**Resident:** Sydney Archer, MD, MPH

**Project Title:** Association between pharmaceutical industry non-research payments and OBGYN physician prescribing practices: a cross-sectional analysis

**Principal Mentor:** Tyler Muffly, MD

**Additional faculty:** Guido, Bastow, Scwartz

**I.**   **Hypotheses and Specific Aims**:

**Hypothesis:** We hypothesize that OBGYN physicians who receive pharmaceutical industry non-research payments are more likely to prescribe medications created by the company from which they received payments, compared to their peers who do not receive pharmaceutical industry non-research payments.

**Aim 1**:  To evaluate whether OBGYN physicians who receive pharmaceutical non-industry payments, including general payments and payments in the form of ownership or investments, are more likely than their peer to prescribe medications created by the company from which they received payments

**Aim 2**:  To assess whether prescribing rates for certain medications differ depending on which type of industry payments OBGYN physicians received including: payments for travel and lodging, food and beverage, consulting, charitable contributions, serving as faculty or as a speaker, royalties or licenses, space rentals or facility fees, honoraria, gifts, and education.

**Aim 3:**  To identify if there is a measurable monetary threshold at which there is an association between pharmaceutical payments to OBGYN physicians and prescribing practices.

**II.** **Background and Significance**:

Prescription costs in the U.S. are the highest in the world [1]. These high costs have been attributed to the complex drug development process, the restriction of price negotiation, as well as the existence of government-protected monopolies granted to drug manufacturers [1]. Pharmaceutical manufacturers employ innovative and diverse strategies to maintain market shares after losing patent protection, including reformulating existing molecules and combining drugs [2]. A pharmaceutical brand’s continued success may depend on brand loyalty and continued relationships between the company and physician prescribers. Pharmaceutical industry non-research payments to physicians may increase healthcare costs if physicians consistently prescribe more expensive medications [3]. The marketing of drugs to physicians includes various practices such as free drug samples, gifts, meals, speaker and consulting fees, and travel sponsorships. Because of the inherent risks for conflicts of interest and bias in physician-industry relations, policy makers have long called for increased transparency in these relationships [4, 5].

The Physician Payments Sunshine Act, passed in 2010, requires that drug manufacturers report all payments made to physicians to the Centers for Medicare and Medicaid Services (CMS). The CMS releases yearly reports in the Open Payments dataset (OPD) which have been publicly available since 2015 due to a Freedom of Information Act request made by the news organization ProPublica [6]. CMS also releases the Medicare Part D Prescriber Public Use Files (MPDPUF) which covers approximately 1.4 billion prescriptions to 37.1 million beneficiaries and allows analysis of prescribing patterns of individual physicians [7]. By linking the OPD and the MPDPUF, previous studies have been able to analyze the association between physician-industry payments and prescribing patterns using real-world data. Recent studies using these linked datasets have found associations between industry payments and brand name prescribing, regional patterns in prescribing of marketed drugs, the prescribing of newer, more expensive medications [8-11].

While prior work has evaluated the magnitude of pharmaceutical industry payments to OBGYN physicians, we aim to expand this body of literature by analyzing the presence of physician-industry relationships associated with prescribing practices [12].

**III**. **Preliminary Studies/Progress Report:** None.

**IV. Research** **Methods**

1. **Outcome Measure(s):**

The primary outcome of interest is the odds of a physician prescribing medications from a manufacturer that they received non-research payments from

Our secondary outcome of interest is the physician prescribing rate of medications within a medication class. We will calculate the prescribing rate as a percentage of all medications associated with physician payment claim counts divided by the total claims counts for all drugs in that class. A claim is the physician’s prescription filled by the pharmacy, which is then submitted to and paid by the insurer. The primary predictor of interest is payment from the pharmaceutical industry, defined as a dichotomous yes/no variable for receipt of any payment. For the purposes of our analysis, physicians were considered to have received non-research payments if they received at least one cash, non-cash (in-kind), dividend or stock payment from pharmaceutical during the study period. Additionally, we will investigate a dose-response relationship between total payment value, frequency of payment, and prescribing practices of physicians.

