AXTRIA
INGENIOUS INSIGHTS

Perspectives on Pharma Company Use of Open Payments Data

January 2019

Perspectives on Pharma Company Use of Open Payments Data

George A. Chressanthis, Ph.D., Principal Scientist, Axtria Inc.
Geeta Padbidri, RPh, MS, MBA, Director, Axtria Inc.

1. Introduction and Paper Objectives

Open Payments Data (OPD) was a creation of the Physician Payments Sunshine Act as part of the 2010 Patient Protection and Affordable Care Act. The database is accessible via https://openpaymentsdata.cms.gov/ and administered by the Centers for Medicare and Medicaid Services.[1] The purpose of the program, as noted on their website, is as follows: "to provide the public with a more transparent healthcare system." Specific details about OPD are noted as follows:[1]

> Open Payments is a national transparency program that collects and publishes information about financial relationships between the healthcare industry (i.e., drug and device companies) and providers (i.e., physicians and teaching hospitals). These relationships may involve payments to providers for things such as research, meals, travel, gifts, or speaking fees.

Table 1 lists major OPD types by category. The database is at the physician level and goes back to August 2013. OPD summary characteristics for a 2017 market data snapshot, covering $8.4 billion in payments paid by 1,525 manufacturers/GPOs to 628 HCPs and 1,158 teaching hospitals, reveals the following:[1]

(1) $8.41 billion of total US value	(2) 11.54 million records
(a) $2.82 billion – General payments	(a) 10.93 million
(b) $4.66 billion – Research	(b) 608,000 HCPs/ 1,158 hospitals
(c) $927 million – Ownership	(c) 2,630

Source: Centers for Medicare and Medicaid Services, https://openpaymentsdata.cms.gov/summary.

Table 1. Major Open Payments Data Types by Category[1]

Payment Category	Payment Sub-category
General	Consulting, Textbook/Educational Materials, Cumulative Food and Beverage spend of >$25, Speaker Program-Attendee, Speaker's Fee
Research	Research grants, R&D-Clinical trial
Ownership	The current cumulative value of ownership or investment interest held

Source: Centers for Medicare and Medicaid Services, https://openpaymentsdata.cms.gov/.

The database contains no interpretations nor draws conclusions from the information. Healthcare consumers of this information are suggested to contact their provider for further understanding if questions arise. However, this has not stopped academic researchers from studying the data and conducting empirical studies on various topics on possible effects from pharma companies making payments to physicians. A later section will summarize key findings from studies by relationships tested. The reasons for going through this review is to show what has been done in utilizing the database but also to caution pharma companies on generating business actions in ways that the database was designed to help limit!

This paper addresses the following issues pertaining to OPD and will proceed in the following fashion by addressing each question before ending with conclusions and business policy directions:

(1) What are the likely factors that helped to create this database? (Section 2)

(2) What are the conclusions from empirical studies that have applied this database and physician prescribing effects from instituting sunshine laws? (Section 3)

(3) How do pharma companies currently apply the database and for what purposes? (Section 4)

(4) What are the data intricacies and challenges in applying OPD? (Section 5)

(5) What are perspectives how pharma companies can use OPD? (Section 6)

(6) Conclusions and business policy directions. (Section 7)

