UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE COUNTY COMMISSION OF MINGO COUNTY, and THE TOWN OF KERMIT, WEST VIRGINIA, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

Case No. 2:22-cv-00054
JURY TRIAL DEMANDED

ZS ASSOCIATES, INC.,

Defendant.

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. For two decades now, the modern opioid crisis has raged. Last year, drug-overdose deaths in the United States soared nearly 30%.[1]

2. This complaint concerns the conduct of one of the little known, but principal architects of the opioid crisis, pharmaceutical consulting firm ZS Associates, Inc. ("ZS" or "Defendant").

3. ZS is a private consulting company founded in 1983 by two professors at the eminent Kellogg School of Business at Northwestern University. Since then, ZS has achieved substantial growth, and now employs thousands of consultants and enjoys hundreds of millions of dollars in annual revenue. "ZS" is the initials of the two founders, Professors Andris Zoltners and Prabhakant Sinha. In 2020 ZS had 8,000 employees and was listed as one the Best Management Consulting Firms by Forbes in 2021.[2]

4. ZS specializes in the pharmaceutical industry. In particular, it specializes in providing critical pharmaceutical sales and marketing services to drive increased sales volume and related profits.

5. The sales and marketing efforts to sell knowingly addictive opioid drugs to as many individuals as possible were not solely designed by the manufacturers themselves, nor did the manufacturers implement these tactics on their own. Rather, pharmaceutical manufacturers routinely relied on ZS to design and implement crucial aspects of the sales and marketing strategies used to sell opioids.

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[1] Betsy McKay, "U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids," *Wall Street Journal*, July 14, 2020, *available at*: https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-in-2020-11626271200

[2] *See* https://www.forbes.com/companies/zs/?sh=12e5e93027d0

6. ZS performed a crucial role in the design and implementation of the strategies used industry-wide to sell as many opioid pills as conceivably possible. It worked for numerous opioid manufacturers for the explicit purpose of maximizing the profits and revenue that its clients could derive from selling opioids. ZS' long-term clients reads like a list of the usual suspects, to include Purdue Pharma, Mallinckrodt Pharmaceuticals, Endo International, Teva Pharmaceuticals, and Johnson & Johnson's Janssen Pharmaceuticals – each a named defendant in ongoing opioid litigation nationwide.

7. As set forth in this complaint, ZS' purpose in working with these companies was singular: to maximize profits for their clients by making sure that every dollar spent on sales and marketing of opioids was designed to generate as many sales of opioid products as possible. Maximizing profits and revenue for ZS' clients was achieved by maximizing the total volume of opioids sold. ZS applied sales and marketing tactics to multiple opioid medications on behalf of numerous manufacturer clients, and often did so contemporaneously, akin to an industry wide common denominator or hub.

8. Simply put, ZS played a central role in the creation, prolongation, and exploitation of the opioid crisis for money. Even after alarm bells sounded repeatedly and often in the early years of the unfolding crisis, ZS continued its work unabated and with alacrity. It continued its sales and marketing work for its clients right up until the bitter end, as their clients chose to cease marketing branded opioid products altogether.

9. ZS treats their client relationships as confidential. Classically, ZS works behind the scenes and does not publicize its work. Until the filing of this complaint, the public had essentially no knowledge or awareness of the extent of involvement that ZS and other consultants had in tearing apart our social fabric for profit. Mingo County and the Town of Kermit, on behalf

of all similarly situated West Virginia local governments, with its eyes now fully open to the true scope of the origins and prolongation of the opioid crisis, seeks to hold all those responsible accountable, including ZS.

II. JURISDICTION AND VENUE

10. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because (i) at least one member of the putative Class is a citizen of a state different from Defendant ZS (ii) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, and (iii) none of the exceptions under the subsection apply to this action.

11. This Court has personal jurisdiction over the Defendant because Plaintiffs claims arise out of, or relate to, Defendant's contacts with West Virginia.

12. At all times relevant hereto, Defendant engaged in the business of researching, designing, and implementing sales and marketing strategies for various opioid manufacturers including Purdue Pharma in the State of West Virginia and within Mingo County, to include the Town of Kermit.

13. This Court has jurisdiction over Defendant due to Defendant's conduct in Mingo County and throughout West Virginia. ZS has deliberately engaged in significant acts and omissions within Mingo County, the Town of Kermit, and Other Class Members that has injured its residents. Defendants purposefully directed their activities at Mingo County, the Town of Kermit, and Other Class Members and their residents, and the claims arise out of those activities.

14. Venue is proper in this District because a substantial part of the events giving rise to Plaintiff's claims occurred in, were directed to, and/or emanated from this District. 28 U.S.C. § 1391(b).

III. PARTIES

15. Plaintiff, the County Commission of Mingo County, is the duly elected governing body that oversees Mingo County, a political subdivision of the State of West Virginia. The County Commission of Mingo County brings this action on behalf and for the benefit of Mingo County at large pursuant to W.Va. Code §§7-1-3kk1 and 8-12-1(3).

16. Plaintiff, the Town of Kermit, West Virginia, is a municipal corporation of the State of West Virginia.

17. Defendant ZS Associates, Inc., is a foreign corporation with its principal office located at 1800 Sherman Avenue, Evanston, Illinois 60201. It may be served with process through its registered agent, Illinois Service Corporation, 801 Adlai Stevenson Dr., Springfield, IL 62703.

IV. FACTUAL ALLEGATIONS

18. The pharmaceutical industry is complex and highly regulated. Drug manufacturers cannot, and do not, do everything on their own. These innovative companies endeavor to research, develop, obtain approval, and bring to market products that improve the health and livelihood of hundreds of millions of people worldwide. Because the scale of the industry is vast, the stakes – both in terms of potential profit and impact on human lives – are high, and the industry's complexity byzantine. From cutting-edge medical and scientific research, to navigating the state and federal regulatory environment, to marketing their drugs in a responsible manner to prescribers and the consuming public, the demands on a traditional pharmaceutical manufacturer are multi-faceted, ever-present, and continuously changing.

19. The reality is pharmaceutical manufacturers routinely rely on third parties to design, implement, and oversee projects and workflows to achieve mission-critical tasks. Given the complexity of the industry, there are numerous companies that find their niche in offering core

services to pharmaceutical manufacturers that are critical to the success of the manufacturers' operations but are not performed by the manufacturer alone. These third parties are necessary components of the drug manufacturing and sales industry as a whole.

20. Manufacturers do not rely on these third-party providers on a one-off basis, but instead rely on companies like ZS again and again to design and implement measures to achieve specific needs. The relationships are recurring and long-term. It is not uncommon for ZS to advise multiple pharmaceutical manufacturers regarding the sales and marketing of competing products, such as branded extended-release opioids. Further, it is common for third-party consultants such as ZS to commoditize their business intelligence in a way which expands markets across the industry. In other words, ZS often sells the same strategy to multiple clients.

a. Marketing and the Origins of the Opioid Crisis

21. Although the introduction of OxyContin by Purdue Pharma in the late 1990's is widely acknowledged as a precipitating cause of the opioid crisis, Purdue was not the only pharmaceutical company to enthusiastically foment and exploit the booming market of controlled substances used for the treatment of pain. An industry-wide sales and marketing effort was deployed over the years by numerous manufacturers of opioid medications in order to maximize the amount of opioids they could sell.

22. As referenced above, OxyContin, the principal product of the Sackler family's Purdue Pharma L.P., had been introduced to the market in 1996. Within six years of its introduction, the increasingly widespread misuse and abuse of OxyContin and similar opioids had drawn the attention of the United States Senate.

23. Two decades ago, Dr. Art Van Zee traveled from the rural coal town of St. Charles, in the southwestern corner of Virginia, to Washington D.C. to provide testimony to the

United States Senate Committee on Health, Education, Labor and Pensions. On February 12, 2002, that Committee held a hearing entitled "Examining the Effects of the Painkiller OxyContin, Focusing on Federal, State, and Local Efforts to Decrease Abuse and Misuse of this Product While Assuring Availability for Patients Who Suffer Daily from Chronic Moderate to Severe Pain."[3]

24. In those early days of the unfolding opioid epidemic, Dr. Van Zee's medical practice in St. Charles put him in a position to offer informed, first-hand observations of the toll that the pharmaceutical industry's efforts to market opioids was exacting from his community. He testified:

> In the 25 years I have practiced as a general internist in St. Charles, which is a small Appalachian coal mining town, there has never been anything to compare to the epidemic of drug abuse and addiction that we have seen the last 3 years with OxyContin. Contrary to what is sometimes portrayed in the media as long-term addicts switching to the drug *du jour*, what we have seen for the most part is numerous young people recreationally using OxyContin and then becoming very rapidly addicted. Many of these kids are good kids, good families with bright, promising futures that are being destroyed in every way by their opioid addiction.[4]

25. Further, Dr. Van Zee identified the sales and marketing practices of the pharmaceutical industry when selling controlled substances as a primary cause of the problem:

> My own personal view of the complicated OxyContin abuse problem is that there are at least three major elements involved. First, there has been an obvious problem with physician misprescribing and overprescribing of this drug. Second, this epidemic has been a vicious indicator of the alarming degree of prescription drug abuse in our society. **Third and perhaps the one closest to this committee and the FDA is that the promotion and marketing of OxyContin by Purdue Pharma has played a major role in this problem.**[5]

26. Five years after Dr. Van Zee's testimony and 80 miles from his hometown of St. Charles, United States Attorney John Brownlee announced in Abingdon, Virginia, the guilty plea

[3] A transcript of the hearing is *available at*: https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm
[4] *See* https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm
[5] *Id*. (emphasis added).

of the Purdue Frederick Company, the parent of Purdue Pharma, L.P., relating to the misbranding of OxyContin. Brownlee stated, "Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal. In the process, scores died as a result of OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug that Purdue led many to believe was safer, less subject to abuse, and less addictive than other pain medications on the market."[6]

27. Along with the guilty plea, Purdue agreed to a Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services. For a period of five years, ending in 2012, Purdue was obligated to retain an Independent Monitor and submit annual compliance reports regarding its marketing and sales practices and training of sales representatives vis-à-vis their interactions with health care providers.

28. Two years later, in 2009, Dr. Van Zee published *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy* in the American Journal of Public Health. As the title suggests, the paper applied formal rigor to some of the personal observations Dr. Van Zee previously provided to the US Senate in 2002.

29. In his 2009 paper, Dr. Van Zee stated the matter plainly: "Compared with noncontrolled drugs, controlled drugs, with their potential for abuse and diversion, pose different

[6] *See* the May 10, 2007 News Release from United States Attorney, John Brownlee at https://media.defense.gov/2007/May/10/2001711223/-1/-1/1/purdue_frederick_1.pdf

public health risks when they are overpromoted and highly prescribed."[7] In one sense, Dr. Van Zee's observation is not particularly novel. Indeed, it approaches tautology: controlled substances are *controlled* precisely because they should not be sold to maximize volume and profits. This did not prevent Purdue and ZS from marketing its opioids full hilt, however. By 2004, "OxyContin had become the most prevalent prescription opioid in the United States."[8]

30. Dr. Van Zee identified the three principal marketing tactics Purdue employed as a source of OxyContin misuse and abuse and suggested that regulation may be appropriate to curtail its use. The first was the use of granular sales and marketing data to profile individual prescribers to identify those that already prescribe large amounts of opioids. "Through these profiles, a drug company can identify the highest and lowest prescribers of particular drugs on a single zip code, county, state, or the entire country. One of the critical foundations of Purdue's marketing plan for OxyContin was to target the physicians who were the highest prescribers for opioids across the country."[9]

31. The second tactic was the use of incentive compensation structures to encourage the salesforce to sell ever more prescriptions of OxyContin. Bonuses at Purdue were "uncapped," meaning there was no upper limit to what an OxyContin salesperson could earn. Rather, salesforce remuneration was a direct function of overall OxyContin sales – the more you sell, the more you make. "A lucrative bonus system encouraged sales representatives to increase sales of OxyContin in their territories, resulting in large numbers of visits to physicians with high rates of opioid prescriptions, as well as a multifaceted information campaign aimed at them."[10]

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[7] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, American Journal of Public Health, February 2009, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf

[8] *Id.*

[9] *Id.*

[10] *Id.*

32. The third tactic was to increase the overall number of individual calls that the salesforce placed to prescribers. "From 1996 to 2000, Purdue increased its internal sales force from 318 sales representatives to 671, and its total physician call list from approximately 33,400 to 44,500 to approximately 70,500 to 94,000 physicians."[11]

33. When combined, these tactics produced the intended result. "The use of prescriber profiling data to target high-opioid prescribers – coupled with very lucrative incentives for sales representatives – would seem to fuel increased prescribing by some physicians – perhaps the most liberal prescribers of opioids and, in some cases, the least discriminate."[12]

34. Dr. Van Zee's 2002 and 2009 observations regarding the direct link between OxyContin marketing and overall opioid overdose mortality would, in time, be confirmed by further academic work, including empirical research published by the National Bureau of Economic Research in 2019.

