-robust empirical support of the current narrative. An often incorrectly cited 2010 work recommended physicians avoid exposure to information from biopharmaceutical companies after a systematic review of dozens of detailing studies.[5] The researchers argued no net benefit from detailing communications have emerged from the literature, while suggesting the potential for harm exists by allowing pharma sales rep-physician interactions. This recommendation came despite acknowledging none of the studies reviewed looked at health outcomes, no conclusive evidence was actually shown to support the paper conclusion of potential harm, and any inference about harm or benefit from detailing would be speculative. This paper is a good starting point to review the mostly ideological papers that have appeared in major medical journals about alleged negative effects of physician interactions with pharma sales reps. Also, this paper is a good example how supposed "evidence" is misinterpreted to advocate an ideology of restrictive policies against pharma sales rep access to physicians. Articles from industry critics also appeared supporting Vermont's position of restricting the flow of physician prescribing data to biopharmaceutical companies as a way to limit detailing.[11-15] However, the 2011 SCOTUS (Supreme Court of the United States) decision in *Sorrell v. IMS Health* ruled against the attorney general representing Vermont, not only on the grounds that prescriber-level data was commercial speech protected under the First Amendment, but also saying limiting detailing would be contrary to promoting public health.[11] A 2013 study reported survey results from 255 physicians across the U.S., Canada, and France and concluded sales reps provided messages that were highly skewed towards noting benefits while downplaying severe risks, thus limits should be placed on interactions to minimize potential harm to patients.[7] This study relied on physician recall, did not take into account the many information sources available to physicians, did not analyze health outcomes, and relied on a very small sample of physicians and thus questions exist on how representable the results are to the broader population of physicians. A 2013 report recommended banning sales rep access to academic medical centers (AMCs),[8] citing a widely referenced study previously noted.[5] A 2014 perspective recommended banning

all biopharmaceutical digital marketing communications to physicians, noting trends in declining access of sales reps to physicians and a skeptical view about the value of biopharmaceutical sales and marketing as justification.[16] No empirical evidence was provided on either intended or unintended effects from such a policy recommendation. Lastly, an interesting 2014 empirical study concluded that restrictions placed on detailing at AMCs reduced off-label prescribing for antidepressants and antipsychotics in children, while the reverse effect occurred at AMCs with less stringent restrictions.[9] This empirical study suggested that detailing contributed to off-label prescribing of these drugs for pediatric use, thus represented a potential harm and risk to patients since such prescribing was not empirically-based on FDA-approved clinical evidence. The irony here is that the authors acknowledged a number of limitations and qualifications of the analysis calling into question the veracity of their policy recommendations. Off-label prescribing persisted even after detailing restrictions were put in place. There are very good reasons why off-label prescribing exists that have nothing to do with any alleged malevolent effects from detailing. The study did not look at health outcomes or total costs of treatment. It is also conceivable that restricting psychiatrists to prescribe these drugs for only on-label use may actually reduce health outcomes and increase costs of care. Treating these mental disorders are very challenging. Limited effective options are available to psychiatrists. Patient responses to drug therapies are often idiosyncratic and unpredictable. While having traditional FDA-approved clinical trial evidence-based data is preferred to information gained by physician practice in scientifically uncontrolled settings, the alternative approach of banning off-label prescribing may not produce desired outcomes by restricting physician options. Lastly, FDA-approved pediatric indications for these conditions are difficult to achieve in part for safety reasons in conducting clinical trials involving children.

The overall conclusion from the preceding discussion is that most papers on this topic are "ideological" and not empirical in nature. Those few studies that do provide empirical evidence, support for increasing sales rep access restrictions is either weak, inconclusive, or where methodological concerns prevent making robust policy recommendations. None of the studies make direct connections to increasing sales rep access restrictions and improvements in health outcomes, nor provide robust empirical estimations by looking at metrics of sales rep access restrictions *at the*

individual physician level. What is needed are more *empirical studies* to test the assertions levied by pharma industry critics that increasing the restrictiveness of sales rep access to physician policies not only actually produce intended outcomes but also whether unintended effects are generated as well.

