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GlaxoSmithKline (GSK) executives made industry news in 2011 by announcing that their sales reps would no longer have their at-risk compensation based on prescription (Rx) volume generated by physicians.[1] The traditional proportion of base-salary to at-risk incentive compensation (IC) for pharma sales reps is about 75%-80% to 25%-20% respectively. The GSK plan was to eliminate Rx-based incentives that could encourage sales reps to engage in "persuasive" activities and potentially lead to problematic sales and marketing practices. Instead, the at-risk compensation component would be calculated on the basis of metrics that measured sales rep "informative" activities that could help physicians and their patients. Reactions to the new IC program have been mixed, with assertions that the program has adversely affected sales, though GSK is still committed to the new approach, albeit with some adjustments.[1] This may explain why other pharma companies have not followed suit with this IC approach. This white paper explores the challenges in continuing to provide at-risk compensation for sales rep performance based on territory-level Rx volume given the rapidly changing environment facing biopharmaceutical companies and why maybe now other companies should take note.

Among the most significant changes in the pharma industry is a shift to specialty medicines that are more expensive to adopt by managed care plans and afford by individuals, and more complex to produce and explain to healthcare decision-makers given the nature of the science involved relative to traditional small molecule drugs.[2] This shift has meant greater scientific skills needed by sales reps to deliver meaningful details to specialty physicians. Also, the gap is widening between what it costs to bring these innovative medicines to market,[3] versus individual and societal willingness and ability to pay for this innovation.[4] Thus, demonstrating value is critical throughout the entire supply chain, from R&D to beyond patent expiration. As a result, pharma companies are increasingly being required to create performance and outcomes-based contracts with payers in order to receive manager care plan formulary adoption and ensure patient access/affordability and adherence.[5] In addition to the shift toward specialty medicines and payer dynamics, there is growing influence from integrated delivery networks (IDNs) and accountable care organizations (ACOs). Taken together, these developments alone would suggest a *team* approach is required for success to engage physicians and follow the patients they treat through today's pharma healthcare ecosystem while dealing with the growing influences of payers on drug utilization. This team approach would imply an IC plan design away from individual-based Rx-volume rewards to a team-based bonus-type structure tied to metrics that measure success in engaging healthcare professionals (HCPs) and their impact on patients.

There is also heightened regulatory scrutiny on industry sales and marketing practices and its effect on physician prescribing patterns (including off-label prescribing), healthcare costs, and conflicts-of-interest that are alleged to work against promoting patient health. Over $30 billion in drug company civil settlements and criminal penalties have been paid to federal and state agencies from 2006-2015.[6] A significant number of pharmaceutical companies are currently under Corporate Integrity Agreements (CIAs) by the Office of Inspector General.[7] Complementing this scrutiny is the trend toward increasing sales rep access restrictions to physicians being erected at healthcare systems, group

practices, hospitals, and academic medical centers (AMCs).[8] So it would appear that eliminating at-risk sales rep compensation based on Rx-volume to reduce inappropriate sales rep practices has face-validity when looking at the preceding compliance metrics and access restriction trends.

What then does an IC plan design look like to drive appropriate sales rep behaviors, lead to actions that generate desirable physician decision-making, and improve patient outcomes consistent with the preceding emerging environmental industry trends? The marketing literature makes two distinctions between pharma sales rep promotion as being "informative" or "persuasive".[9] While in reality pharma sales reps engage in both activities, the differentiating points being one of degree, intent, and effect, what can companies do to develop IC plans consistent with "informative" sales rep activities?

Why is this distinction important? The medical and health policy literature associate "persuasive" sales reps with many negative connotations, such as: a) encouraging higher price branded drug prescribing when therapeutically equivalent lower-cost generic drug options may exist, b) promoting inappropriate drug use and off-label prescribing that lack FDA-approved empirical clinical trial data, c) creating conflicts-of-interest that distort physician prescribing that do not promote or may even work against patient health, d) creating congestion in physician offices, e) taking physician time away from seeing their patients, f) sending samples that increase the cost and lower the quality of prescribing, and g) providing information that is skewed toward benefit while down-playing risks. Thus to industry critics, persuasive pharma sales rep activities represent a fundamental reason why companies are continually charged (and where companies generally settle) on allegations of improper sales practices.

"Informative" sales rep activities imply engaging in practices that encourage delivering value to physicians and their patients. Company end goals are metrics based on patient health outcomes and costs of care (important for outcomes-based payer contracts), with intermediate outputs like patient compliance/adherence rates, incidence of adverse events, and rate of physician on-label prescribing as indicators of success. Sales rep activity metrics used as indicators of final outcomes through achieving intermediate goals could be the following and included in IC plans:

- qualitative assessments from physicians on whether sales reps are adding value in their interactions.
- qualitative assessments from the office staff (nurses, office manager, etc.) on whether sales reps are adding value in their interactions.
- providing physicians information on and enrollment of patients in disease management programs.
- connecting physicians to medical science liaisons who can provide deeper answers to medical questions.
- providing physicians information on and enrollment of patients in a co-pay card and coupons (helpful to patients for drug adoption and adherence).
- number of patients enrolled in a patient assistance program.
- sending physicians optimal level of samples that can be helpful for physicians to try patients on new therapies when other approaches have failed to reach clinical goals.
- alerting physicians to new drug indications, FDA-imposed black-box warnings, and other important drug updates.
- call activity metrics, i.e., calls completed, calls completed to plan, completion rates on product details (primary, secondary, tertiary).