35. Year after year, things got worse. Meanwhile, Redacted, one year after Purdue's accession to the CIA and six years after Dr. Van Zee's Senate testimony, ZS began a Redacted working relationship with Purdue Pharma, L.P. to design and implement the precise sales and marketing tactics previously identified by Dr. Van Zee as a primary driver of the opioid epidemic.

36. Indeed, throughout the unfolding of the opioid epidemic, ZS partnered with numerous opioid manufacturers over decades to design and implement the tactics identified by Dr. Van Zee for the explicit purpose of maximizing opioid sales and profits to devastating effect.

[11] *Id.*

[12] *Id.*

b. The Salesforce Specialists – What ZS does.

37. Management consulting is the business of providing solutions to corporate clients. "Business consulting is really focused on solving our clients' business problems, and it is a very diverse set of issues that we might tackle, for example, 'where are the growth the growth opportunities in our business, and how to we go after them,' to something very specific, like 'what is the comp design that we should put together to incentivize our sales representatives next quarter,'" explained Kelly Tousi, a Principal at ZS Associates.[13] "That's a wide range, as you can imagine, and we do everything in between," she said.[14]

38. Solutions take many forms, depending on and tailored to the client's needs. "Management consulting includes a broad range of activities, and the many firms and their members often define these practices quite differently."[15]

39. Broadly speaking, there are two schools of management consulting, namely "Strategy Consulting" and "Implementation Consulting."

40. "Strategy Consulting," provides big-picture advice to clients about how they approach their business: how the business is structured, which markets to compete in, potential new business lines, and mergers and acquisitions. The strategy consultant provides a plan to their client that the client may choose to adopt or not.

41. "Implementation Consulting," is what comes next. If Strategy Consulting is providing advice to a client, then "implementation" work is what happens once the client has adopted the consultant's plan. After a client has adopted the strategy consultant's

[13] *See* "Business Consulting at ZS: learn how ZS recruits and interviews talent," ZS Associates, March 16, 2018, *available at* https://www.youtube.com/watch?v=YZ3ZjARBnrI
[14] *Id*.
[15] Arthur Turner, *Consulting is More Than Giving Advice*, Harvard Business Review, September 1982, *available at*: https://hbr.org/1982/09/consulting-is-more-than-giving-advice.

recommendations, the implementation consultant remains in place with the client to complete the necessary work in order to execute the plan. It is quite common for companies to formally hire implementation consultants during or immediately after the project.

42. In his 1982 *Harvard Business Review* article entitled "Consulting is More Than Giving Advice," Professor Arthur Turner of the Harvard Business School described the then-current state of the consulting industry's attitude toward implementation work as follows: "The consultant's proper role in implementation is a matter of considerable debate in the profession. Some argue that one who helps put recommendations into effect takes on the role of manager and thus exceeds consulting's legitimate bounds. Others believe that those who regard implementation solely as the client's responsibility lack a professional attitude, since recommendations that are not implemented (or implemented badly) are a waste of money and time. And just as the client may participate in diagnosis without diminishing the value of the consultant's role, so there are many ways in which the consultant may assist in implementation without usurping the manager's job."[16]

43. ZS describes itself as "a professional services firm that works side by side with companies to help develop and deliver products that drive customer value and company results."[17] "Impact where it matters," the ZS webpage declares.[18] ZS describes its impact as results, not just ideas. "That's why we partner with our clients from strategy to implementation and beyond." [19]

44. Consistent with the origins of ZS in academia, the company's initial focus was on building models that could be used by their clients to drive decision-making regarding salesforce structure and operations. As the founders explain, "early in our modeling careers in the

[16] Arthur Turner, *Consulting is More Than Giving Advice*, Harvard Business Review, September 1982, *available at*: https://hbr.org/1982/09/consulting-is-more-than-giving-advice.
[17] *See* https://twitter.com/ZSAssociates.
[18] *Id*.
[19] *See* https://www.zs.com/about/our-impact.

1970's, our thinking was centered on models and we believed that the model was a large and prominent art of solving sales-resource-optimization problems."[20]

45. Like many consulting firms, ZS performs both strategy and implementation work for its clients. But what sets ZS apart is that it has developed a particular niche in offering these services in the context of pharmaceutical sales and marketing. ZS specializes in the optimization of pharmaceutical sales forces in order to maximize sales and profit. In fact, ZS boasts that, "[i]n its first three years, ZS helped eight of the 10 largest pharmaceutical companies in the world align territories and resize their sales forces. By 2011, ZS worked with 40 of the 50 largest drug makers in healthcare and 17 of the 20 largest medical device makers."[21]

46. In addition to developing overall sales and marketing strategies for specific drugs and drug portfolios, ZS regards implementation work as a core component of its overall product offerings to its clients. Indeed, implementation – and in some instances wholesale outsourcing of key business functions to ZS – are included as a component of practically every project that ZS takes on for a client.

47. In the broadest of generalities, then, ZS' business model, as a provider of strategy and implementation consulting services to the pharmaceutical industry, is to partner with clients to pursue business objectives identified by ZS. Once the objective is identified, the client and ZS then engage in concerted action, as a seamless and cohesive unit, in order to implement the necessary means to achieve the objectives for the client.

48. Beyond these traditional consulting services, ZS Associates are also known to serve as thought leaders by authoring articles or providing soundbites or quotes in order to

[20] *See* Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*, Interfaces 31:3, Part 2 of 2, Pg. S35-36, May-June 2001.
[21] *See* https://www.zs.com/about/our-story.

influence perceptions in their client's favor. For example, when physician's offices began restricting access to sales representatives, ZS joined with manufacturers to create content designed to counter this movement.[22]

49. ZS optimizes pharmaceutical sales forces for the explicit purpose of increasing sales and profit for the manufacturer client. In 2001, the founders of ZS published a paper entitled "Sales-Force Decision Models: Insights from 25 Years of Implementation." Describing ZS specialist expertise, the founders stated, "Over 25 years, we have developed many sales-force and modeling insights through over 2,000 projects with several hundred selling organizations in over 50 countries … Two to three percent of all of the field salespeople in the US have been touched by the results. The firms had pressing issues that required quick attention. Companies sought help when merging separate selling organizations, when launching new products, when facing deregulation, or when faltering in performance."[23]

50. In 2013, Chris Wright, ZS' current Chief Executive Officer, explained to the *New York Times*: "There's a group of geeks, if you will, who are running the numbers and helping the sales guys be much more efficient."[24] The effect is "what would happen if Arthur Miller's Willy Loman met up with the data whizzes of Michael Lewis's 'Moneyball.'"[25]

51. Wright was only a managing director at ZS when he provided his comments to the *Times* in 2013. In his 25 years at ZS, according to an "Impact Fact" described on ZS' website,

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[22] See George Chressanthis et. al., *Can Access Limits on Sales Representatives to Physicians Affect Clinical Prescription Decisions? A Study of Recent Events With Diabetes and Lipid Drugs*, The Journal of Clinical Hypertension, Vol. 14, No. 7, July 2012, *available at*: https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1751-7176.2012.00651.x

[23] *Id.* at S9.

[24] Katie Thomas, "Pills Tracked from Doctor to Patient to Aid Drug Marketing," *New York Times*, May 16, 2013, *available at: https://www.nytimes.com/2013/05/17/business/a-data-trove-now-guides-drug-company-pitches.html*

[25] *Id.*

"Chris has helped dozens of pharmaceutical companies differentially resources their sales deployments, leading to multibillion-dollar industry cost savings."[26]

52. By exploiting "vast databases of patient and doctor information," companies like ZS can provide advanced analytics capabilities to clients to maximize sales efforts. "They know whether patients are filling their prescriptions – and refilling them on time. They know details of patients' medical conditions and lab tests, and sometime even their age, income and ethnic backgrounds."[27]

53. ZS cannot drive customer value or company results, however, if its work is placed in a drawer and ignored. As such, ZS does not merely provide advice or models to clients. Instead, it works "side by side" with them to achieve results the client alone cannot. This reality was recognized early on in the history of ZS. "Over the years, we have realized that we spend much more energy on other activities, such as articulating the issues, building databases, and dealing with change management and implementation. For example, in the geographic deployment work we have done, we spend over 95 percent of the time in activities *unrelated to model building*."[28]

54. Likewise, clients of ZS do not wish to pay top dollar for specialized management consulting services regarding their crucial sales and marketing practices merely for suggestions about how best to do things on their own. Just as an automobile manufacturer does not hire an airbag company to advise it on how to design, create, and install safe airbags in its cars, but instead just hires the airbag company to sell it safe airbags; pharmaceutical manufacturers hire consultants

[26] *See* https://www.zs.com/about/our-people/Chris-Wright
[27] Katie Thomas, "Pills Tracked from Doctor to Patient to Aid Drug Marketing," *New York Times*, May 16, 2013, *available at: https://www.nytimes.com/2013/05/17/business/a-data-trove-now-guides-drug-company-pitches.html*
[28] *Id.* at S36.

like ZS to implement mission-critical salesforce tasks they do not have the capability to perform on their own.

55. ZS speaks in terms of "optimizing" its clients' efforts to sell its products. ZS' clients are for-profit companies, and "optimization" implies a specific variable you are optimizing. In the case of ZS, the variable is the amount of money the client can make.[29]

56. ZS applied its hard-won expertise to multiple clients, "optimizing" their salesforces for the purposes of maximizing the profits derived from selling controlled substances.

c. Controlled substances are substances ZS' clients are required to control.

57. In 1970, Congress enacted the Controlled Substances Act ("CSA") in order to combat the spread and use of drugs known to dangerous and/or addictive. It is also the legal regime that regulates the lawful production, possession, and distribution of substances deemed deserving of control, but that have some recognized medical use.

58. The Drug Enforcement Administration ("DEA") administers the act. The CSA allocates substances meriting control to one of five classifications based on the characteristics of each substance and the attendant risks posed.

59. In order to produce and market certain substances meriting control, pharmaceutical companies must register with the DEA and be bound by the reporting requirements of the CSA. The act requires any person who seeks to manufacture, distribute, dispense, or conduct research involving any controlled substance to obtain and maintain a registration from the DEA. *See* 21 U.S.C. 823(e); 21 C.F.R. 1301.74(b).

[29] *See* https://www.zs.com/solutions/artificial-intelligence-and-analytics/analytics (Touting ZS's "Analytics optimization" solutions, ZS emphasized, "You need to ensure that you're investing in the right analytics capabilities, tapping into the right data sets and maximizing your ROI with key insights that drive business transformations.")

60. The opioids that ZS and its clients marketed are classified as Schedule II controlled substances under the CSA. Schedule II substances "have a high potential for abuse for which may lead to severe psychological or physical dependence."[30] As such, opioids are subject to control under the CSA because the diversion of these substances poses recognized risks to public health and safety.