Covariables will include physician gender, American Board of Obstetrics and Gynecology-approved fellowship training status, American College of Obstetricians and Gynecologists district, overall physician prescribing volume, and prescribing volume in the therapeutic category. The overall prescribing volume of a physician is calculated as the total days’ supply of all drugs of any category prescribed by that physician. The therapeutic category prescribing volume is calculated as the days’ supply of all prescriptions for any drugs within the same therapeutic category as the drug made by the company paying the physician.

1. **Description of Population to be Enrolled:**

We will include prescribing practice data and industry payment data from all OBGYN physicians who appear in both the Physician Compare National Database (PCND) a directory of physicians enrolled in Medicare, and the Medicare Part D Prescriber file, which reports an end-of-year count of each physician’s filled prescriptions [13]. We will collect publicly reported demographic information including physician name, medical school, medical school graduation date, and gender. We will confirm board certification status through data collected by CMS from national certifying boards. These demographic records can be linked through the unique NPI number to the MPDPUF data set (see Demographics Dummy Table).

We will exclude OBGYN physicians whose total number of brand-name prescriptions was redacted because of low claim count. Physician records with missing name, city or state were also excluded. Prescriber groups that do not have prescriptive authority or are not eligible for payments from the pharmaceutical industry (e.g., nurse practitioners, physician assistants, and pharmacists) will be excluded.

1. **Study Design and Research Methods**

This study is a retrospective, cross-sectional analysis which links two publicly available datasets for 2014 through 2017: the OPD General Payments and the MPDPUF [7]. These databases are both publicly available and, therefore, this project is exempt from approval by the University of Colorado Multiple Institutional Review Board. The OPD, a national disclosure program mandated by the Affordable Care Act (ACA) and managed by CMS, contains information on the total value of and type of financial payments made by pharmaceutical and medical device companies to physicians and teaching hospitals [6]. MPDPUF captures data on prescription drugs prescribed by physicians and other health care providers to Medicare Part D beneficiaries, including 40 million seniors and disabled persons in the U.S. [14]. It provides the number of claims, duration of prescription, and cost for each provider-drug combination. MPDPUF only includes prescriptions that were filled. For each prescriber and medication, MPDPUF includes the brand and generic name, the total days’ supply prescribed by that provider, including original prescriptions and refills, as well as the total drug cost based on the total amount paid by the Part D plan, Medicare beneficiary, government subsidies, and any other third-party payers.

MPDPUF uses NPI numbers as unique identifiers while the OPD uses a randomly generated unique identification number. Due to the absence of a common variable, we will use a two-step process to link OPD with MPDPUF. First, OPD will be linked to National Provider Identification database using physician first and last names, cities, and states. The OPD and the MPDPUF can then be linked. The final linked database includes physician name, gender, address, city, state, zip code, specialty, drug name, total drug cost, total days’ supply for the drug, the total amount of payments received, and the amount of payment received by individual manufacturers. A specific prescription associated with a particular physician is included in the database only if there were ten or more claims for that drug associated with that physician. We plan to analyze the data after safely storing it in the Denver Health REDCap repository (http://dhharedcap.ucdenver.edu).

Two authors (BB and TM) developed a candidate list of drugs from the MPDPUF database based on use for common obstetric or gynecologic conditions, high cost, lack of benefit compared to other therapies in the same therapeutic category, and presence of similarly effective, less expensive therapies. These co-authors applied *a priori* criteria based on their clinical experience and the approved drugs database by the Federal Drug Administration (FDA) to determine a list of drugs in each class [15, 16]. Table X shows the proposed list of drug groupings.

1. **Data Analysis Plan:**

We plan to use R 3.6.1 to perform all statistical analyses.

*Descriptive Statistics*

For our descriptive statistics, we will use chi square analysis to compare demographic characteristics of physicians who received non-research pharmaceutical industry payments versus those who did not.