2. What Factors Helped Create Open Payments Data?

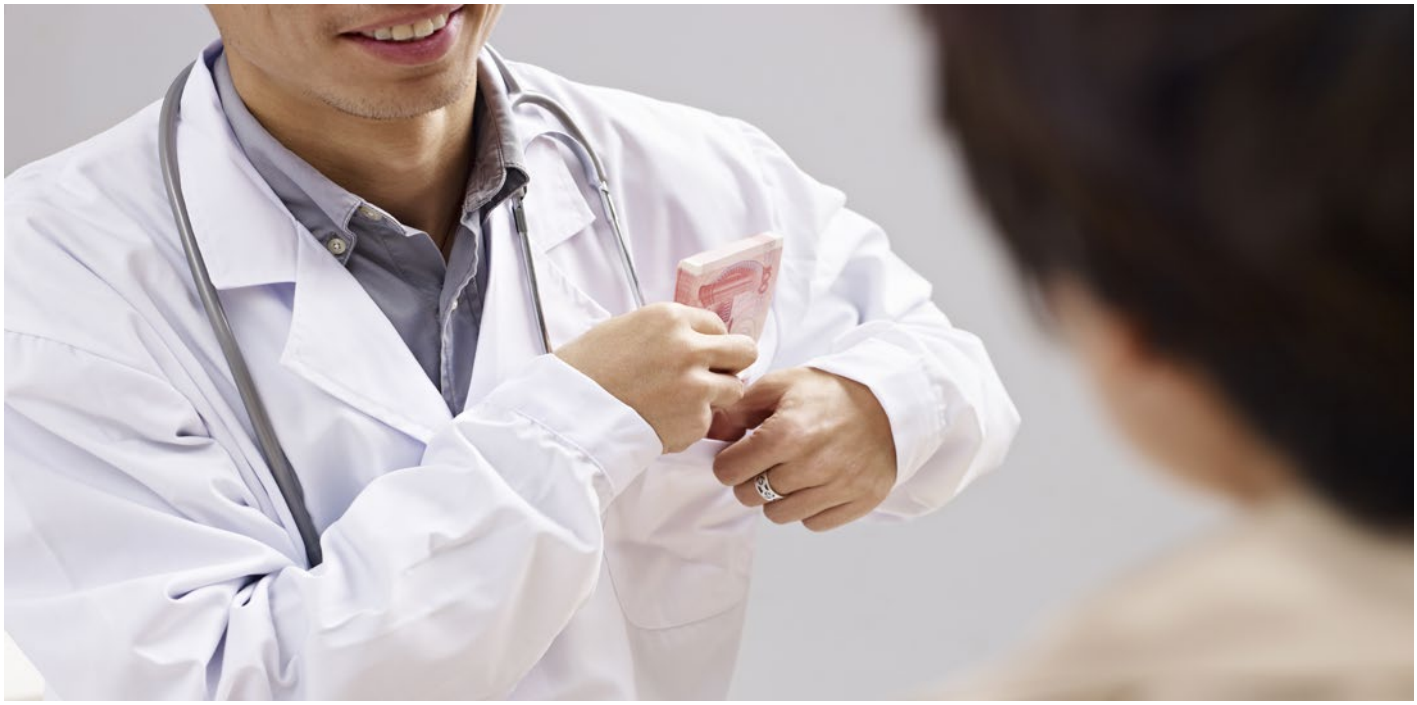
A search of the literature did not find the motivating factors behind the creation of OPD. However, we surmise its creation can likely be traced back to three forces:

(1) *Motivated by past questionable, unethical, and illegal behaviors by drug and medical device representatives to influence physician prescribing and product use*. These behaviors, for example, spawned the P*h*RMA Code on Interactions with Health Care Professionals published in January 2009 for companies to self-regulate themselves against being bad actors.[2] While questionable activities from companies still exist post-P*h*RMA code enactment, it would be safe to say that the rate of occurrence has likely diminished.

(2) *Generated from the growing influence of the "conflict of interest" narrative, which seeks to limit significantly or ban all industry communications and interactions with healthcare professionals.* This trend is evident as seen through articles published in the major academic medical and health services research journals as explained by a critic of this trend.[3] Some notable examples of calls to ban certain pharma sales and marketing activities include detailing at academic medical centers,[4] digital communications from pharma companies to physicians,[5] and direct-to-consumer (DTC) advertising.[6] Even popular culture has taken note of the creation of OPD with a sardonic parody of a TV DTC advertisement illustrating the influence of pharmaceutical money on physicians.[7]

(3) *Caused by the underlying Rx volume-based commercial model design applied by pharma companies.* The current focus objective function of companies is to drive Rx-volume. This model design explains the motivation behind payments to key opinion leaders (KOLs) and physicians to gain access and further drive Rx volume, though at the cost of appearing that such money biases physician response for treatment in ways that are not beneficial to patients and the healthcare system.