Effects from Implementing the Current Narrative – Another View

Another view about pharmaceutical detailing in the literature is that such activities are "informative", thus pharma sales rep-physician interactions should be encouraged, while under traditional FDA guidelines.[10,17-24] A long-time outspoken critic against policies generated from the prevailing conflict-of-interest and "pharmaphobia" narratives spread by anti-industry advocates that pervade the top medical journals has argued the potential for adverse effects on pharmaceutical innovation and patient health.[18,24] This view argues that collaborations between industry representatives and medical professionals have been a major factor in the rise of pharmaceutical innovation over time that have benefited patients. Pharmaceutical sales representatives provide physicians with a wide range of benefits such as the following non-exhaustive list: latest information on new drugs and indications, leave-behind medical journal articles that speak to the FDA-approved clinical benefits and risks from clinical trial work, announcements regarding appropriate use of medicines as well as newly-found risks, adverse events and black-box warnings, information on disease management programs that can benefit patient drug adherence and health outcomes, drug samples that can help physicians with changes in current therapies that are not achieving medical goals, and important managed care plan information on co-pays and coupons helpful for patient affordability, access, and drug adherence. Sales representatives can also bring in more scientifically trained specialists like MSLs (medical science liaisons) to answer off-label questions posed by physicians. Surveys continue to show a high rate of physician satisfaction with their pharmaceutical sales representative, despite the messages distributed from the top medical journals.

Increasing sales rep access restrictions therefore can be seen as adversely disrupting the dissemination of important FDA-regulated medical information that can potentially harm patients. Is there empirical evidence to support this notion? A 2012 study found strong robust empirical evidence that

increasing access sales restrictions were associated with *slower* and *less amount* responses by the end of the first year to important new medical information events in the following 3 drug cases:

1. a first-in-class drug that could help patients with type-2 diabetes,
2. perceived negative clinical trial news on a combination statin drug, and
3. the first black-box warning imposed on a drug to treat type-2 diabetes patients.

The study was the first of its kind to look at the effects of sales rep access restrictions at the physician-level and on a large scale, covering the top 80% of prescribers per drug in each case, amounting to approximately 58,000 to 72,000 physicians analyzed. While not analyzing the effect on health outcomes, other key outcomes of this study were as follows that are important to pharma public and commercial policies:

1. PCPs (primary care physicians) were more affected to access restrictions than specialists, a result of having to treat more patients across a broader set of disease conditions, thus keeping current is more difficult;
2. Access restrictions mattered more in the first-in-class drug launch than the negative news cases, since sales reps likely have more novel and new medical information of interest to physicians than the other cases, and where physicians likely rely on other sources for such information; and
3. Results showed physicians as more sophisticated consumers of medical information than given credit by anti-pharma advocates.

For example, specialists like endocrinologists and diabetologists behaved differently in the black-box warning case than PCPs, demonstrating a more nuanced approach to drug risks. These specialists likely see patients having more severe diabetes and A1c control issues, where limited continuing effective options exist. Thus, these experienced physicians are more comfortable weighing the benefit vs. risk for the most difficult of patients to treat, even with drugs having a black-box warning. A follow-up 2013 study effectively responded to critics of the 2012 article with data to support their conclusions.[26] Complementary empirical analysis to this study was also published in 2014 on the determinants of sales rep access restrictions found variations strongly affected by unique attributes defined by local MSA (metropolitan statistical area), managed care control (important as the payer and provider of healthcare consolidate), and physician prescription volume.[27] There are suggestions from analysis that access restriction policies at AMCs per MSA have spilled over into office practices in the surrounding healthcare community.[28]