61. The CSA also imposes reporting requirements on manufacturers, whereby registrants must monitor and report suspicious conduct regarding the manufacturing and sale of opioids. These obligations include recordkeeping, whereby registrants must maintain complete and accurate inventories and records of all transactions involving controlled substances and make those records available to the DEA. In addition, registrants must periodically report all sales, delivery, disposal, or dispensing activities of any controlled substance. Schedule II controlled substance manufacturers, such as ZS' clients, must also file Automated Reports and Consolidated Orders System (ARCOS) reports with the DEA.

62. Upon information and belief, ZS, in its efforts to increase opioid sales for its clients by ever-more-refined and granular analysis of sales data, possessed and shared with its clients detailed data on the prescribing and dispensing of its clients' Schedule II opioids. Using the same data sets ZS employed to tells its clients how to sell more opioids, ZS and its clients could determine when the prescribing or dispensing of a given clients' opioid product was unusual. For instance, upon information and belief, ZS and its clients could identify aberrations in the number of units sold, dose prescribed, prescriptions written per prescriber, method of payment used, and other factors relevant to changes in the volume of its clients' opioid sales.

[30] *See* https://www.deadiversion.usdoj.gov/schedules/#define Schedule I substances also have a high potential for abuse and dependance. The difference is that Schedule I substances have no recognized medical use. Schedule II substances, like opioids, do.

63. The inputs necessary for a Registrant to identify suspicious orders that merit reporting are the same inputs ZS collects, analyzes, and synthesizes in order to optimize its clients' sales forces. Upon information and belief, the same information gathered and synthesized by ZS and presented to its clients for purposes of targeting opioid sales and marketing efforts should have led to obligations by ZS' clients – as registrants under the CSA - to report suspicious activity to the DEA.

64. Many states, including West Virginia, enacted similar state laws, rules and regulations in order to regulate the manufacture, marketing, distribution and dispensing of controlled substances and provide oversight over this unique industry.[31]

65. In order to keep these dangerous and addictive drugs out of the wrong hands, this closed system of state and federal authority imposes specific duties upon Registrants to monitor, identify, halt and, perhaps most importantly, report suspicious orders of controlled substances. 21 C.F.R. § 1301.74; *Masters Pharm., Inc. v. Drug Enf't Admin*., 861 F.3d 206 (D.C. Cir. 2017).

d. The Salesforce – Pharma's Engine

66. Sales forces are a major component of pharmaceutical companies' operations. Indeed, they are the core of the industry. In 2007, it was estimated that there were 100,000 pharmaceutical sales representatives in the United States pursuing approximately 200,000 prescribers.[32]

67. These armies of sales reps are employed by pharmaceutical companies and detailed to health care providers to market the companies' drugs to those with the power to prescribe them. By 2000, at the outset of the opioid crisis, pharmaceutical companies were

[31] *See* W.Va. Code § 60A et seq.
[32] Tobias L. Milrood, *When Drug Representatives Go Too Far*, American Association for Justice, February 2007.

spending in excess of $15 billion annually promoting drugs, with 84% of the total spend directed at detailing sales representatives to prescribers, drug samples, and ads in medical journals.[33]

68. "Because of the large size of pharmaceutical sales forces, the organization, management, and measurement of effectiveness of the sales force are significant business challenges."[34] This is ZS' niche. ZS tells its clients how to optimize, incentivize, and deploy these armies of pharmaceutical sales representatives for the purpose of maximizing revenue. In the words of ZS' founders, "[t]hat marketing investment drives sales is a fundamental principle supported by data."[35] ZS has observed the statistically significant relationship between sales force effort and sales of pharmaceuticals, as depicted in the following scatter plot[36]:

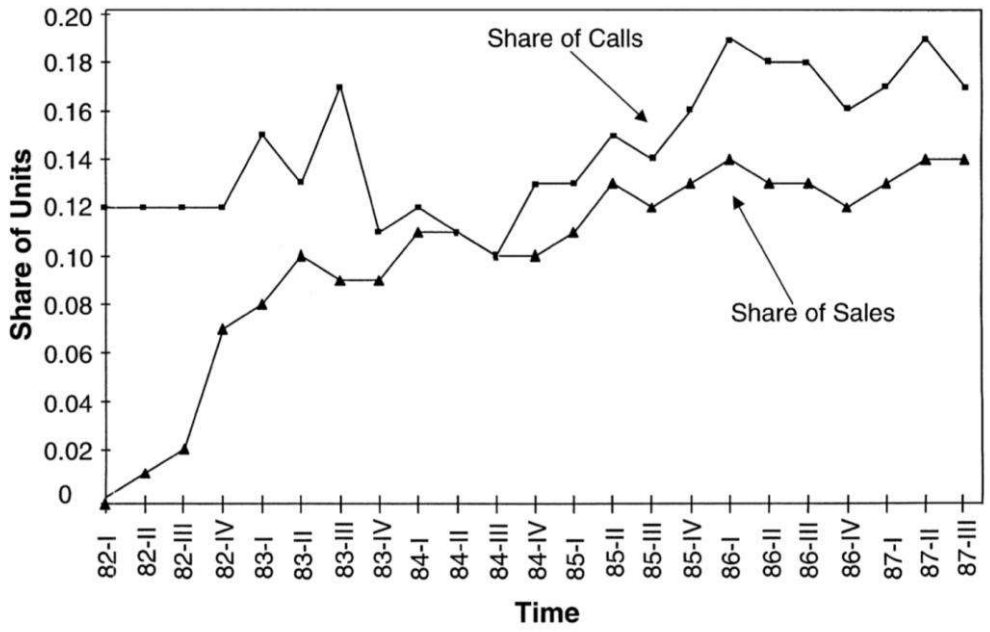

Figure 2: This scatter plot using longitudinal data shows a statistically significant relationship between sales-force effort and sales for a product sold by a pharmaceutical sales force. Every dot represents a quarter of the year.

[33] M.B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers,* 346 New England J. Med. 498 (2002).
[34] Tobias L. Milrood, *When Drug Sales Representatives Go Too Far*, American Association for Justice, February 2007.
[35] Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*, Interfaces 31:3, Part 2 of 2, Pg. S10, May-June 2001.*Id*. at S10.
[36] *Id.* at S12.

69. ZS provided these services to numerous opioid manufacturers, which produced controlled substances known to be addictive at the time ZS advised them, for the explicit purpose of maximizing the sales and revenue of these deadly and addictive drugs during the pendency of a nationwide opioid crisis wrought by the over-selling of opioids by ZS' clients.

e. ZS, Pharma's long-term partner

70. Like many participants in the pharmaceutical consulting space, ZS does not merely provide advice to its clients on a one-off basis. Rather, according to ZS, a client relationship is "about results, not just ideas. That's why we partner with our clients from strategy to implementation and beyond."[37] "We work side-by-side with you at every stage to help you achieve success."[38] These partnerships are *long term*. For instance, ZS' founders have observed that, "having worked with some managers *repeatedly for over a decade or more*, we have observed patterns in the ways managers use consulting assistance and models."[39]

71. At ZS, "business consulting is really focused on solving our clients' business problems, and it is a very diverse set of issues that we might tackle, for example you could be anything from 'where are the growth opportunities in our business and how should we go after them,' to something very specific, like 'what is the comp design that we should put together to incentivize our sales representatives next quarter'? So that's a wide range, as you can imagine; we do everything in between."[40]

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[37] *See* https://www.zs.com/about/our-impact

[38] *Id*.

[39] Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*, Interfaces 31:3, Part 2 of 2, Pg. S37, May-June 2001 (emphasis added).

[40] *See* ZS Associates, "Business consulting at ZS: learn how ZS recruits and interviews talent," *available at*: https://www.youtube.com/watch?v=YZ3ZjARBnrI. Incidentally, the factors ZS articulates in its sales pitch as firm competencies – identifying growth opportunities and incentivizing the sales representatives – are *both* identified as principal origin points of the opioid epidemic by Dr. Van Zee as early as 2002.

72. In other words, ZS does not merely provide ideas and advice to its clients. Rather, it designs and implements sales force models aimed at the most efficient allocation of marketing spending and maximization of profits for their manufacturer clients. In fact, ZS' recommendations are routinely implemented on such a systematic and industry-wide basis that ZS itself is now able to draw on its own history of implementing change for its clients, as a data set of its own worthy of academic study.[41]

f. ROI is King

73. In providing consulting services to pharmaceutical clients, return on investment ("ROI") is the coin of the realm. The profit motive drives behavior. If a consultant cannot help a client increase revenue and profit, they are worthless.

74. Describing the bottom line regarding the services ZS provides its clients, ZS Principal John Bienko stated, ""Of course, the biggest question on anybody's mind is 'what is the financial impact I'm getting from these promotions, what's the bang for the buck?'"[42]

75. ZS' *raison d'etre* is maximizing return on investment for all sales and marketing spending for a pharmaceutical manufacturer. ZS was not shy about couching its entire product line to pharmaceutical manufacturer clients in terms of ROI[43]:

[41] Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*, Interfaces 31:3, Part 2 of 2, Pg. S18-19, May-June 2001 ("The repeated application of several normative sales-force-decision models has produced a series of insights that have led to a number of valuable sales-force insights.")

[42] *See* ZS Associates, "Marketing mix strategy: why it's so important for pharmaceutical marketing," available at: *https://www.youtube.com/watch?v=V8mppVKr9_0*

[43] *See* https://www.zs.com/solutions/marketing/promotions-and-marketing-mix

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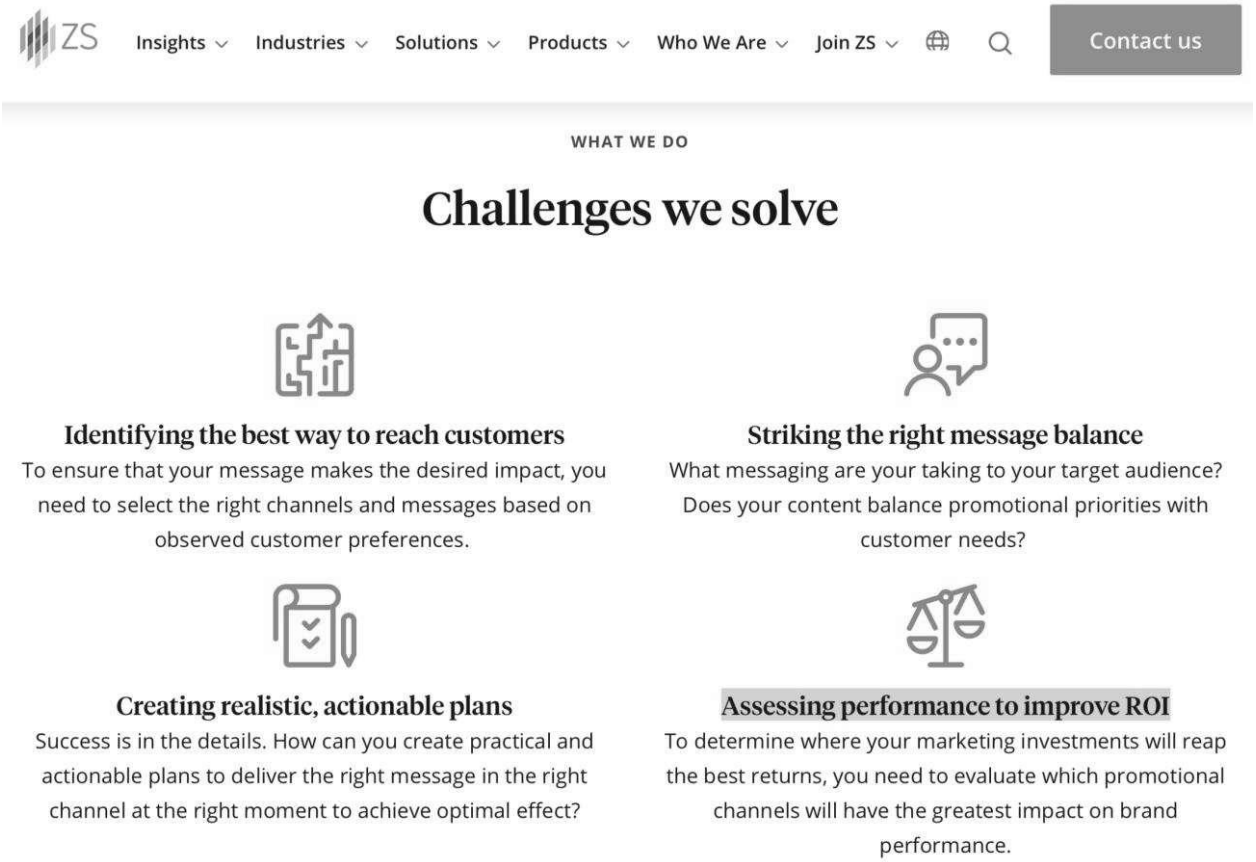

76. ROI is the basis upon which ZS advertises and sells its services to pharmaceutical companies, and it is the principal reason that a pharmaceutical company hires ZS in the first place. As established herein, ZS couched substantially *all* of its proposals to work for opioid manufacturers in terms of how much money they will make by doing what ZS recommends.