It is important to keep these forces in mind as this paper reviews the conclusions from empirical studies applying OPD and recommendations how pharma companies should leverage this data going forward.



3. Summary of Academic Empirical Studies on OPD and Sunshine Laws

Academic researchers in the health services and policy, medical journal, and marketing/economics areas have taken great interest in analyzing OPD. Part of this interest may be caused by the general overall negative view academic researchers have on the pharma industry.[3] The articles reviewed here represent just a sample of the total empirical studies completed. However, they capture the kinds of conclusions reached by the total universe of studies analyzing OPD and the effects of sunshine laws.

(a) Positive association between company payments and prescribing of higher cost brand-name drugs.[8-11]

(b) Association between company payments and regional patterns in prescribing of marketed drugs.[12]

(c) Positive association between company payments and prescribing of brand-name drugs of uncertain medical benefit.[13]

(d) Positive association between company payments for meals and brand-name prescribing.[14]

(e) Negative association between company payments for brand-name drugs and generic-drug prescribing.[15]

(f) Higher healthcare costs and lower patient economic welfare due to the conflict of interest created by company payments.[9,16-18]

(g) Positive association between company payments and prescribing of newer more expensive medications.[19]

(h) Calling into question the unbiasedness of physician decision-making when confronted with interactions by and payments from the industry.[20-23]

(i) Studies that look at the effects of sunshine laws, with the overall effect that such laws may lower healthcare costs via brand to generic prescribing or curtail prescriptions overall:

(1) Increased public scrutiny as a result of the disclosure might persuade firms to decrease payments.[24]

(2) Render physicians less willing to accept payments.[25]

(j) Studies that show sunshine laws may not change physician 'biased' decision-making.[26-27]

(k) Study that shows enactment of a sunshine law reduces both brand and generic drug prescribing (looking at 3 classes of drugs – statins, antidepressants, antipsychotics), though the former was reduced by a larger amount. No conclusions were reached on healthcare costs and patient outcomes.[28]

What is missing from the above empirical studies are links between payments made to providers and value-based messaging, patient health outcomes, and total treatment costs. These links require the merging of open payments with claims, electronic health records, and laboratory databases. Let us assume for the time being that the above summary of studies is true, that payments captured through OPD influence physician prescribing and encourage greater branded versus generic drug use, thus increasing drug costs. Critics of the pharma industry contend that this shows the negative influence of payments. However, missing in the analysis is the other side of the equation - the effect of disseminating useful FDA-regulated scientific/medical/clinical information during say a lunch & learn, speaker program, invitation to hear a KOL, or knowledge gained through conducting paid clinical research, etc. Another avenue of possible effects is how physician knowledge gained through activities funded by such payments allows for better patient drug adherence/compliance, increased patient enrollment in a disease management program, etc., which are all leading indicators of improved health and economic outcomes through lowering overall treatment costs. Also, different types of payments likely yield different effects. Different programs funded by such payments disseminate useful information in ways that generate varying effects, in an analogous way how marketing-mix analysis shows different allocations of sales and marketing channels producing different Rx-volume effects. Pharma companies would stand on firmer ground if they avoided using payments as a substitute promotional vehicle. Instead, they should be focused on using OPD for improving on HCP targeting and valuation models and patient-centered applications designed to generate "informative"-driven outcome and value-based effects, rather than for "persuasive" and adverse Rx volume-based effects as noted by industry critics. Industry critics would stand on firmer ground in their conclusions about the negative influences of payments if drug costs comprise a disproportionate share of total treatment costs and the technology differences between branded/biologic versus generic/biosimilar drugs respectively are quite small. Also, it is possible that even if there are beneficial patient outcome and treatment cost effects associated with payments, those positive effects could be offset by the amount spent by drug companies. However, all this are empirical questions that have yet to be decided. These unknown effects represent a significant gap in knowledge and an important opportunity for pharma companies to demonstrate the value associated with "informative" activities funded through OPD.