*Evaluating prescribing practices of physicians who received non-research payments*

Physicians receiving payments for one of the Table X medications (‘‘compensated’’) who did (‘‘prescribers’’) or did not (‘‘nonprescribers’’) prescribe Table X medications will be compared in terms of number and dollar value of payments using a chi-square test. Of physicians who prescribed table X medications, those receiving payments will be compared to those who did not (‘‘noncompensated’’) in terms of the mean rate of medications prescribed. The mean rate is defined as the mean of individual physicians’ prescribing rates, which a percentage of all medications associated with physician payment claim counts divided by the total claims counts for all drugs in that class.

*Correlation of prescribing rate to dollar value of payments*

In compensated providers we will use the Spearman rank correlation test to assess the relationship between the number of payments and dollar value of payments, and percentage of medication prescriptions that are from that company prescribed by the physician. Physicians will then be stratified by specialty as general OBGYNs, female pelvic medicine and reconstructive surgeons, gynecologic oncologists, maternal-fetal medicine specialists, or reproductive endocrinologists, and the above analysis will be repeated. This analysis will be performed for each drug in Table X. The correlations between prescribing patterns and payment number and value will be compared between drugs in each therapeutic class.

*Effects of Different Payment Types*

We will use the Welch’s T-test to examine whether the nature of the payments received by physicians was associated with different prescribing practices of drugs for which physicians receive payments. Specifically, we are interested in whether or not compensation for speaking engagements had a disparate effect of prescribing rates than payments for meals. We believe that physicians who receive speaking payments will have higher prescribing rates for medications that they receive money for than those who received other types of payments. Conversely, we will test that physicians whose only payments were for meals have lower rates of brand prescribing than those who received other types of payments (either alone or in combination with meals.). Lastly, we will compare doctors who received no payments to those who received only meals for rates of prescribing drugs sponsored by manufacturers.

*Zero-inflated Regression Model*

In many studies count data may possess excess amount of zeros. We will use zero influenced regression models to analyze the association between the intensity of physician-industry relationships, determined by the total value of industry payments, and prescribing of brand-name medications. We will perform sensitivity analyses to check for nonlinearity of this relationship by including a squared term of payments received in the model and by re-estimating the linear model using various cut-offs of total payments received. Adding a squared term for payments to the model allows for the possibility of a curvilinear relationship between payment and prescribing. A large coefficient on the squared term may be evidence of nonlinearity.

We will use univariate logistic regression analysis to analyze the association between industry payments and prescription of drugs of uncertain medical benefit. We will use multivariate logistic regression to analyze the association between receiving any industry payment with prescribing the drug of uncertain medical benefit, controlling for physician gender, specialty, region, therapeutic category prescribing and overall prescribing volume. All analyses will be performed at an *a priori* alpha level of 0.05.

1. **Description, Risks and Justification of Procedures**

 There are few risks associated with our data collection and analyses. We do not use protected health information, nor will we publish data that can be linked to specific providers. Data will be stored in a REDCap database.

1. **Data Collection Tools:**

We will use a combined database that links the OPD and the MPDPUF databases.

**E.   Potential Scientific Problems:**

Our cross-sectional study has notable limitations. We can detect an association only between prescribing practices and financial relationships, and cannot determine causation. It is possible that the physicians who more frequently prescribed pharmaceuticals were also those who were more open to receiving industry funding for meals, conferences, or other purposes. Alternatively, high prescribers of certain drugs may have been sought after by pharmaceutical companies to promote their products through various marketing activities, such as participation in speakers’ bureaus. Manufacturers purchase prescribing data for individual physicians from IMS Health and other vendors and use such information to guide their marketing efforts. Because the Medicare Part D prescription database includes only insurance claims for prescriptions that were filled, our analysis may have underestimated the extent of prescribing. We also cannot comment on drugs that are not covered by Medicare part D, which could exclude medications commonly prescribed for younger patients.