77. This myopic focus on the bottom line, when applied to controlled substances known to be addictive, would have predictable consequences.

g. ZS services its clients.

78. Even though the marketing of OxyContin has been described as the "taproot" of the opioid epidemic, Purdue was not the only manufacturer to zealously market their own opioids. Nor was Purdue ZS' only opioid client.

79. ZS provided similar services, as explained below, to fellow opioid manufacturers Mallinckrodt Pharmaceuticals, Endo Pharmaceuticals, Teva Pharmaceuticals, and Johnson & Johnson's Janssen Pharmaceuticals. Consistent with its work for Purdue, ZS designed, implemented, and optimized salesforce strategies to maximize the profits derived from selling a controlled substance for practically every major opioid manufacturer. ZS' client work is described in individual detail below.

1. Purdue

80. In the wake of Purdue's 2007 guilty plea and accession to the Corporate Integrity Agreement, Purdue faced newly imposed constraints on its sales and marketing practices. Rather than causing a shift in Purdue's approach to marketing the highly addictive drug Oxycontin, the Corporate Integrity Agreement was merely a problem Purdue needed to solve. Despite the agreement's constraints (i.e., do not lie about OxyContin), Purdue and its controlling owners, the Sackler family, desired to maximize OxyContin sales. They contracted with ZS to so increase OxyContin sales despite the Corporate Integrity Agreement.

81. The problem was complex. As a result of the 2007 guilty plea, the Sacklers made the strategic decision to distance the family from Purdue, which was regarded as an increasingly "dangerous concentration of risk" for Purdue's owners.[44] Ten days after the guilty plea was announced, David Sackler wrote to his father, Richard Sackler, and uncle, Jonathan Sackler, describing precisely what that "risk" was: legal liability for selling OxyContin. In response to Jonathan stating that "there is no basis to sue 'the family,'" David replied:[45]

[44] *See* https://news.bloomberglaw.com/health-law-and-business/sackler-memo-shows-purdue-pharma-owners-worried-about-exposure-1?context=article-related

[45] *See* https://www.washingtonpost.com/business/2020/12/22/sackler-unsealed-documents/

Message

From: David Sackler [redacted]
Sent: 5/17/2007 11:08:08 PM
To: 'Sackler, Jonathan' [redacted] Sackler, Dr Richard [redacted]
CC: Ives, Stephen A. [redacted]
Subject: RE: Idea
Attachments: image001.jpg

Well I hope you're right, and under logical circumstances I'd agree with you, but we're living in America. This is the land of the free and the home of the blameless. We will be sued. Read the op-ed stuff in these local papers and ask yourself how long it will take these lawyers to figure out that we might settle with them if they can freeze our assets and threaten us.

82. Given concern over this "dangerous concentration of risk," the two sides of the Sackler family spent considerable time and energy debating the best way to achieve distance from Purdue, and collectively considered a variety of options for doing so. One option was to sell the company to, or merge the company with, another pharmaceutical manufacturer. Shire was discussed as a possible target, as was Cephalon, UCB, and Sepracor. The proceeds of such a transaction could then be re-invested in diversified assets, thereby achieving the Sacklers' desired distance and impunity.

83. Another option was to have Purdue borrow money to assure Purdue had adequate funds to continue operating, while the Sacklers, as owners, began to make substantial distributions of money from the company to themselves. Once again, the proceeds of the distributions could then be re-invested in diversified assets, thereby achieving the Sacklers' desired distance and impunity.

84. In order to pursue *either* of these options, the Sacklers needed to maximize opioid sales *in the short term* so as to make Purdue – by then the subject of substantial public scrutiny – appear either as an attractive acquisition target or merger partner to another pharmaceutical manufacturer, or as a creditworthy borrower to a lender.

85. In short, the Sacklers planned to engage in a final flurry of opioid pushing in order to make as much money as they could, while they could.

86. Given the complexity of the problem, the Sacklers and Purdue realized that they would need assistance in achieving these internally contradictory objectives. Since Purdue had to comply with the Corporate Integrity Agreement, it could not implement a sales and marketing strategy for OxyContin consistent with the Sacklers' wishes. Purdue turned to ZS to help them do what they could not.

87. ZS happily accepted the assignment, and by Redacted ZS and Purdue were working together to increase sales of Purdue's opioids. Redacted based on ZS' own independent research and unique methodologies, including modelling expertise. Purdue adopted ZS' strategies and worked closely with ZS to implement ZS' plan. Despite the strictures imposed upon Purdue by the Corporate Integrity Agreement, OxyContin sales began to multiply.

88. ZS' relationship with Purdue lasted at least through Redacted, during which ZS engaged in numerous projects for Purdue, each with the intent of maximizing sales and profits of Purdue's controlled substances.

89. Purdue hired ZS for Redacted These Redacted were necessary in light of the Sackler family's – Purdue's sole owners – decision to exit the opioid business in light of the perceived risks of staying there.

90. From the outset, Redacted – an acknowledgement by both Purdue and ZS of the real-world stakes at issue in ZS' work.

91. ZS' first known work for Purdue commenced in the final months of Redacted and focused on Redacted One of the Redacted ZS observed, was Redacted

[redacted] In other words, ZS would find ways to get prescribers to *change their prescribing behavior* by prescribing more extended-release opioids for longer periods of time.

92. Once ZS identified the drivers behind these prescriber behaviors, ZS developed a plan to "correct" the behavior in ways beneficial to Purdue, and, once adopted by the client, began implementing changes at Purdue to increase OxyContin sales. ZS would "evaluate and determine optimal sales and marketing strategy to support OxyContin," and would "draw an implementation roadmap" incorporating "tangible action steps regarding identified OxyContin hurdles in terms of sales, marketing, and managed care approach. ZS would also conduct "Solution Design Workshops" with Purdue's staff regarding the best ways to undertake the changes in strategy identified by ZS.

93. In [redacted] while Purdue was still bound by the Corporate Integrity Agreement. This time ZS' work related to [redacted]

94. The work took a holistic approach to Purdue's entire sales and marketing efforts for its pain portfolio, including OxyContin, MS Contin, and RyzoltTM.

95. In addition to working on Purdue's existing pain portfolio, in [redacted] ZS assisted Purdue in [redacted] At that early point in the opioid crisis, Purdue was already interested in expanding into products for the treatment for opioid use disorder, which, according to ZS, [redacted]

96. ZS focused on answering mission-critical questions for Purdue, including but not limited to:

- Redacted

97. As always, ZS' work included an implementation component, including Redacted and Redacted ZS assured Purdue that Redacted

98. In 2012, Redacted

99. Redacted ZS agreed to Redacted and Redacted

Redacted ZS agreed to address "key questions" like Redacted Additionally, ZS undertook an analysis to Redacted

100. ZS conducted this work in conjunction with a core team of Purdue employees Redacted

101. By 2013, one year after Purdue was no longer shackled by the constraints of the 2007 Corporate Integrity Agreement that expired in 2013, Purdue also engaged with a separate consulting company, McKinsey & Company, Inc., to design a new company-wide sales and marketing approach. McKinsey's proposals, initially dubbed *Project Turbocharge*, were eventually rechristened *Evolve to Excellence* and were implemented by McKinsey and Purdue for the explicit purpose of maximizing opioid sales despite the by-then obvious risks associated with selling as much OxyContin as possible.

102. ZS worked in cooperation with McKinsey and Purdue to implement and continually refine *Project Turbocharge*, including Redacted McKinsey's efforts to target the highest prescribers of OxyContin and blitz them with the newly turbocharged sales force. ZS worked with an Executive Oversight Team and Project Management Office, comprised of Purdue and McKinsey staff, to implement McKinsey's plans for Purdue.

103. That same year, despite significant headwinds, OxyContin sales finally peaked. The restrictions on Purdue's sales and marketing methods contained in the Corporate Integrity

Agreement should have resulted in fewer overall OxyContin sales. Within five years of Purdue's guilty plea, however, OxyContin sales tripled.

104. ZS played a crucial role in accomplishing this feat. It presented specific plans to Purdue, which Purdue adopted and spent hundreds of millions of dollars implementing alongside ZS and other consultants. The result: a final spasm of OxyContin sales before the inevitable decline of the drug.[46]

105. In August of 2013, McKinsey urged, as part of the overall sales maximization approach, that sales representatives should devote two-thirds of their time to selling OxyContin and one-third of their time selling Butrans, another Purdue product. Previously, the split had been fifty-fifty.

106. Two months later, Redacted. ZS sought to answer the question, Redacted Within months of McKinsey's recommendation that Purdue should shift its resource allocation from a 50/50 split between OxyContin and Butrans to 2/3's OxyContin and 1/3 Butrans, Redacted

107. In other words, Redacted As stated earlier (and exemplified here), the pharmaceutical industry is complex, and manufacturers do not do

[46] On February 10. 2018, Purdue announced that it is no longer marketing opioids, and disbanded its OxyContin sales force.

everything themselves. Purdue continually sought the ongoing assistance of ZS and many others to achieve its aims.

108. In conjunction with the ongoing implementation of McKinsey's *Evolve to Excellence* at Purdue, ZS' relationship with Purdue flourished. With the rollout of *Evolve to Excellence* in 2014, ZS was intimately involved in Purdue's sales transformation. Redacted [redacted] The requests for support were granular in their detail, including a Redacted [redacted] and Redacted [redacted] which was work necessary to implement the overall physician targeting strategy espoused and directed by McKinsey at Purdue, such as the design of a Redacted [redacted]

109. By this time, ZS had also begun providing its AccessMonitor software for Purdue to use. AccessMonitor is one example of a common tactic used by consultants to maintain an ongoing revenue stream from its clients, separate and apart from traditional project-based work: the development and marketing of "leave-behind" products, such as software applications, that are sold to clients as tools that can be used by the business on an on-going and recurring basis, separate and apart from the project-based consulting work that is ZS' core offering.

110. As described by famed Harvard Business School Professor Clayton Christensen, these sorts of "software and technology-based analytics and tools that can be embedded at a client,"

are a tool used by a consultancy to deepen its partnerships with clients and earn additional and recurring revenue from them. Tools such as ZS' AccessMonitor, Prof. Christensen noted, provide "ongoing engagement outside the traditional project-based model" traditionally used by consultants.[47]

111. In December of 2015, ZS' client Purdue agreed to a settlement with the State of Kentucky relating to the improper marketing of OxyContin and other Purdue products. Purdue agreed to pay $24 million in conjunction with the settlement.

112. Despite this second enforcement action against its client, ZS' work on Purdue's sales and marketing efforts continued unabated. Throughout its relationship with Purdue, ZS worked on core functions of Purdue's efforts to sell its drugs.