4. Current Pharma Applications of OPD

How do pharma companies currently apply OPD? An informal internal analysis within Axtria of people knowledgeable of client activities provided applications in the following commercial operations and analytics areas. Below is a summary of survey findings:

(a) Commercial Operations Applications

(1) HCP target refinement.

(2) HCP target identification for pre/new launch of a drug.

(3) Understand competitive share of voice.

(4) Analogue for physician potential importance and/or measure of value.

(5) Influence of competitive voice on brand TRxs.

(6) Accessibility of physicians/accounts (i.e., willingness to engage pharma companies).

(b) Commercial Analytics Applications

(1) Pre-launch analytics (e.g., go-to-market (GTM) strategy).

(2) Commercial model design (e.g., segmentation, customer valuation, and targeting).

(3) Call planning (e.g., target refinement).

(4) Marketing analytics (e.g., spend benchmarks, guidance on promotion-mix, competitive promotion assessment, part of the marketing-mix resource allocation decision).

(5) Prediction modeling (e.g., predict future adopters, predictor of uptake).

The focus of pharma company activities is on prescribing behavior and associated applications. There are no rigorously assessed applications on how payments can affect value-based messaging to HCPs nor any applications that are patient-centered and tied to better clinical practice and ultimately outcomes. Before such analyses can be undertaken, a review of the challenges using OPD will be reviewed.

5. Data Intricacies and Challenges in Applying OPD

There are multiple challenges using the data despite the wealth of information contained in the database. Below is a summary of key issues:

(a) Identifying Physicians

Physician NPI (National Provider Identifier) code is not present. "Fuzzy" matching is needed for identifying and linking physicians to other relevant data. ~90% match rates have been obtained. For the same profile ID (HCP ID) on OPD, multiple addresses / variants of the same address might be populated depending on how individual manufacturers report the data.

(b) Co-Promoted Drugs

Identifying product level information will not be possible when payments like Food & Beverage are incurred while promoting multiple drugs together.

(c) Low Expense Channels

Capture rates for low expense channels like calls could potentially be low because of the $10 per activity cut-off amount.

(d) Disease States

Disease states are not available and can be derived in some cases based on products promoted and HCP specialty.

(e) Excluded Payment Types

Information on some payments/transfers of value like samples, educational materials for patient use will not be available.

(f) Lag in Reporting

The data is annual and lags by about 6 months. For example, the data for 2017 was released in late July 2018.

The preceding intricacies and challenges do not eliminate the possibilities of utilizing this database, though they do present challenges and potentially limit their value. It is also important to keep these limitations in mind when interpreting results obtained through applications of OPD.

6. Perspectives How Pharma Companies Can Use OPD

All the applications noted in Section 4 are more closely tied to Rx volume-based outcomes. However, this policy approach runs the risk of playing right into the issue that critics charge about transfer of payments to physicians and their adverse biasing effects on prescribing and resulting higher drug costs without commensurate improvements in value-based outcomes. The key here is one of intent. Applications of OPD for improved HCP targeting and valuation, refinements for HCP measurement, help with fine-tuning sales operation processes, etc. as elaborated earlier are all fine if the intent is ultimately tied to improvements in serving HCPs and the patients they treat. The closer the connection between increasing payments and Rx-volume, especially through using payments to HCPs as a substitute promotion, then companies risk generating negative optics. What pharma companies need to demonstrate is that the intent of using OPD is designed to better serve the clinical needs of HCPs, the transfer of useful FDA-regulated scientific/medical/clinical information to HCP through value-based messaging, and patient-centered applications that show how OPD uses in turn produce improved outcomes. The latter effects mean applications of OPD that empirically analyze the mix of payments on both intermediate and final outcomes:

(a) Commercial operations and analytics applications (HCP-centered, see Section 4, non-exhaustive list)

(1) Drive improved servicing of HCPs and the needs of their patients.