Our findings are also limited by the accuracy of reporting of industry payments. Education might be reported under several payment categories, such as grants/educational gifts, and educational training. We cannot determine the frequency of misattribution of the payment category or underreporting of payments. Nor are we able to control for certain physician characteristics not found in either database (e.g., practice characteristics, level of experience) that may have an impact on prescribing patterns. Moreover, our analysis will differentiate between payments for medical devices and those for medications. There may be fewer options for medical devices than medications; therefore, it is plausible physicians would receive different proportions of non-research payments for devices versus medications.

Finally, while our analysis will likely achieve a very high match rate between the Open Payments data and the Part D prescribing data (> 99%), there is a possibility that some providers who should have matched did not, excluding physicians who should have been included.

1. **Summarize Knowledge to be Gained:**

We aim to better characterize the association between the receipt of pharmaceutical industry non-research payments and the prescribing of women’s health medications. There are inherent tensions between the profits of health care companies and the affordability of medical care. Policy makers, physicians, and patients should be aware of the effect of pharmaceutical industry non-research payments on prescribing practices and its potential financial consequences. Improved transparency of payments to physicians can increased shared decision making between physicians and their patients.

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**Graphs and Figures**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Demographics Dummy Table: Percentage of doctors who received Non-research payments for OBGYN Medications prescribed to Medicare Part D Beneficiaries** | | | | | | | |
|  |  |  |  |  |  |  |  |
|  |  |  | **Receipt of Industry Payments N (%)** | | |  |  |
|  | **All Physicians** |  | **Yes** |  | **No** |  |  |
|  | **n = 32320** | **%** | **n = 23142** | **%** | **n = 9178** | **%** | **P-value** |
| **Prescriber characteristics** |  |  |  |  |  |  |  |
| *Sex* |  |  |  |  |  |  |  |
| Female | 18,892 | 58.5% | 13,026 | 56% | 5,866 | 64% |  |
| Male | 13,428 | 41.5% | 10,116 | 44% | 3,312 | 36% |  |
|  |  |  |  |  |  |  |  |
| *Age (y)* |  |  |  |  |  |  |  |
| Younger than 65 | 28,545 | 88.3% | 20,238 | 87% | 8,307 | 91% |  |
| Older than 65 | 3,651 | 11.3% | 2,808 | 12% | 843 | 9% |  |
| Unknown | 124 | 0.4% | 96 | 0% | 28 | 0% |  |
|  |  |  |  |  |  |  |  |
| *Medical school training* |  |  |  |  |  |  |  |
| Osteopathic training (DO) |  |  |  |  |  |  |  |
| MD |  |  |  | | | | |
| Unknown |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| *Medical School Location* |  |  |  |  |  |  |  |
| U.S. | 24,893 | 77.0% | 18,030 | 78% | 6,863 | 75% |  |
| Non US | 7,427 | 23.0% | 5,112 | 22% | 2,315 | 25% |  |
|  |  |  |  |  |  |  |  |
| *ACOG District* |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| District I (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) | 1,988 | 6.2% | 1,189 | 5% | 799 | 9% |  |
| District II (New York) | 2,306 | 7.1% | 1,607 | 7% | 699 | 8% |  |
| District III (Delaware, New Jersey and Pennsylvania) | 2,634 | 8.1% | 1,987 | 9% | 647 | 7% |  |
| District IV (District of Columbia, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia) | 4,322 | 13.4% | 3,307 | 14% | 1,015 | 11% |  |
| District V (Indiana, Kentucky, Ohio, Michigan) | 3,563 | 11.0% | 2,613 | 11% | 950 | 10% |  |
| District VI (Illinois, Iowa, Minnesota, Nebraska, North Dakota, South Dakota, Wisconsin) | 3,282 | 10.2% | 2,042 | 9% | 1,240 | 14% |  |
| District VII (Alabama, Arkansas, Kansas, Louisiana, Mississippi, Missouri, Oklahoma, Tennessee) | 3,511 | 10.9% | 2,768 | 12% | 743 | 8% |  |
| District VIII (Alaska, Arizona, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming) | 3,492 | 10.8% | 2,307 | 10% | 1,185 | 13% |  |
| District IX (California) | 2,935 | 9.1% | 1,926 | 8% | 1,009 | 11% |  |
| District XI (Texas) | 2,448 | 7.6% | 1,914 | 8% | 534 | 6% |  |
| District XII (Florida) | 1,839 | 5.7% | 1,482 | 6% | 357 | 4% |  |
|  |  |  |  |  |  |  |  |
| **Prescriber practice factors** |  |  |  |  |  |  |  |
| *Certification* |  |  |  |  |  |  |  |
| Critical Care | 4 | 0.0% | 2 | 0% | 2 | 0% |  |
| Family Planning | 38 | 0.1% | 23 | 0% | 15 | 0% |  |
| Female Pelvic Medicine and Reconstructive Surgery | 651 | 2.0% | 500 | 2% | 151 | 2% |  |
| Gynecologic Oncology | 727 | 2.2% | 562 | 2% | 165 | 2% |  |
| Hospice and Palliative Care | 2 | 0.0% | 2 | 0% | - | 0% |  |
| Maternal-Fetal Medicine | 1,282 | 4.0% | 382 | 2% | 900 | 10% |  |
| Obstetrics and Gynecology | 25,587 | 79.2% | 19,404 | 84% | 6,183 | 67% |  |
| Unknown | 4,028 | 12.5% | 2,266 | 10% | 1,762 | 19% |  |
|  |  |  |  |  |  |  |  |
| Annual number of Medicare Part D beneficiaries served?? | | |  |  |  |  |  |
| 0 - 50 | 5,006 | 15.5% | #REF! | #REF! | #REF! | #REF! |  |
| 51 - 100 | 2,018 | 6.2% | #REF! | #REF! | #REF! | #REF! |  |
| 101 - 250 | 2,651 | 8.2% | #REF! | #REF! | #REF! | #REF! |  |
| 251 and above | 3,706 | 11.5% | #REF! | #REF! | #REF! | #REF! |  |
| Unknown | 18,939 | 58.6% | #REF! | #REF! | #REF! | #REF! |  |
|  |  |  |  |  |  |  |  |
| Annual number of Medicare Part D claims | |  |  |  |  |  |  |
| 0 - 100 | 7,357 | 22.8% | #REF! | #REF! | #REF! | #REF! |  |
| 101 - 400 | 7,340 | 22.7% | #REF! | #REF! | #REF! | #REF! |  |
| 401 - 2000 | 7,091 | 21.9% | #REF! | #REF! | #REF! | #REF! |  |
| 2001 and above | 2,054 | 6.4% | #REF! | #REF! | #REF! | #REF! |  |
| Unknown | 8,478 | 26.2% | #REF! | #REF! | #REF! | #REF! |  |

