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Gifts and influence: Conflict of interest policies and prescribing of psychotropic medications in the United States

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ABSTRACT

The pharmaceutical industry spends roughly 15 billion dollars annually on detailing – providing gifts, information, samples, trips, honoraria and other inducements – to physicians in order to encourage them to prescribe their drugs. In response, several states in the United States adopted policies that restrict detailing. Some states banned gifts from pharmaceutical companies to doctors, other states simply required physicians to disclose the gifts they receive, while most states allowed unrestricted detailing. We exploit this geographic variation to examine the relationship between gift regulation and the diffusion of four newly marketed medications. Using a dataset that captures 189 million psychotropic prescriptions written between 2005 and 2009, we find that uptake of new costly medications was significantly lower in states with marketing regulation than in areas that allowed unrestricted pharmaceutical marketing. In states with gift bans, we observed reductions in market shares ranging from 39% to 83%. Policies banning or restricting gifts were associated with the largest reductions in uptake. Disclosure policies were associated with a significantly smaller reduction in prescribing than gift bans and gift restrictions. In states that ban gift-giving, peer influence substituted for pharmaceutical detailing when a relatively beneficial drug came to market and provided a less biased channel for physicians to learn about new medications. Our work suggests that policies banning or limiting gifts from pharmaceutical representatives to doctors are likely to be more effective than disclosure policies alone.

Pharmaceutical companies invest heavily in marketing. Between 1990 and 2008, pharmaceutical expenditures on marketing increased more than six-fold from $3 billion dollars to $20.5 billion dollars (Congressional Budget Office, 2009). A practice commonly known as detailing, in which drug company representatives make sales calls to physicians and provide them with information, free samples, meals, and gifts, accounted for the majority of promotional expenses. Collectively, pharmaceutical companies spent $15.7 billion dollars on detailing in 2011 or roughly $19,000 for every physician in the United States (Kaiser Family Foundation, 2013; Pew Charitable Trusts, 2013).

Amidst growing concern about potential conflicts of interests generated by detailing, a host of states, medical schools, and interest groups within the U.S. began to advocate for policies to regulate interactions between physicians and pharmaceutical representatives (Gorlach and Pham-Kanter, 2013; King et al., 2013). Efforts to transform the pharmaceutical industry have taken a variety of forms ranging from self-regulation to laws prohibiting physicians from receiving gifts. Academic medical centers have implemented policies to limit interactions between students and faculty and pharmaceutical representatives. States adopted laws regulating interactions between pharmaceutical representatives and physicians ranging from bans on gift giving to disclosure of gifts and payments. Finally, the Physician Payments Sunshine Act requires all drug manufacturers to publicly disclose financial relationships with physicians including gifts and meals. Surprisingly, little empirical research has examined the relative efficacy of these various policies.

While one might think that regulation of detailing should have obvious and strong effects on physician behavior, the canonical expectation from social psychology is that disclosures and gift restrictions are unlikely to be effective (Dana and Loewenstein, 2003; Sah and Fugh-Berman, 2013). Dana and Loewenstein argue, for example, that "limiting gift size, educational initiatives, and mandatory disclosure are unlikely to eliminate bias because they

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rest on a faulty model of human behavior" (Dana and Loewenstein, 2003:254). Gift restrictions are thought to be ineffective because even small gifts can create unconscious biases and disclosure can produce moral licensing, which perversely increases bias. Given the literature, it is not immediately obvious what effect, if any, regulations will have on new drug diffusion.

Recent empirical research has found that medical school policies limiting or prohibiting detailing lead to lower rates of new drug uptake (King et al., 2013), higher rates of generic prescribing (Epstein et al., 2013), and reduced off-label prescribing (Larkin et al., 2014). While this work has significantly advanced our understanding about the impact of medical schools' conflict of interest policies, three gaps remain in the existing literature. First, the comparative efficacy of various policy strategies-gift bans, gift restrictions, and disclosure policies-has received little attention. Second, it is unknown whether policies implemented at the state or federal level, rather than academic institutions, will be associated with prescribing patterns. Academic institutions, unlike states, have considerable control over detailer's access to providers and substantial monitoring and enforcement capacity. Finally, prior research has not examined whether physicians have and use alternative mechanisms to learn about efficacious medications when detailing is restricted. In places where detailing is limited or prohibited, it is imperative that physicians have an alternative way to learn about new effective medications. We address this issue by examining whether physician peer networks acted as alternative source of information about clinically advantageous medications when restrictions on pharmaceutical detailing existed. Prior research has found that peer networks influence physician prescribing behavior (Coleman et al., 1957; Manchanda et al., 2008) making network-based social learning a promising substitute for marketing.