- proportion of call plan physicians who listen to a detail through a notebook/non-paper delivery.
- proportion of call plan physicians who attend and the qualitative assessment of local speaker programs organized by the sales rep.
- proportion of call plan physicians who seek added drug information through the company/drug website.

The challenges for companies that continue to use Rx volume-based at-risk sales rep IC will mean addressing the following concerns. How do companies technically handle targeting of physicians for drug detailing who treat patients for a specific demographic characteristic for which no FDA-approved exists, i.e., drug use for pediatric or geriatric patients? Even if details are strictly on-label, could companies with Rx volume-based IC designs be accused of promoting off-label use? An even finer distinction, what if a physician treats a proportion of pediatric and/or geriatric patients out of a total base of patients, what is the threshold rate that should guide companies to steer clear of a physician or discount the amount of total prescriptions to account for off-label Rxs? Further, while the existence of off-label Rxs by physicians are well known to pharma companies, determining their extent is more problematic. Some therapy classes are known to have Rxs dominated by off-label physician prescribing. Sales rep incentives on the basis of total territory Rx-volume could be seen as implicitly rewarding activities that generate off-label prescriptions, and thus the legal foundation for claiming pharma companies are intent on promoting off-label drug use.

Pharma companies can respond in a number of ways. Companies can say it is very difficult to know in a robust way given data limitations why an individual physician prescribes a drug since sales reps cannot have off-label discussions with physicians to determine the extent of such prescribing. Claims data can elicit the reason behind drug utilization, though not without some caveats such as the cost of obtaining the data, accuracy, and fragmentation of claims databases so obtaining national physician coverage is very difficult. The preceding arguments would suggest pharma companies do not have a precise manner to measure off-label physician-level prescribing to adjust targeting, territory alignment, call planning, objective setting, and IC plans. Continuation of the status quo will increasingly require pharma companies to institute costly flagging procedures and greater complexity in sales operations systems to account for what may constitute appropriate vs. inappropriate targeting of physicians and rewards to sales reps based on Rx volume. The likelihood of costly errors and legal challenges on pharma companies will only increase given these complexities.

More recently, the applications of advanced analytics are providing insights into ways to measure individual physician-level off-label prescribing. Researchers have proposed a detection-controlled estimation approach to provide a more informed and accurate assessment on the on-label vs. off-label prescribing patterns of individual physicians.[10] Applying this method may be used to discount territory level Rxs based on the estimate of off-label Rx per physician. In addition, pharmaceutical companies are increasingly gaining access to patient claims and electronic medical records (EMR) data that can further elucidate on the reasons for physician-level on-label vs. off-label use. However, the utilization of specialty medicines that treat small orphan drug-like patient populations lessens the insights these fragmented databases can generate. In short, the legal standing of pharma companies will be increasingly placed in jeopardy if they do not take steps to estimate and adjust Rx-based IC plans for off-label prescribing while knowing methods and data sources may exist to make an informed and robust estimate.

What can pharma companies do? First, pharma companies can ask the FDA for greater clarification on the standard of knowledge that pharma companies should have to know what constitutes an "off-label" physician and how much analytics should be undertaken by companies to determine a reliable estimate of physician-level off-label prescribing. Second, external pressures on pharma companies from payers (private and public) are demanding greater evidence on improvements in health outcomes and costs of care contingent on formulary access. This would suggest a change in Rx-based IC plans would seem to be in order and move toward incentives that affect sales rep behaviors that ultimately drive improvements in patient health outcomes and cost effectiveness. A critical challenge here is the lack of commercially available IC-grade datasets that capture patient-level outcomes. Third, the preceding arguments would


suggest eliminating at-risk Rx-based territory sales goals and incentives, and move to a base-salary with bonus model with evaluation of rep performance dependent on management by objectives (MBOs) consistent with informative sales rep activities as described earlier. Another challenge raised by this point is a greater reliance on qualitative subjective measurements and thus relative consistency across sales reps on their performance. The consistency of rep performance has implications not only on IC plan rewards but also rep morale and assessments for special year-end top-performance awards. Fourth, implementing a new approach in IC design will require pharma companies to acquire new databases and adopt different analytical techniques to measure how changes in rep performance metrics affect desired outcomes. Experimentation will be required to develop robust metrics that reps will have the confidence to have in their IC plans that affect desired outcomes, metrics first-line sales managers (FLSMs) can coach/mentor/train sales reps on, and where headquarters can assess the ROI on resources employed to affect changes in rep performance metrics and outcomes. Currently, this body of knowledge does not exist and would have to be created through research and experimentation. These technical issues will likely make it more difficult to convince pharma companies to move away from traditional IC plans, despite the preceding identified risks and benefits. Fifth, as changes in sales rep performance metrics are implemented, greater attention must be placed on defining, creating, and enabling the group of FLSMs necessary to support sales rep activities in the field.[11] While pharma companies focus their sales force efforts on front-line sales reps, research suggests the FLSM team is actually the most critical group for sales force success.[11-12]

Changes in emerging environmental trends facing the pharma industry are requiring companies to rethink different strategic and operational sales force plans along with the analytics and big data required for support to drive new outcome measures (i.e., health outcomes, cost effectiveness, patient compliance and adherence, etc.).[13] There are numerous challenges implementing with success an IC design that moves away from traditional Rx-volume measurement. There are known issues as elaborated here and likely unknown ones that will arise only from experimentation and execution. The GSK experience thus far would suggest success has not yet arrived. Despite this, companies need to rethink the role of the sales force and develop the right IC plan design to drive appropriate behaviors and activities to affect new outcomes in response to environmental trends in an ever-changing pharma world.

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