**Dummy Prescription Table: Prescription Days Supply made by OBGYN Physicians from 2013 to 2017.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Drug** | **Median** | **Q1** | **Q3** |
| atelvia | 20.865 | 15.21 | 39.04 |
| combipatch | 14.4 | 11.785 | 14.4 |
| detrol la | 1.88222222 | 1.595 | 5.84 |
| divigel | 28.0925 | 13.59 | 83.5725 |
| duavee | 14.1 | 5.04111111 | 56.4988889 |
| elestrin | 11.81 | 4.07 | 16.7 |
| enablex | 19.08 | 15.84 | 25.29 |
| estrace | 27.93 | 15.7 | 50.57 |
| estring | 6.59777778 | 2.83 | 14.3911111 |
| fosamax | 99.53 | 99.18 | 121.07 |
| gelnique | 15.76 | 13.465 | 15.76 |
| intrarosa | 21.24 | 14.1 | 37.88 |
| metronidazole | 300 | 300 | 300 |
| osphena | 44.945 | 20.7075 | 113.06 |
| premarin | 11.9194444 | 5.02361111 | 27.7693056 |
| prempro | 2.39777778 | 1.155 | 3 |
| prolia | 32.04 | 14.52 | 79.29 |
| risedronate | 20.865 | 15.21 | 39.04 |
| tinidazole | 16.13 | 13.2525 | 23.9525 |
| toviaz | 17.96 | 9.88375 | 48.94 |
| vagifem | 4999.375 | 2034.3325 | 6490.435 |
| vesicare | 10.04 | 4.858125 | 23.431875 |