(2) Improve value-based messaging to HCPs through better targeting and valuation.

(3) Improve the resourcing and mix of payments as long as the intent is to better serve HCPs.

(4) Generate appropriate drug prescribing (e.g., this could entail improvements in drug pre-launch preparations and launch uptake).

(5) Improve sales force strategy (segmentation) and operation (call planning, assumptions of HCP access) processes designed to better serve HCPs.

(b) Intermediate outcomes (patient-centered)

(1) Patient drug adherence/compliance.

(2) Rate of receipt of standard therapy.

(3) Rate of receipt of patented/branded drug.

(4) Rate of receipt of new drug(s).

(5) Rate of appropriate receipt of targeted biologic agent.

(c) Final outcomes (patient-centered)

(1) Rate of adverse events.

(2) Drug costs.

(3) Total treatment costs.

(4) Health outcomes (in the case of cancer or other terminally-fatal diseases, length of survival).

(5) Treatment cost effectiveness.

This potentially means not all payments are associated positive effects, and if so, then they should either be stopped, or, the information conveyed during those funded interactions be changed to be more outcome-producing. The underlying theoretical foundation for relating open payments with intermediate and final outcomes is that they are part of the process of access to physicians in conveying useful information in their treatment of patients. Prior empirical work shows the significant effect of changes in physician access sales rep access restrictions with their Rx-response to new medical information events in ways that potentially work against protecting patient health.[29-30] The process of sales and marketing, as with activities associated with open payments, should be information-producing that benefits physicians in treating patients. A similar theoretical structural model was presented at the 2017 International Society for Pharmacoeconomics and Outcomes Research (ISPOR) international meeting in the context of sales and marketing affecting the intermediate and final outcomes in the treatment of colorectal and breast cancers, and non-small-cell lung carcinoma (NSCLC).[31]

The execution of the above empirical model structure would entail merging OPD with traditional pharma commercial analytics databases and claims data (see the ISPOR presentation diagrammed structure of the modeling process and data requirements).[31] Claims data contains the necessary data elements to measure resources employed to treat patients and outcomes. This will require the linking/merging of OPD with other databases. The intricacies and challenges noted in the previous discussion can be overcome to conduct this kind of analysis.

7. Conclusions and Business Policy Directions

The application of OPD provides an opportunity for pharma companies to demonstrate what is beneficial about physician and industry interactions, and potentially, what is also detrimental about such interactions. Companies need to move away from a focus on using payments as a way to

generate Rx-volume effects and instead choose to look at value-based outcome effects, which can include producing greater appropriate drug prescribing for patients who can benefit from such utilization. Scrutiny of pharma company activities is only likely to get more intense and negative about the alleged adverse effects of industry interactions with HCPs. In response, pharma companies need to reevaluate and empirically assess the effects of all their engagement activities with HCPs. Some activities may indeed be found as producing negative effects, and if so, need to be addressed. Critics of industry interactions with HCPs argue that only through banning all company activities will outcomes improve. This assertion in the opinion of the authors here is untested, and flies against the intuitive notion that by restricting the flow of FDA-regulated information to HCPs this somehow produces *better* outcomes. Encouraging greater physician ignorance by restricting the flow of medical information can only result in *lower* outcomes, all things being equal. This relationship can only be true if what companies are doing in their interactions is indeed detrimental to patients. *We therefore advise companies to reassess their activities, look at the intent of such activities, and determine if they do indeed produce beneficial HCP and patient outcome effects through spending captured via OPD*. Pharma companies need to ensure that the intent of their actions is one designed to help HCPs and their patients, countering the notion contained in the quote below.