113. These core functions were previously identified as particular areas of concern with respect to Purdue's business conduct, and were specifically monitored and regulated under the 2007 Corporate Integrity Agreement, which governed, *inter alia*:

- "selling, marketing, promoting, advertising, and disseminating Materials or information about Purdue's products in compliance with all applicable FDA requirements, including requirements relating to the dissemination of information that is fair and accurate … including, but not limited to information concerning the withdrawal, drug tolerance, drug addiction or drug abuse of Purdue's products;

- compensation (including salaries and bonuses) for Relevant Covered Persons engaged in promoting and selling Purdue's products that are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion or sales of Purdue's products; …

- the process by which and standards according to which Purdue sales representatives provide Materials or respond to requests from HCP's [health care providers] for information about Purdue's products, including information concerning withdrawal, drug tolerance, drug addiction, or drug abuse of Purdue's products," including "the form and

[47] Clayton Christensen, Dina Wang, and Derek van Bever, "Consulting on the Cusp of Disruption," *Harvard Business Review*, October 2013, *available at* https://hbr.org/2013/10/consulting-on-the-cusp-of-disruption

> content of Materials disseminated by sales representatives," and "the internal review process for the Materials and information disseminated by sales representatives."[48]

114. In fact, under the terms of Paragraph II.C.1(b) of the Corporate Integrity Agreement, ZS, as a contractor to Purdue performing sales and marketing functions for the company, was a "Covered Person" subject to the strictures of the CIA.[49]

115. In addition to ZS' "expertise and thought leadership," ZS' assumption of these obligations for Purdue involved the deployment of Javelin, its proprietary salesforce optimization software tool. Like AccessMonitor, described *supra*, Javelin was a software tool that ZS could embed with clients. With Javelin, a ZS client can "streamline sales performance management with a comprehensive platform that simplifies sales strategy management and helps you build and motivate a successful sales force."[50] The Javelin products include "suites" of software for the management and operation of Incentive Compensation (IC) and Call Planning (CP) functions.[51]

116. Upon information and belief, all of Purdue's then 712 sales representatives were licensed users of ZS' trademarked Javelin suite of software solutions.

117. On October 20, 2020, Purdue entered into a plea agreement with the United States Department of Justice to plead guilty to improper marketing of OxyContin and other opioids, again.[52] This time the plea agreement concerned conduct from 2010 to 2018. ZS

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[48] *See* https://s3.documentcloud.org/documents/6452110/2007-Purdue-Corporate-Integrity-Agreement.pdf at pgs. 7-9.

[49] The relevant language in the CIA provides: "Covered Persons" includes … all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, or regulatory functions … on behalf of Purdue." *Id.* at 2.

[50] *See* https://www.zs.com/products/javelin.

[51] *Id.*

[52] *See* https://www.justice.gov/opa/press-release/file/1329576/download

collaborated with Purdue on its sales and marketing practices Redacted the time period relevant to Purdue's second guilty plea.[53]

118. Purdue agreed to plead guilty to a dual-object conspiracy to defraud the United States and violating the Food, Drug, and Cosmetic Act, 21 U.S.C. § 331, 353, among other charges, relating to its opioid sales and marketing practices after the 2007 guilty plea.[54] Purdue's co-conspirators were not identified in the plea agreement.

119. Purdue's second guilty plea concerns Covered Conduct (as defined in the plea agreement) relating to Purdue's sales and marketing efforts that directly implicates ZS in the conspiracy. ZS' work for Purdue described in this Complaint was a core component of the sales and marketing tactics that lead to Purdue's second guilty plea.

2. Mallinckrodt

120. Upon information and belief, around the same time ZS was working with Purdue to implement McKinsey's *Project Turbocharge* to maximize OxyContin sales by continual refinement of physician targeting and other sales and marketing tactics, ZS was also working with another long-term client, Mallinckrodt, Redacted

121. Mallinckrodt is the largest supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States. In 2015, for instance, Mallinckrodt's opioids accounted for approximately one quarter (25%) of the entire annual

[53] On February 10, 2018, Redacted, Purdue announced that it is no longer marketing opioids, and disbanded its OxyContin sales force. "OxyContin maker stops promoting opioids, cuts sales staff," *Reuters*, February 10, 2018, *available at*: https://www.reuters.com/article/us-usa-opioids-purduepharma/oxycontin-maker-stops-promoting-opioids-cuts-sales-staff-idUSKBN1FU0YL ("OxyContin maker Purdue Pharma LP said on Saturday that it has cut its sales force in half and will stop promoting opioids to physicians, following widespread criticism of the ways that drugmakers market addictive painkillers."). As such, Redacted Redacted

[54] *See https://www.justice.gov/opa/press-release/file/1329576/download*

production quota for controlled substances under DEA regulations. Mallinckrodt produced the following branded and generic opioids:

Product Name	Chemical Name
Exalgo	Hydromorphone hydrochloride, extended release
Xartemis XR[104]	Oxycodone hydrochloride and acetaminophen (extended release)
Roxicodone[105]	Oxycodone hydrochloride
Generic	Oxymorphone hydrochloride (extended release) (generic Opana)
Generic	Oxycodone (extended release) (generic OxyContin)
Generic	Morphine sulfate, extended release
Generic	Morphine sulfate oral solution
Generic	Oxycodone and acetaminophen (Percocet)
Generic	Hydrocodone bitartrate and acetaminophen (Vicodin)
Generic	Hydromorphone hydrochloride
Generic	Hydromorphone hydrochloride, extended release (Generic Exalgo)
Generic	Fentanyl transdermal system
Generic	Oral transmucosal fentanyl citrate
Methadose	Methadone hydrochloride
Generic	Methadone hydrochloride
Generic	Buprenorphine and naloxone

122. Previously, Redacted

Mallinckrodt sought to use ZS' expertise to Redacted and to Redacted

123. Mallinckrodt promoted Exalgo as having characteristics that made the drug less likely to be addictive or abused, despite the lack of FDA approval for the drug as "abuse-deterrent."

124. Then, on March 12, 2014, Mallinckrodt obtained FDA approval for Xartemis XR, its extended-release opioid tablet.[55] Upon information and belief, by the time Mallinckrodt

[55] *See* "Xartemis receives approval: May reduce opioid abuse," Formulary Watch, March 28, 2014, *available at* https://www.formularywatch.com/view/xartemis-xr-receives-fda-approval-may-reduce-opioid-abuse

obtained approval to market its opioid, ZS had already established a long-term working relationship with Mallinckrodt regarding the sales and marketing of Mallinckrodt's portfolio of pain medications.

125. ZS was intimately involved in Redacted from the outset.

126. In anticipation of Xartemis' launch, Mallinckrodt augmented its salesforce by adding hundreds of contracted sales representatives to promote the drug. CEO Mark Trudeau anticipated Xartemis would generate "hundreds of millions" in revenue for Mallinckrodt.[56]

127. In September, only months after FDA approval, ZS unveiled an overall sales and marketing strategy for the drug. The scope of the plan was all-encompassing, including overall global strategy as well as granular details of execution and implementation. Tactics to be deployed in ZS' plan included the deployment of marketing materials in the offices of health care providers (including "in-office patient education materials" meant for the consuming public), physician targeting and decile segmentation, a video series interviewing clinicians about the benefits of the drug, patient testimonials, a speaker program, patient co-pay cards, targeting promotion outreach to regional associations of physician assistants[57], and other efforts to maximize sales and revenue. Many of these same tactics were weapons in Purdue's arsenal, designed by ZS.

128. Part of ZS' plan for Redacted

Redacted[58], Redacted

[56] *See* https://www.bizjournals.com/stlouis/blog/health-care/2014/01/mallinckrodts-new-drug-should.html

[57] This focus on physician's assistants is consistent with ZS' finding in an August 2016 report it issued, arguing that "[a]nother way to increase reps' chances for success is to expand the potential audience beyond the physician." ZS explained, "Other people on staff at the physician's office could be worthwhile targets for pharmaceutical messaging, such as nurse practitioners and physician assistants. *On average, people in these roles are incrementally more accessible than physicians.*" *Physicians Becoming More Restrictive About Rep Sales Calls; Digital Communications Picks Up*, 28 No. 8 FDA Advertising & Promotion Manual News. 8, October 2016 (emphasis added).

[58] "TRx" is an abbreviation for the measurement of increase in "total prescriptions," meaning all new prescriptions **plus** refills on those prescriptions. "Growing TRx," in other words, means encouraging refills of new prescriptions. This approach to maximizing revenue by encouraging refills of controlled substances known to be addictive carried obvious risks.

[redacted] in addition to adopting [redacted]

129. ZS' [redacted]

130. Ominously, [redacted]

131. Mallinckrodt encouraged its sales reps to aggressively market its new opioid by implementing ZS' marketing and sales strategy. One supervisor urged the Xartemis sales force to "ATTACK" health care providers and informed representatives that they could obtain "big bonus dollars" by waiting in front of doors of health care providers and using free trial offers to gain prescriptions.[59]

132. Another sales supervisor encouraged sales representatives that Xartemis "is the BEST opportunity to make lots of money!! !"[60]

133. ZS designed and implemented the incentive compensation plan for Xartemis.

[59] William K. Rashbaum, Roni Caryn Rabin and Danny Hakim, "Opioid Sales Reps Swarmed New York at Height of Crisis," *New York Times*, April 19, 2019, *available at* https://www.nytimes.com/2019/04/11/health/opioids-sacklers-new-york-purdue.html

[60] *Id.*

134. The above is even more alarming in light of the fact that ZS had been using its hub-like position among many manufacturers to develop a business intelligence tool by analyzing call note reports from over 45,000 sales reps across the country.[61] Given their ability to analyze the large amounts of data ZS possessed, ZS were the only ones with the keys to unlock the prescribing practices of each target physician.

135. Mallinckrodt repeatedly promoted Xartemis ZR as having physical properties that made the drug less likely to be addictive or abused, even though the drugs had never been approved by the FDA as abuse-deterrent. For instance, promotional materials provided to prescribers stated "Xartemis XR has technology that requires abuses to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[62]

136. Not only had the FDA not approved Xartemis as an abuse-deterrent formulation, the marketing claims were false and misleading in that none of the characteristics of Xartemis address the most common form of opioid abuse: simple oral ingestion, swallowing the pill.

137. As stated above, the data and analytics capabilities of ZS, when tasked to the purpose of maximizing drug sales and revenue, should result in the unearthing of suspicious orders worthy of reporting to the DEA.[63] Despite ZS working with Endo to assiduously study in granular detail the topic of where its pills are sold (and how to sell more of them), Endo nonetheless failed in its reporting obligations under the Controlled Substances Act.

138. In a July 2017 Memorandum of Agreement with the DEA and the Department of Justice, Mallinckrodt agreed that "at certain times during the Covered Time Period prior to

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[61] See "Crossing the threshold: More than half of physicians restrict access to sales reps," *ZS Associates*, September 1, 2015, *available at*: https://www.zs.com/about/newsroom/crossing-the-threshold-more-than-half-of-physicians-restrict-access-to-sales-reps

[62] *See* "Xartemis receives approval: May reduce opioid abuse," *Formulary Watch*, March 28, 2014, *available at* https://www.formularywatch.com/view/xartemis-xr-receives-fda-approval-may-reduce-opioid-abuse

[63] *See supra,* ¶ 64-65.

January 1, 2012, certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control to registrants [Mallinckrodt] dated September 27, 2006, and December 27, 2007."[64]

3. Endo

139. ZS' relationship with Endo Pharmaceuticals [redacted]

140. Upon information and belief, [redacted] months after Endo's launch of Opana ER, its extended release oxymorphone tablet in 2006. At the time, Endo's marketing efforts were primarily focused on Opana ER, its branded extended release oxymorphone hydrochloride tablet. Oxymorphone hydrochloride is three times as strong as morphine.