Increasing sales rep access restrictions also have real effects on sales force strategy, sales operations, and marketing channel strategy. PCPs and key specialties, such as nephrology, oncology, cardiology, psychiatry, and neurology all have the majority of physicians with moderate to severe access restrictions.[28] Given pharma companies shifting their product focus to launching more expensive specialty medicines to address difficult unmet medical needs,[29] disseminating and demonstrating drug value will be more challenging for these new medicines to achieve financial success given sales rep access restrictions, thus reducing reinvestment of resources into the next generation of new drugs. Access restrictions vary at the MSA and physician-specialty levels affecting underlying assumptions on sales rep call production and sales response. Limits on localized call production at the micro individual physician and macro segment levels reduce sales production on the margin thereby affecting traditional sales force strategy outcomes (size, structure, allocation, targeting, targeting quality, and rep-physician relationship disruption). These localized effects are made bigger when coupled with sub-national variations in managed care plan control and access, IDNs (integrated delivery networks), and ACOs (accountable care organizations). These effects in sales force strategy in turn affect sales operations outcomes in territory alignment, call planning, and incentive compensation. Finally, increasing access restrictions affect marketing and sales strategy on how to engage important physicians that are inaccessible through sales reps. Combinations of digital channels and e-sales approaches will be required to engage physicians in place of sales rep activity where no-see or severe access-restrictions exist. Ignoring increasing sales

rep access restrictions means companies building greater call infeasibility into rep performance plans which in turns produces a number of costly effects such as poor rep morale, rep turnover (implying hiring and training costs), and disruption of sales rep-physician relationships.

What Should Biopharmaceuticals Do in Response to the Current Narrative?

What should pharma companies do in the face of increasing restrictions placed on sales rep access to physicians? The first response by pharma companies could be to do nothing and allow the trend of greater sales rep access restrictions to continue unabated and spread into restricting pharma communications through other channels (i.e., digital channels, DTC advertising).[16,30] This response means pharma companies will be disengaged from the debate on whether increasing restrictions on sales rep access makes public health policy sense and create potential onerous effects that work against promoting patient health as earlier noted. This response could reduce the ROI on R&D investment since disseminating medical information on drug value is made more difficult, does nothing to counter the increasing cost of developing and maintaining internal sales force strategy and operations systems to account for local variations in access restrictions, and has the potential for adverse effects on patient outcomes and cost of care if the positive "informative" view of sales reps dominates any negative "persuasive" effect.

The second response is to support *empirical studies* that look at the effect of variations in sales rep access restrictions on drug utilization patterns and outcomes (drug costs, treatment costs, patient health outcomes, and cost effectiveness). As previously noted, the current narrative has gone virtually unchallenged and lacks robust empirical validation, placing patient health and costs to the healthcare system at risk. A research design has been proposed to look at this question through various tests of hypotheses by leveraging patient claims data and a wide range of complementary data sources typically available to pharma company researchers.[31]

The third response is to *build systems*, *robust analytical capabilities*, and *execution prowess* to incorporate variations in sales rep access restrictions into sales force strategy, sales operations, sales response analytics, digital marketing strategy, and sales execution. Sales rep access restrictions create significant variations at the local and regional geographic levels, requiring greater granularity in analytical modeling and analytics in support of sales and marketing strategy and operations, and sales execution. Significant geographic variations in sales rep access restrictions means a "one-size-fits-all" national approach to sales force strategy and operations is no longer valid, requiring localized/regional thinking, on top of existing important trends that also vary at sub-national levels (i.e., IDNs, managed care). The growing trend of increasing sales rep access restrictions was identified as an important environmental trend factor affecting emerging (beyond 2 years out) sales force science issues in a 2015 survey of pharma industry practitioners.[32]

What the second and third policy responses share and require is the will by pharma companies to make *investments in advanced analytics* that support strategic and operational imperatives critical to the business and most important of all to patients. Companies can be passive and have the public health policy narrative by critics dictate the commercial landscape that will only become more restrictive and potentially adversely affect patients. The alternative is take a more aggressive proactive stance to challenge the status quo. Also, such empirical studies would provide learning what improvements can be implemented in the sales force / commercial model with support provided through empirical evidence by showing the total implications of policies restricting sales rep access to physicians. Ensuring the dispersion of innovative industry drug technology to patients through a range of medical information channels to physicians that can positively impact health outcomes and healthcare system deserves no less of an effort by pharma companies. The suppression of FDA-regulated pharmaceutical commercial speech, regardless of the channel, is not in the best interests of physicians and patients.[26]

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