> Money has transformed every watchdog, every independent authority. Medical doctors are increasingly gulled by the lobbying of pharmaceutical salesmen.
>
> ***Thomas Carr Frank***
> *American political analyst, historian, and journalist*

References

1. Centers for Medicare and Medicaid Service. Open Payments Data. Published online and available https://openpaymentsdata.cms.gov/.
2. P*h*RMA. Code on interactions with health care professionals. Published online 2 February 2017, available at https://www.phrma.org/codes-and-guidelines/code-on-interactions-with-health-care-professionals.
3. Stossel T. *Pharmaphobia: how the conflict of interest myth undermines American medical innovation*. Lanham, MD: Rowman & Littlefield; 2015.
4. Korn D and Carlat D. Conflicts of interest in medical education: recommendations from the Pew Task Force on Medical Conflicts of Interest. *JAMA* 2013; 310: 2397-2398.
5. Manz C, Ross J and Grande D. Marketing to physicians in a digital world. *New England Journal of Medicine* 2014; 371: 1857-1859.
6. American Medical Association. AMA calls for ban on direct to consumer advertising of prescription drugs and medical devices. Published online 17 November 2015, available at http://www.ama-assn.org/ama/pub/news/news/2015/2015-11-17-ban-consumer-prescription-drug-advertising.page.
7. Oliver J. Marketing to doctors. HBO's Last Week Tonight with John Oliver, episode air date 8 February 2015, available at https://www.youtube.com/watch?v=YQZ2UeOTO3I (caution regarding the some of the language used in this episode, start at the 13:52 minute mark).
8. Fleischman W, Ross J, Melnick E, et al. Financial ties between emergency physicians and industry: insights from open payments data. *Annual of Emergency Medicine* 2016; 68: 153-158.e154.
9. Ornstein C, Tigas M and Jones Grochowski R. Now there's proof: docs take company cash tend to prescribe more brand-name meds. *ProPublica*, published online 17 March 2016, available at https://www.propublica.org/article/doctors-who-take-company-cash-tend-to-prescribe-more-brand-name-drugs.
10. Perlis R and Perlis C. Physician payments from industry are associated with greater Medicare part D prescribing costs. *PLoS One* 2016; 11: e015574.
11. Yeh J, Franklin J, Avorn J, et al. Association of industry payments to physicians with the prescribing of brand-name statins in Massachusetts. *JAMA Internal Medicine* 2016; 176: 763-768.
12. Fleischman W, Agrawal S, King M, et al. Association between payments from manufacturers of pharmaceuticals to physicians and regional prescribing: cross sectional ecological study. *BMJ* 2016; i4189: 354.
13. Sharma M, Vadhariya A, Johnson M, et al. Association between industry payments and prescribing costly medications: an observational study using open payments and Medicare part D data. *BMC Health Services Research* 2018; 18: 236.
14. DeJong C, Aguilar T, Tseng C, et al. Pharmaceutical industry-sponsored meals and physician prescribing patterns for Medicare beneficiaries. *JAMA Internal Medicine* 2016; 176: 1114-1122.
15. Qian J, Hansen R, Surry D, et al. Disclosure of industry payments to prescribers: industry payments might be a factor impacting generic drug prescribing. *Pharmacoepidemiology and Drug Safety* 2017; [Epub ahead of print] PubMed PMID: 28485111.
16. Carey C, Lieber E and Miller S. Drug firms' payments and physicians' prescribing behavior in Medicare part d. Published online 23 September 2015, SSRN 2663681, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2663681.
17. Engelberg J, Parson C and Tefft N. Financial conflicts of interest in medicine. Published online 23 July 2013, revised 27 January 2015, SSRN 2297094, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2297094.
18. Manchanda P and Honka E. The effects and role of direct-to-physician marketing in the pharmaceutical industry: an integrative review. *Yale Journal of Health Policy, Law, and Ethics* 2013; 5: 8.
19. Taylor S, Huecker J, Gordon M, et al. Physician-industry interactions and anti-vascular endothelial growth factor use among US ophthalmologists. *JAMA Ophthalmology* 2016; 134: 897-903.
20. Perry J, Cox E and Cox A. Trust and transparency: patient perceptions of physicians' financial relationships with pharmaceutical companies. *The Journal of Law, Medicine & Ethics* 2014; 42: 475-491.
21. Agrawal S, Brennan N and Budetti P. The sunshine act-effects on physicians. *New England Journal of Medicine* 2013; 368: 2054-2057.