141. ZS' first known work for Endo involved developing and implementing [redacted] ZS acknowledged.

142. ZS designed [redacted] for Opana. This was crucial, as Endo required a [redacted] in order for Endo to [redacted]

143. Moreover, ZS was engaged not only [redacted]

[64] *See* the July 2012 Memorandum of Agreement between Mallinckrodt and the DEA at https://www.justice.gov/usao-edmi/press-release/file/986026/download

Redacted

144. By 2009, Redacted As such, ZS was tasked with Redacted

145. ZS' focus on ROI for its clients, described in Section D, above, is front and center in the title of its July 16, 2012, presentation to Endo Pharmaceuticals: "Promotional Mix Optimization Brand Level Model Results and ROI." In it, ZS conducted a "historical ROI and marginal ROI analysis" of Endo's "pain brands." As explained in the presentation, at the time Endo had been employing "a variety of marketing tactics to **drive prescribing volume** within the Pain and UEO portfolios," and Endo "would like to better understand the effectiveness of each of these tactics, and to **optimize marketing spending to drive efficiency**."[65] Key questions ZS sought to answer for its client were "how effective is each of Endo's marketing activities in terms of driving prescription volume," and "what is the ROI for each marketing activity."[66]

146. ZS informed Endo plainly that, regarding its portfolio of pain medications, "[s]ales force detailing is the most impactful tactic, detailing accounts for 35-65 & of all sales and marketing impact."[67] With respect to Opana, Endo's extended-release opioid tablet meant to compete with Purdue's OxyContin, sales force detailing accounted for 11.7% of the contribution

[65] ZS Presentation to Endo dated July 16, 2012, *In re: National Prescription Opiate Litigation*, Case No. 1:17-md-02804-DAP, Doc. 2421-2, filed August 15, 2019 (N.D. OH).
[66] *Id.*
[67] *Id.*

to annual sales and profitability among Endo's sales tactics for Opana. In second place was co-pay cards, with 4.4%:[68]

% Contribution to annual sales and profitability by promotional tactic for each brand

Modeling time frame	Apr'11- Mar'12	Jan'11- Dec'11		Apr'11- Mar'12
Tactic	LIDODERM	OPANA	Voltaren Gel	FROVA
SF Detailing	● 8.3%	● 11.7%	● 5.9%	○ 8.2%
NPP	● 3.1%	● 0.0%*	● 3.5%	● 7.5%
Samples	● 5.0%	N/A	● 2.1%	● 1.0%
Website	● 2.0%	● 2.1%	● 0.0%*	● 0.1%
Journals	● 0.5%	○ 0.3%	N/A	N/A
Copay cards	● 0.4%	● 4.4%	● 2.7%	● 6.4%
Speaker programs	Not planned for 2012	● 0.2%	N/A	N/A
ALL TACTICS	19.3%	18.7%	13.2%	23.2%
CARRYOVER	77.1%	73.4%	70.8%	45.2%
OTHER FACTORS	3.6%	7.9%	15.0%	31.6%

● *Positive mROI*
○ *Approximately Breakeven mROI*
● *Negative mROI*

** Not a statistically significant impact*

)12 ZS Associates – 9 – 2012_07_16 Promo Mix Optimization - ROI analysis v!

147. Opana ER constituted $383 million in annual sales for Endo at the time of the ZS Associates analysis, good enough for the second highest selling Endo product analyzed by ZS. Of that $383 million in sales, ZS determined that 19%, or $72 million, is "driven by Sales and Marketing."[69] Furthermore, ZS informed Endo that "most of the promotional channels for Opana ER have high ROI." These "promotional channels" include marketing tactics such as copay cards, website advertising, medical journal sponsorship, speaker programs, and detailing to prescribers.

148. The Opana marketing messages whose delivery ZS sought to optimize for Endo conveyed misrepresentations regarding the dangers of the drug. For example, Endo maintained

[68] *Id.*

[69] *Id.*

until April 2012 the website opana.com, which stated, "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." Upon information and belief, Endo did not conduct and does not possess data or evidence to support that statement. Furthermore, the statement is misleading in that it suggests that addiction is not a risk from taking extended-release opioids such as Opana.

149. Thus, ZS worked with Endo for at least a decade optimizing and implementing misleading sales and marketing tactics, *including managing critical sales and marketing functions* such as Incentive Compensation (IC) and Call Planning (CP). ZS' successful performance of these tasks was critical to Endo's efforts to market Opana. Without ZS, Endo could not have achieved its opioid revenue goals.

150. On March 3, 2016, the New York Attorney General announced a settlement with Endo to address the misleading marketing of Opana. The settlement required Endo "to cease all misrepresentations regarding properties of Opana ER, to describe accurately the risk of addiction to Opana ER, and to summarize studies regarding Opana ER on its website."[70] The settlement further required Endo to create programs to prevent its sales representatives "from promoting [Opana ER] to health care providers who may be involved in the abuse and illegal diversion of opioids.[71] Those safeguards were not in place under the sales and marketing program ZS designed and helped Endo implement for years. Even at the time of the settlement announcement, ZS was still working with Endo to shape and manage its Opana ER sales force.

151. In May 2017, an advisory committee to the Food and Drug Administration recommended that Opana ER be withdrawn from the market due in part to the fact Opana ER could be "readily prepared for injection" (thereby bypassing the purportedly "abuse-deterrent" features

[70] *See* https://ag.ny.gov/press-release/2016/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo
[71] *Id.*

of the formulation that Endo touted in its marketing) and was associated with outbreaks of HIV and a blood-clotting disorder known as thrombotic thrombocytopenic purpura ("TTP"). On June 8, 2017, the FDA adopted the committee's recommendation.[72]

152. One month later, on July 6, 2017, Endo announced that it would agree to cease marketing and selling Opana ER altogether.

153. Just as was the case with Purdue, ZS was working with Endo on marketing its branded opioid product at the time that the company voluntarily ceased selling and marketing the drug in response to the dangers of continuing to market it.

4. Teva

154. Not to be left out, Teva Pharmaceuticals also relied on ZS Redacted [redacted][73]

155. Fentora is a fentanyl buccal tablet that is, "used for the treatment of breakthrough pain in cancer patients receiving opioid treatment and who have become tolerant to it."[74] It was approved by the Food and Drug Administration in 2006 for this limited use, but, as the FDA noted two years later, "off-label prescribing has, unfortunately, been widely practiced."[75]

156. The Food and Drug Administration, in an April 26, 2008, memorandum discussing the possibility of an "expanded indication for Fentora for use in break-through pain in

[72] "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, *available at*: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm
[73] *See* Teva Completes Acquisition of Cephalon, Fierce Pharma, October 11, 2011, *available at*: https://www.fiercepharma.com/pharma/teva-completes-acquisition-of-cephalon
[74] *See* Fentanyl Buccal Tablets (marketed as Fentora) Information, *available* at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fentanyl-buccal-tablets-marketed-fentora-information.
[75] Memorandum from Bob A. Rappaport, MD to the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) dated April 26, 2008, Doc. 2231, *In re National Prescription Opiate Litigation*, No. 1:17-md-02804-DAP (N.D. Ohio) (filed August 13, 2019).

patients with chronic pain not caused by malignancy," expressed concern about Fentora's active ingredient, fentanyl, and the growing misuse of opioids despite the safeguards already put in place by the FDA:

> Fentanyl has an extremely narrow therapeutic window, and even in opioid tolerant patients' misuse and errors in dosing can result in significant morbidity and mortality. Exposure to minute quantities of fentanyl in opioid non-tolerant people, especially children and the elderly, can be lethal in minutes. If this product is to be indicated for increased widespread use, and if availability increases, a risk mitigation program that will attempt to prevent, monitor, and intervene, when necessary, will be essential. However, as already noted, *the current paradigms for risk management for potent opioid drug products may not have been fully successful*.[76]

157. Consistent with Dr. Rappaport's concerns, on December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy ("REMS") for Fentora and other Transmucosal Immediate Release Fentanyl ("TIRF").[77]

158. The following year, ZS determined that Redacted

159. Redacted

[76] Memorandum from Bob A. Rappaport, MD to the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) dated April 26, 2008, Doc. 2231, *In re National Prescription Opiate Litigation*, No. 1:17-md-02804-DAP (N.D. Ohio) (filed August 13, 2019) (emphasis added).

[77] *See* https://www.fda.gov/drugs/information-drug-class/questions-and-answers-fda-approves-class-risk-evaluation-and-mitigation-strategy-rems-transmucosal.

[redacted][79]

160. [redacted]

161. After Teva acquired Cephalon in 2012, ZS was tasked not only with specific recommendations [redacted], such as [redacted] but in [redacted][80]

[78] *See* Corporate Integrity Agreement dated September 28, 2008, *available at*: https://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf

[79] *See* Corporate Integrity Agreement dated September 28, 2008, *available at*: https://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf

[80] The concept of "marketing mix" is one used by ZS to contextualize the product offerings it provides clients. "Marketing mix, simply stated is really just the set of promotional tactics that a product is using to sell and market itself. In the pharmaceutical industry, this can include a broad set of different kinds of promotional activities, things from very traditional tactics such as salesforce promotion or sampling, to more recent advances, things like co-pay cards, digital media," explained ZS' John Bienko. "Of course, the biggest question on anybody's mind is 'what is

162. In short, ZS was in charge of maximizing Teva's profit from selling fentanyl by optimizing and assisting in managing Teva's sales force.

5. Johnson & Johnson/Janssen

163. In addition to the manufacturer clients described above, ZS also worked for Janssen Pharmaceuticals, Johnson & Johnson's subsidiary that sold opioids, on Redacted [redacted] Johnson & Johnson used ZS just like everyone else: always.

164. The foregoing paragraphs make clear ZS' central role in the operations of its clients. Just as all pharmaceutical companies rely on IMS Health for sales data, or McKinsey for strategy consulting, practically *all* opioid manufacturers depend on ZS for salesforce optimization and sales and marketing advice. ZS is a critical part of the economic ecosystem that sells drugs in the United States.

h. ZS' aggressive marketing of controlled substances optimized for ROI kills people.

165. In 2009, Dr. Van Zee identified the *precise tactics* that ZS deployed for all of its opioid clients, including Purdue, as a source of OxyContin misuse and abuse, and suggested that regulation may be appropriate to curtail the use of the tactics in which ZS specializes: "The use of prescriber profiling data to target high-opioid prescribers – coupled with very lucrative incentives

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the financial impact I'm getting from these promotions, what's the bang for the buck?'" he added. *See* https://www.youtube.com/watch?v=V8mppVKr9_0

Obtaining an optimal marketing mix is an overarching goal of any client relationship ZS maintains. For example, in addition to its work for Teva, the concept of marketing mix was front of mind for ZS' work for Endo as well. *See supra, Paragraph 135*. "Optimal," in this context, means most profitable.

for sales representatives – would seem to fuel increased prescribing by some physicians – perhaps the most liberal prescribers of opioids and, in some cases, the least discriminate."[81]

166. In time, additional evidence mounted supporting the conclusion that ZS' sales and marketing tactics were demonstrably exacerbating the nationwide opioid crisis. One way of demonstrating the link between aggressive sales and marketing of opioids and worsened mortality outcomes arose out of a quirk of Purdue's own marketing tactics.

167. In 1996, when OxyContin was introduced, five states – California[82], Idaho, Illinois, New York and Texas – maintained "triplicate" programs that required prescribers of Schedule II controlled substances to fill out prescriptions in triplicate.[83] One of the triplicate copies would then be filed with the state agency in charge of maintaining a prescription database intended to monitor diversion and other potential issues relating to the over-dissemination of Schedule II narcotics. These triplicate programs were precursors to modern prescription drug monitoring programs that have been instituted in nearly every state in response to the opioid crisis.

168. Purdue recognized that the requirement to submit records of controlled substance prescriptions to a governmental database chilled prescribers' willingness to prescribe medications subject to the constraints of the triplicate programs. Because Purdue viewed these triplicate requirements as an overly burdensome hindrance on prescribing, the company chose to focus its marketing efforts on other states that did not impose these constraints.

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[81] Art Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99 AM. J. PUB. HEALTH 221, 221, 224 (Feb. 2009), *available at:* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf.