Table X: Drug classes of interest.

|  |  |
| --- | --- |
| Anti-Infectives | Metrogel/etronidazole  Tinidazole |
| Anticholinergics for Overactive Bladder | Detrol/ Tolterodine  Detrol LA  Ditropan/ Oxybutinin  Ditropan XL  Enablex/ Darifenacin  Gelnique/ Oxybutinin  Oxytrol/ Oxybutinin  Sanctura/ Trospium chloride  Sanctura XR  Toviaz/ Fesoterodine  Vesicare/ Solifenacin |
| Anti-Virals | Valtrex/ Valacyclovir  Zovirax/ Acyclovir |
| Anti-Bisphosphonates | Atelvia/ Risendronate  Boniva/ Ibandronate  Divigel/ Estradiol  Elestrin/ Estradiol  Fosamax/ Alendronate  Prolia/ Denosumab |
| Hormone Therapy (single ingredient) | Alora/ Estradiol  Climara/ Estradiol  Cenestin/ Conjugated estrogens  Premarin/ Conjugated estrogens  Depo-Provera/ Medroxyprogesterone acetate  /  Enjuvia/ Conjugated estrogens  Vivelle-Dot/ Estradiol |
| Oral Combined Estrogen and Progestin Products for Hormone Therapy | Activella/ Estradiol Norethinrdone Acetate  Amabelz/ Estradiol Norethindrone Acetate  Climara pro/ Estradiol Levonorgestrel  Combipatch/ Estradiol Norethindrone Acetate  Femhrt/ Estradiol Norethindrone Acetate  Menest/ Esterified estrogens  Mimvey/ Estradiol Norethindrone Acetate  Mimvey loPremphase/ Conjugated estrogens/medroxyprogesterone acetate  Prempro/ Conjugated estrogens/medroxyprogesterone acetate |
| Transdermal Estrogen | Alora/ Estradiol  Climara/ Estradiol  Menostar/ Estadiol  Vivelle-dot/ Estradiol |
| Vaginal Estrogen Hormone Therapy | Duavee/ Conjugated estrogens/bazedoxifene  Estrace/ Estradiol  Estring/ Estradiol  Intrarosa/ Prasterone  Menest/ Esterified estrogens  Osphena/ Ospemifene  Premarin/ Conjugated estrogens  Vagifem/ Estradiol  Yuvafem/ Estradiol |

**Supplemental Figure.  CONSORT-like diagram of matching process.**

**Records in 2013-2017 Medicare Part D databases**

N = ??,???

Omit non-individual records

N = ??,???

Omit all non-MD and all non-DO physicians

N = ??,??? individuals with DO or MD degree

Filter Physicians by Taxonomy Code for only OBGYNs

N = ??,???

**Records in 2013-2017 Open Payments Database:**

**N = ?,???,???**

Omit non-individual records

N = ?,???

Omit medical device records

N = ???,???

Round 1: OP First NP AltFirst, last, address, city, state

N = ??,??? (x.xx%)

Round 2: First, OP last NP AltLast , address, city, state

N = ??,??? (x.xx%)

Round 3: OP Alt First NP First, last,address, city, state

N = ??,??? (x.xx%)

N = ?,???,??? OPD records with multiple records per individual

N = ???,??? OPD individuals

N = ???,??? individuals with DO or MD degree

Physician Matching Between Medicare Part D Database and Open Payments Database

Round 1: First, middle, last, suffix, address, city, state

n = ???,???? (xx.xx%)

Round 2:  First, last, suffix, address, city, state

n = ??,??? (x.xx%)

Round 3: First, last, address, city, stat

n = ??,??? (x.xx%)

n = ??,??? matches remain.

Omit ambiguous from third round

N = ?,???

N = ??,??? matches remaining

Collapse ??? duplicate NPI

N = ??,??? matched individuals with MD or DO degree