22. Kesselheim A, Robertson C, Siri K, et al. Distributions of industry payments to Massachusetts physicians. *New England Journal of Medicine* 2013; 368: 2049-2052.

23. Campbell E, Gruen R, Mountford J, et al. A national survey of physician-industry relationships. *New England Journal of Medicine* 2007; 356: 1742-1750.

24. Inderst R and Ottaviani. Competition through commissions and kickbacks. *American Economic Review* 2012; 102: 780-809.

25. Chen D, Levonyan V, Reinhart S, et al. Mandatory disclosure: theory and evidence from industry-physician relationships. Published online 2 March 2016, revised 30 August 2018, SSRN 2740559, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2740559.

26. Cain D, Loewenstein G and Moore D. When sunlight fails to disinfect: understanding the perverse effects of disclosing conflict of interest. *Journal of Consumer Research* 2011; 37: 836-857.

27. Cain D, Loewenstein G and Moore D. The dirt on coming clean: perverse effects of disclosing conflict of interest. *The Journal of Legal Studies* 2005; 34: 1-25.

28. Guo T, Sriram S and Manchanda P. "Let the sun shine in": the impact of industry payment disclosure on physician prescription behavior. Published online 17 April 2017, revised 1 October 2018, SSRN 2953399, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2953399.

29. Chressanthis G, Khedkar P, Jain N, et al. Can access limits on sales representatives to physicians affect clinical prescription decisions? A study of recent events with diabetes and lipid drugs. *Journal of Clinical Hypertension* 2012; 14: 435-446.

30. Chressanthis G, Khedkar P, Jain N, et al. Suppressing commercial speech is not in the best interest of physicians and patients. *Journal of Clinical Hypertension* 2013; 15: 219-220.

31. Chressanthis G. Implications from HEOR and RWE models for biopharmaceutical commercial analytics to demonstrate value through sales and marketing of specialty medicines. Poster presentation at the ISPOR 22nd Annual International Meeting, 22 May 2017, Boston.

George A. Chressanthis, Ph.D.
Principal Scientist, Axtria Inc.
300 Connell Drive, Suite 5000
Berkeley Heights, NJ 07922
E: george.chressanthis@axtria.com

Geeta Padbidri, RPh, MS, MBA
Director, Axtria Inc.
300 Connell Drive, Suite 5000
Berkeley Heights, NJ 07922
E: geeta.padbidri@axtria.com

Contact Us

+1-877-9AXTRIA
info@axtria.com

Disclaimer

Axtria® understands the compliance requirements behind personalization and we do not work with any personally identifiable data that can identify an end-customer of a business.

We have the strictest data security guidelines in place as we work with businesses to improve the experience for their customers.

www.axtria.com
facebook.com/AxtriaInc/
info@axtria.com
linkedin.com/company/axtria
@Axtria

Founded in 2010, Axtria® is a Big Data Analytics company which combines industry knowledge, analytics and technology to help clients make better data-driven decisions. Our data analytics and software platforms support sales, marketing, and risk management operations in the life sciences, finance, retail, and technology industries. We serve clients with a high-touch on-site and onshore presence, leveraged by a global delivery platform that focuses on reducing the total cost of ownership with efficient execution, innovation, and virtualization.

For more information, visit www.axtria.com

Follow Axtria on Twitter, Facebook and LinkedIn