[82] California was the first state to implement a triplicate program in response to concerns about the diversion of opium-based pharmaceuticals. The year was **1939**. Abby E. Alpert, William N. Evans, Ethan M.J. Lieber, and David Powell, *Origins of the Opioid Crisis and its Enduring Impacts*, NBER Working Paper No. 26500, November 2019, *available at*: https://www.nber.org/papers/w26500

[83] Patrick Radden Keefe, *Empire of Pain*, Pg. 407.

169. This resource-allocation decision by Purdue to focus more marketing efforts on states with fewer regulations regarding the prescribing of controlled substances provided a way to test whether *marketing* of OxyContin, by itself, was a cause of not only increased overdose rates for OxyContin, but of *all* opioid-related overdoses, *including* those involving illicit opioids such as heroin and fentanyl.

170. The results were stark. In 2019, economists from the University of Pennsylvania, Notre Dame, and the RAND Corporation analyzed the disparate outcomes in overall opioid overdose mortality experienced in the triplicate states where Purdue did not focus its marketing efforts and non-triplicate states where Purdue did focus those efforts.[84]

171. The economists found that "OxyContin distribution was about 50% lower in 'triplicate states' in the years after the launch. While triplicate states had higher rates of overdose deaths prior to 1996, this relationship flipped shortly after the launch [of OxyContin] and triplicate states saw substantially slower growth in overdose deaths, continuing even twenty years after OxyContin's introduction. **Our results show that the introduction and marketing of OxyContin explain a substantial share of overdose deaths over the last two decades."**[85]

172. Separately, a recent Journal of American Medical Association study analyzed the Centers for Medicare and Medicaid Services' Open Payments database regarding pharmaceutical company marketing efforts towards doctors, as well as CDC data on prescription opioid overdose deaths and prescribing rates, in order to assess whether pharmaceutical marketing

[84] Abby E. Alpert, William N. Evans, Ethan M.J. Lieber, and David Powell, *Origins of the Opioid Crisis and its Enduring Impacts*, NBER Working Paper No. 26500, November 2019, *available at*: https://www.nber.org/papers/w26500

[85] *Id*. (emphasis added).

of opioids to physicians affected the rate of prescription opioid overdose deaths. Notably, the study analyzed these marketing practices beginning August 1, 2013, and ending December 31, 2015.[86]

173. The study noted "physician prescribers are the most frequent source of prescription opioids for individuals who use opioids nonmedically."[87]

174. The study found that "increased county-level opioid marketing was associated with elevated overdose mortality 1 year later, an association mediated by opioid prescribing rates; per capita, **the number of marketing interactions with physicians demonstrated a stronger association with mortality** than the dollar value of marketing."[88]

175. Referring to the types of sales and marketing tactics ZS provided to its clients, and helped them implement, the authors concluded, "amid a worsening opioid crisis, our results suggest that industry marketing to physicians may run counter to current efforts to curb excessive opioid prescribing."[89]

176. The authors' proposed solution was plain simple, and echoed Dr. Van Zee's congressional testimony from 2002: "Pharmaceutical companies might also consider, as one manufacturer recently did, **voluntarily ceasing marketing opioid products directly to physicians**."[90]

i. ZS knew its work kills people.

177. As the preceding paragraphs make clear, ZS was in a truly unique position, given its dominance of pharmaceutical sales and marketing consulting, practically all industry participants were its clients. While advising multiple industry participants regarding the sales of

[86] Scott E. Hadland *et. al.*, *Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality from Opioid-Related* Overdoses, JAMA Network, January 18, 2019, *available at:* https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2720914.
[87] *Id.*
[88] *Id.* (emphasis added)
[89] *Id.*
[90] *Id.*

competing products (OxyContin and Opana, for instance) **at the same time**, ZS was in a position to know confidential information and trade secrets of these clients. Indeed, the contracts between ZS and its clients specify that ZS will have access to the clients' confidential and proprietary information. Given the nature of ZS' work, it cannot adequately perform its function for clients without that access.

178. ZS' clients were repeatedly subjected to enforcement actions for their work selling opioids both before and during the pendency of the ZS client relationship. For instance, in addition to its 2007 guilty plea with the United States Department of Justice ("DOJ"), Purdue Pharma settled with the State of Kentucky in 2015 for $24 million.[91] The settlement concerned similar conduct as the 2007 guilty plea, including the sales and marketing of Purdue's opioids. ZS was involved in this work.

179. Two years later, on July 11, 2017, another ZS client settled charges that it failed to report suspicious orders of opioids and for various recordkeeping violations. In this case, Mallinckrodt's failure to comply with DEA regulations regarding the sales of opioids resulted in a $35 million payment to the DOJ.[92]

180. The settlement agreement related to conduct between 2008 and 2011, during which time ZS was advising Mallinckrodt.

181. Because of these client relationships, ZS was in a unique position to know how the entire industry's opioid sales and marketing tactics were playing out, both in terms of return on investment for their individual clients, as well as overall market trends such as the rise of the opioid crisis. Endo may not have known the specifics of competitor Purdue's marketing efforts for

[91] *See* the December 22, 2015, settlement between the Commonwealth of Kentucky and Purdue Pharma Inc., *available* at https://ag.ky.gov/pdf_news/purduepharmaoxycontin.pdf.
[92] *See* https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

OxyContin, just as Purdue may not have known the specifics of Endo's Opana plan. But ZS knew both, as well as what Teva and Mallinckrodt were doing with their own branded opioid sales and marketing efforts *in real time*.

182. As the opioid epidemic became apparent and the subject of nationwide attention, ZS toiled diligently behind the scenes *everywhere* in the pursuit of one goal: maximizing volumes and profit from the sale of these Schedule II controlled substances.

V. CLASS ACTION ALLEGATIONS

183. Plaintiff bring this case on behalf of themselves and as a class action under Fed. R. Civ. P. 23(b)(2) and 23(b)(3) on behalf of all members of the following Class: **All Counties and Municipal Corporations In The State Of West Virginia From 2004 To Present.**

184. Plaintiff reserves the right to amend or modify the Class definition with greater specificity or further division into subclasses or limitation to particular issues.

185. The material facts relevant to this action are substantially identical for all members of the Class.

186. **Numerosity.** The potential members of the Class as defined are so numerous that joinder of all members is unfeasible and not practicable. While the precise number of Class Members has not been determined at this time, Plaintiffs are informed and believe there are 55 counties in West Virginia and 232 incorporated municipalities.

187. **Commonality and Predominance**. There are questions of law and fact common to the Class, which predominate over any questions affecting only individual Class Members. These common questions of law and fact include, without limitation:

i. Defendant's conduct in creating, proposing, and implementing salesforce optimization and sales and marketing strategies for opioids manufactured by

numerous opioid manufacturers including Purdue after Purdue's first guilty plea in 2007 relating to misbranding of OxyContin;

ii. Whether Defendant performed reasonable due diligence in ascertaining the risks associated with Defendant's strategies for increasing return on investment for opioid sales and marketing strategies for its opioid manufacturer clients;

iii. Whether Defendant's implementation of its own sales and marketing strategies at numerous clients including Purdue, Johnson & Johnson, Teva, Mallinckrodt, and Endo caused or contributed to an increase in opioid addiction;

iv. Whether Defendant's conduct with respect to developing and implementing nationwide opioid sales and marketing practices for numerous opioid manufacturers designed to maximize opioid sales and profit was negligent, grossly negligent, or reckless;

v. Whether Defendant's conduct with respect to developing and implementing nationwide opioid sales and marketing practices at numerous clients including Purdue, Johnson & Johnson, Teva, Mallinckrodt, and Endo caused or contributed to causing a public nuisance;

vi. Whether Defendant's conduct with respect to developing and implementing nationwide opioid sales and marketing practices at numerous clients including Purdue, Johnson & Johnson, Teva, Mallinckrodt, and Endo constituted fraudulent misrepresentations to healthcare providers regarding the safety of the opioid products Defendant helped market and sell;

vii. Whether Defendant conspired with or aided and abetted Purdue Pharma, Johnson & Johnson, Teva, Mallinckrodt, and/or Endo with respect to developing and implementing nationwide opioid sales and marketing practices; and

viii. Whether Defendant's acceptance of funds from its opioid manufacturer clients regarding Defendant's work promulgating and implementing nationwide opioid sales and marketing strategies constitutes unjust enrichment.

188. **Typicality**. The claims of the named Plaintiff are identical to or at least typical of the claims of the Class. Plaintiff and all Class Members were exposed to undeviating behavior and sustained damages arising out of and caused by Defendant's unlawful conduct.

189. **Adequacy of Representation**. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Counsel representing Plaintiffs is competent and experienced in litigating class actions.

190. **Superiority of Class Action**. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all the members of the Class is impracticable. Furthermore, the adjudication of this controversy through a class action will avoid the possibility of inconsistent and potentially conflicting adjudication of the claims asserted herein. While certain individual claims relating to the opioid epidemic against other defendants involved in the opioid stream of commerce into the State of West Virginia have already been initiated by a few Class Members, no Class Member has initiated any action against ZS Associates. A class action would provide a superior vehicle for resolving the issues for all similarly affected and situated. Moreover, based upon the considerable anticipated expense of discovery and case preparation, completion of individual cases is not financially feasible for most Class Members especially considering the amount of damages in play for each member of the Class. There will be no difficulty in the management of this action as a class action.

191. **Policies Generally Applicable to the Class**: Defendant has acted and failed to act on grounds generally applicable to Plaintiff and the other Class members, requiring the Court's imposition of uniform relief to ensure compatible standards of conduct toward the Class.

192. **Notice to the Class**. Plaintiff contemplates that the eventual issuance of notice to the proposed Class Members would set forth the subject and nature of the instant action. Plaintiff believes that information related to the total number of municipalities in West Virginia and publicly available information related to those municipalities at issue are sufficient for direct mail notice to reach the vast majority of putative Class Members. To the extent that any further notices may be required, published notice in appropriate newspapers, professional publications and journals can also be provided.

VI. CAUSES OF ACTION

COUNT I:
Negligence

193. Plaintiff realleges and incorporates by reference the allegations set forth above.

194. Negligence is established where the defendant owes the plaintiff a duty of care, breaches that duty, and the plaintiff sustained an injury or loss proximately caused by the defendant's breach.

195. ZS, through its work with Purdue and other opioid manufacturers, owed a duty of care to the Plaintiff and the Class Members, pursuant to which it would not encourage the over-marketing and over-prescribing of a controlled substance known at the time to be addictive and known at the time to be a threat to public health.

196. In violation of this duty, for decades ZS devised and assisted Purdue, and other opioid manufacturers, with implementing sales and marketing campaigns, including prescriber targeting and salesforce incentive compensation structures that would dramatically increase the amount of opioids prescribed and distributed in Mingo County, the Town of Kermit, and Other Class Members.

197. As a direct and proximate result of ZS' negligent conduct, Mingo County, the Town of Kermit, and Other Class Members have suffered and will continue to suffer harm.

COUNT II:
Gross Negligence

198. Plaintiff realleges and incorporates by reference the allegations set forth above.

199. The oversupply of opioids and plague of addiction led to a widespread epidemic of overdoses, illness, and death that claimed thousands of lives and cost many millions of dollars of public spending—circumstances that constituted an imminent or clear and present danger amounting to more than normal and usual peril.

200. ZS, through its work with Purdue and other opioid manufacturers, owed a duty of care to the Plaintiff and the Class Members, pursuant to which it would not encourage the over-marketing and over-prescribing of a controlled substance known at the time to be addictive and known at the time to be a threat to public health.

201. In violation of this duty, for decades ZS devised and assisted Purdue and other opioid manufacturers with implementing sales and marketing campaigns, including Purdue's *Evolve to Excellence* campaign, that would dramatically increase the amount of opioids prescribed and distributed to Mingo County, the Town of Kermit, and Other Class Members.

202. As a direct and proximate result of ZS' negligent conduct, Mingo County, the Town of Kermit, and Other Class Members have suffered and will continue to suffer harm.