To preview our main findings, we show that policies banning, limiting, and requiring disclosure of gifts to physicians were associated with lower prescribing rates of newly marketed medications. We observed significantly lower prescribing rates in states with gift bans and gift limits, than in states that relied on non-public disclosure alone. In states that ban gift-giving, peer influence substituted for pharmaceutical detailing when a relatively advantageous drug came to market.

1. Background

1.1. State level pharmaceutical marketing regulation

Eight states had adopted laws regulating pharmaceutical marketing by 2009. These state laws can be divided into three categories: (1) states that required disclosure of payments and gifts to physicians but do not limit or ban gifts, (2) states that required companies to adopt and comply with codes of conduct developed by the Pharmaceutical Research and Manufacturers of America, which limits gifts, and (3) states with both statutory gift bans and publicly available disclosure requirements (Gorlach and Pham-Kanter, 2013).

Vermont, Massachusetts and Minnesota banned most gifts to physicians and had the most comprehensive disclosure requirements for non-prohibited payments. Gifts, according to Vermont law, are defined as "anything of value provided for free to a health care provider" (V.SA. 4361a). Minnesota introduced the first state-level regulation prohibiting gifts in 1993. The legislation, which remains among the most stringent in the United States, banned gifts totaling $50 or more in a given year from a single company. Similar legislation requiring mandatory reporting of payments exceeding $25 was enacted by Vermont in 2002. This legislation was subsequently strengthened in 2009 to include a ban on all gifts, including food, to health care professionals. In 2009, Massachusetts implemented regulation restricting payments and gifts and establishing a mandatory reporting requirement. Honoraria, consulting payments, clinical trials, research funding, samples, and educational materials are not considered gifts but must be disclosed. Disclosure data are publicly available and identify individual physicians.

Three states—Maine, West Virginia, and Washington D.C.—required pharmaceutical companies to report aggregated marketing expenditures to the state. Disclosure laws typically exempted small gifts, reimbursements for clinical education, remuneration for conducting clinical trials, and drug samples. Unlike data from Minnesota, Vermont, and Massachusetts, the disclosure data from these three states is not readily available via public websites.

California and Nevada mandated that pharmaceutical companies adopt and comply with the guidelines developed by the Pharmaceutical Research and Manufactures of America (PhRMA) (National Conference of State Legislatures (2013); Gorlach and Pham-Kanter, 2013). PhRMA's Code on Professional Interactions with Health Care Professionals prohibits entertainment and recreational items, as well as gifts not related to patient care or education. The guidelines allow for meals accompanied by educational presentations and discussions, as well as educational gifts of $100 or less per item. Payments or gifts that fall outside of the guidelines do not have to be disclosed.

To examine how regulatory environments shaped drug diffusion processes, we classified states by the strength of their regulation and assigned them to one of four groups: (1) states with gift bans and publicly available disclosure data, (2) states with codes of conduct and gift restrictions, (3) states with disclosure requirements, and (4) states without marketing regulation. Since Massachusetts and Connecticut adopted regulation after the study period, they are conservatively included in the set of states with "no policy."

1.2. Mental health medications

Mental health medications are currently among the best-selling and most heavily marketed classes of drugs in the United States. One in five adults in the United States received a mental health medication in 2010. In that year, sales of antidepressant, antipsychotic, and stimulant medications yielded close to $35 billion dollars and accounted for 11.4% of U.S. spending on pharmaceuticals (IMS Incorporated 2010). These three drug classes are also among the top five most heavily detailed drug classes (Congressional Budget Office, 2009). Given the importance of these classes of medications to the pharmaceutical industry, our study focuses on newly introduced mental health medications.

Newly introduced drugs are substantially more expensive than the older alternatives and have contributed to both rising health care costs, as well as pharmaceutical revenues (Duggan, 2005). However, the majority of new drugs developed by pharmaceutical companies are minor variations on existing medications that offer few or no benefits over existing alternatives but often produce significant adverse reactions (Light and Lexchin, 2012). Over 90 percent of newly approved drugs have been found by independent assessors to offer no or minimal advantages over existing alternatives (Light et al., 2013). Thus, to assess the true impact of pharmaceutical marketing regulations, it is important to distinguish between clinically superior medications and minor variations.

With respect to efficacy, the FDA simply requires medications to be more efficacious than a placebo, even when effective drugs already exists. It does not mandate that companies compare the effectiveness of a newly introduced drug to existing alternatives in what are known as head-to-head drug trials. Since head-to-head