COUNT III:
Negligent Misrepresentation

203. Plaintiff realleges and incorporates by reference the allegations set forth above.

204. ZS, in the course of its business with Purdue and other opioid manufacturers, failed to exercise reasonable care or competence by communicating false information regarding ZS' clients' opioids that ZS knew would be used for guidance by others in their business transactions, including the healthcare providers within Mingo County, the Town of Kermit, Other Class Members who were capable of prescribing Purdue's drugs.

205. Mingo County, the Town of Kermit, and Other Class Members are one of a limited group of entities to whom ZS knew Purdue and other opioid manufacturers intended to supply with false information regarding opioids.

206. ZS knew that the false information was material to healthcare providers' decision to prescribe opioids to patients. ZS intended that such statements be relied upon to encourage additional opioid prescriptions.

COUNT IV:
Public Nuisance

207. Plaintiff realleges and incorporates by reference the allegations set forth above.

208. West Virginia courts have long recognized that anything which interferes with public health and promotes the spread of disease, bodily injury, and/or death, may be considered a public nuisance, and that a use or interference with real property is not required. A public nuisance is one which interferes with public health and welfare and creates an imminent risk of public harm.

209. ZS, though its work with Purdue Pharma and numerous other opioid industry participants, created and continues to perpetuate and maintain a public nuisance to the citizens of Mingo County and the Town of Kermit through the massive manufacturing and distribution of millions of doses of highly addictive, commonly abused prescription pain killers known as opioids.

210. ZS' conduct, including its misrepresentations and omissions regarding opioids, as well as its efforts designed to sell as many units of controlled substances as conceivably possible, have fueled an opioid epidemic within the corporate limits of Mingo County, the Town of Kermit, and Other Class Members that constitutes a public nuisance. ZS and its opioid clients, to include Purdue, Mallinckrodt, Endo, and Teva, knowingly exacerbated the opioid epidemic that affects entire municipalities, towns, and communities.

211. ZS' conduct, including its misrepresentations and omissions regarding opioids, as well as its efforts designed to sell as many units of controlled substances as conceivably possible, constitute unlawful acts and/or omissions of duties, that annoy, injure, or endanger the comfort, repose, health, and/or safety of others.

212. As a direct and proximate result of the wrongful conduct of ZS as set forth herein, ZS negligently, intentionally, and/or unreasonably interfered with the rights of Mingo County, the Town of Kermit, and Other Class Members to be free from unwanted injuries, addictions, diseases, sicknesses, overdoses, criminal actions, and have caused ongoing damage, harm, and inconvenience to Class Members and their residents.

213. As a direct and proximate result, Class Members and their residents have been exposed to the risk of addiction to prescription opioids, have become addicted, and/or have suffered other adverse consequences from their use of the addictive prescription opioids, and have been adversely affected by the addiction and abuse of others in their communities from the highly addictive, prescription pain medication.

214. The annoyance, injury, and danger to the comfort, repose, health, and safety of residents of Mingo County, the Town of Kermit, and Other Class Members includes, but is not limited to:

i. In 2009, the first known year in which ZS advised Purdue regarding sales and marketing efforts for OxyContin, there were 399 opioid-related overdose deaths in West Virginia. ZS designed and implemented marketing strategies that led to a *tripling* of OxyContin sales in subsequent years;

ii. In 2014, while ZS conducted work in furtherance of Project Turbocharge at Purdue, 638 West Virginians died as a result of an opioid-related overdose. Project Turbocharge was developed by McKinsey in 2013 and implemented at Purdue the following year, when it was adopted as Purdue's national sales theme, under the rubric of "Evolve to Excellence";

iii. From 2004 to 2014, West Virginia's drug overdose mortality rate effectively doubled, from 18.8 deaths per 100,000 individuals to 35.5. Prescription opioids contributed to the majority of those deaths.

iv. By 2018, the drug overdose mortality rate had climbed significantly once again, to 50.2 deaths per 100,000 individuals.

v. From 2013 to 2014, West Virginia had the highest overdose death rate of any state, with the rate increasing 10.2% in that interval.

vi. By 2018, the number almost doubled, to 1,132.

vii. Prescription opioid addiction often leads to illicit opioid use and addiction;

viii. According to the Centers for Disease Control, past misuse of prescription opioids is the strongest risk factor for heroin initiation and use;

ix. West Virginia hospitals are reporting increasing numbers of newborns testing positive for prescription medications; and

x. ZS crafted deceptive marketing strategies that were prepared for Purdue and other opioid manufacturers, purchased by them, and implemented with ZS's ongoing assistance. These strategies enflamed, purposefully, an opioid abuse and addiction epidemic that has caused Mingo County, the Town of Kermit, and Other Class Members, its residents, its businesses, and communities to bear enormous social and economic costs including increased health care, criminal justice, and lost work productivity expenses, among others.

215. ZS' conduct annoys, injures, and/or endangers the comfort, repose, health, and safety of others. In addition, ZS' conduct caused and continues to cause harm to Mingo County, the Town of Kermit, and their residents.

216. Mingo County, the Town of Kermit, and Other Class Members seek to abate the public nuisance ZS enflamed and all necessary relief to abate such public nuisance.

COUNT V.
Fraud (Actual and Constructive) and Deceit

217. Plaintiff realleges and incorporates by reference the allegations set forth above.

218. ZS made and caused to be made false representations to healthcare providers working in Mingo County, the Town of Kermit, and Other Class Members, and/or omitted material facts, regarding the risks, efficacy, and medical necessity of opioids, generally, and ZS' clients' opioids, specifically. ZS knew these representations were false, made recklessly without knowledge of the truth, and/or had no reasonable ground for believing such assertions. Specifically, ZS knowingly and/or recklessly:

i. Downplayed the substantial risks of addiction and other side-effects of opioids, including crafting its clients' opioid sales and marketing strategies;

ii. Overstated the efficacy of opioids generally, including making false statements regarding the effectiveness of the drugs for treating specific subsets of the patient population (i.e., those with osteoarthritis) and their ability to improve patient function; and

iii. Misrepresented the medical usefulness and necessity of opioids, generally, and Purdue's and other opioid manufacturer's opioids specifically, including affirmatively marketing their drugs for off label uses (i.e., fibromyalgia osteoarthritis) without solicitation and not in response to questions from healthcare providers.

219. ZS and its clients' misrepresentations and omissions had a tendency to deceive others, to violate public confidence, and/or injure public interests. ZS, having chosen to craft the marketing plans used by Purdue and other opioid manufacturers to make representations to healthcare providers regarding their opioids, was under a duty to disclose the whole truth, and not disclose partial and misleading truths.

220. ZS intended healthcare providers to rely upon the false representations regarding the risks, efficacy, and medical necessity of opioids, generally, and ZS' clients' opioids, specifically, to increase the number of opioid prescriptions made by healthcare providers.

221. Healthcare providers working in Mingo County, the Town of Kermit, and Other Class Members did in fact rely on the false representations made in the course of numerous opioid sales and marketing plans created by ZS and implemented with ZS' ongoing assistance to its clients.

222. Mingo County, the Town of Kermit, and Other Class Members seek to recover all damages caused by ZS' fraudulent representations and omissions.

223. ZS acted with knowledge and willful intent, with reckless disregard for the rights of others, and/or intentionally and with malice towards others. As such, Mingo County, the Town of Kermit, and Other Class Members seek to recover punitive damages against ZS.

COUNT VI:
Civil Conspiracy/Joint and Several Liability

224. Plaintiff realleges and incorporates by reference the allegations set forth above.

225. ZS and its opioid clients, working together for decades, agreed to commit numerous unlawful acts relating to the sale and marketing of their opioid products. ZS and its opioid clients also agreed to use unlawful means to commit lawful acts as part of these sales and marketing efforts.

226. ZS and its numerous opioid clients agreed to pursue the unlawful act of knowingly misrepresenting the addictive nature of opioids in marketing their opioids to health care providers within Mingo County, the Town of Kermit, and Other Class Members.

227. ZS and Purdue deployed the unlawful means of evading Purdue's reporting and compliance obligations to the Inspector General of the United States Department of Health and Human Services for the five years Purdue was subject to a Corporate Integrity Agreement after it pled guilty in 2007 to criminal misbranding.

228. ZS and its numerous opioid clients discussed herein conspired to violate the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-1-101, *et seq*... ZS and its clients engaged in deceptive trade practices including, making, and causing to be made misrepresentations and omissions in marketing of opioids in general, and ZS' clients' opioids, specifically, that deceived or could reasonably be expected to deceive or mislead consumers.

229. ZS and its numerous opioid clients engaged in unfair trade practices, including, intentionally downplaying the risks, overstating the benefits, and misrepresenting the medical necessity of opioids, generally, and ZS' clients' opioids, specifically, including for off-label uses. These practices offend established public policy and are immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers.

230. ZS knowingly made or caused to be made false or misleading representations as to the characteristics, ingredients, uses, and benefits of opioids, generally, and ZS' clients' opioids, specifically, by downplaying the risks of addiction and abuse, overstating the efficacy, and misrepresenting the medical necessity of opioids, generally, and ZS' clients' opioids, specifically.

231. ZS and its numerous opioid clients agreed to deploy unlawful sales and marketing tactics to achieve the lawful purpose of maximizing ROI for ZS' opioid clients.

232. As a consequence, ZS is jointly and severally liable with its opioid clients for the salesforce optimization and sales and marketing practices used to promote ZS' clients' opioid products, including Purdue's OxyContin, Teva's Fentora, Endo's Opana, Mallinckrodt's Xartemis XR, and others.

233. Mingo County, the Town of Kermit, and Other Class Members were damaged as a result of the unlawful acts ZS conspired with its clients to commit.

COUNTY VII:
Civil Aiding and Abetting

234. Plaintiff realleges and incorporates by reference the allegations set forth above.

235. ZS gave substantial assistance and encouragement to Purdue and its other opioid clients regarding conduct ZS knew to be tortious and/or in violation of a duty owed by its clients to third persons, including Mingo County, the Town of Kermit, and other Class Members.

236. Mingo County, the Town of Kermit, and other Class Members were damaged as a result of the specific conduct that ZS encouraged and substantially assisted.

COUNT VIII
Unjust Enrichment

237. Plaintiff realleges and incorporates by reference the allegations set forth above.

238. Unjust enrichment is established where the plaintiff alleges: (a) a benefit conferred upon the defendant by the plaintiff; (b) an appreciation or knowledge by the defendant of the benefit; and (c) the acceptance or retention by the defendant of the benefit under such circumstances as to make it inequitable for the defendant to retain the benefit without the payment of its value.

239. ZS was compensated for its decade of work increasing opioid sales and maximizing profits for its opioid clients.

240. The compensation ZS accepted from opioid manufacturers for maximizing sales of their deadly opioid products constitutes money in the possession of ZS that, in equity and good conscience, ZS ought not be allowed to retain.

VII. JURY DEMAND

Plaintiff, on behalf of itself and all others similarly situated, requests a trial by jury on all issues so triable.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and all others similarly situated, respectfully prays that this Court grant the following relief:

i. For an order certifying the proposed Class herein;

ii. Enter Judgment in favor of Plaintiff, on behalf of itself and all others similarly situated, against Defendant awarding Plaintiff its actual damages caused by the opioid epidemic, including but not limited to (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths (2) costs for providing treatment, counseling and rehabilitation services, (3) costs for providing treatment of infants born with opioid-related medical conditions, (4) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation, (5) costs associated with law enforcement and public safety relating to the opioid epidemic, and (6) costs associated with drug court and other resources expended through the judicial system;

iii. Order that Defendant compensate Plaintiff, on behalf of itself and all others similarly situated, for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

iv. Order Defendant to fund an "abatement fund" for the purposes of abating the opioid public nuisance;

v. Enter judgment against Defendant requiring Defendant to pay punitive damages;

vi. Enter judgment against Defendant awarding Plaintiff its reasonable attorneys' fees, all costs and expenses, pre-judgment and post-judgment interest; and

vii. All other such and further relief as this Court may deem just and proper.

Dated: January 27, 2022

//s// Letitia Neese Chafin
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