Pennsylvania H.B. 2643 Could Prohibit Pharmaceutical/Medical Device Marketing Research with Doctors

The Pennsylvania Pharmaceutical Manufacturing Prohibited Gifts Act (H.B. 2643) would prohibit drug and medical device manufacturers, “or any agent thereof” from offering or giving “any gift to a health care provider.” Moreover, "[e]xcept for allowable expenditures, no manufacturer or other entity on behalf of a manufacturer” would be allowed to “provide any fee, payment, subsidy or other economic benefit to a health care provider in connection with the provider's participation in research."

Absent amendment, H.B. 2643 would potentially prohibit respondent incentives for health care providers participating in pharmaceutical and medical device marketing research studies because such incentives are not enumerated under the definition of “allowable expenditures.” This would be the case even though such incentives are usually offered by independent marketing research companies and the sponsoring manufacturers are not typically aware of which providers participated.

As a result, health care providers in Pennsylvania may not be properly represented in marketing research, leading to an inaccurate view of their and their patients’ needs, which will hinder the development and delivery of medicines, devices and services to address unmet patient needs across the state.

The Insights Association has proposed amendments to Pennsylvania H.B. 2643 to exempt respondent incentives to health care providers for participating in pharmaceutical and medical device marketing research studies, as long as the studies are conducted by third party research companies and the sponsors are not aware of which providers participated.

Similar amendments have been adopted in laws/regulation in Massachusetts (2009), Minnesota (2010), the District of Columbia (2011), New Jersey (2019) and the federal Physician Payments Sunshine Act (2010).

Why the amendment would help

Most research studies are “blinded” to protect the research from bias. The respondents, and often the interviewers, are not told who sponsored the study. Sponsors normally do not know about or choose specific respondents and are not given access to respondents’ personally identifiable information. Most importantly, research industry codes, including the Insights Association Code of Standards and Ethics, forbid researchers and their clients from marketing to research study respondents.

However, the drug and device industry and its regulators often fail to recognize such distinctions between marketing and marketing research, at least when it comes to compliance.

We understand and appreciate the concerns about pharmaceutical and medical device manufacturers pursuing influence with health care providers through gifts, especially in the context of the opioid crisis, but the only influence sought through respondent incentives is to encourage a difficult to reach but highly important community to participate in research.

Marketing research participation by health care providers is routinely tied to respondent incentives because of the high demands on and value of their time. Respondent incentives are clearly neither gifts designed to accrue influence, nor are they lavish. Rather, the payments are modest amounts (usually ranging from less than one hundred dollars to a few hundred per study) paid to compensate the providers for their time. Moreover, these incentive payments are not determined on an ad hoc or willy-nilly basis, but are instead subject to rigorous fair market value analyses performed by both manufacturers’ marketing research staff and their outside research company partners.

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A study of doctors found 9-in-10 GP (92%) and specialist (93%) physicians indicated that incentives play at least some part in motivating them to participate in market research. *Less than 1-in-10 general practice (6%) and specialty (5%) physicians signified that they would participate in marketing research absent an incentive.*

Marketing research provides benefits beyond just the insights delivered to clients

- **Controlling health care costs**: Studies with doctors are an integral part of controlling costs. More and better marketing research results in cost savings as it can unveil potential flaws in drugs and treatment regimens before they pose a real risk to patients. Marketing research also helps focus limited resources on effective and necessary product and service development, technical support and education.
- **Preventing medical errors**: Marketing research helps measure comprehension of materials and differentiation of names among prescribers for drugs, which can help prevent "medical errors."
- **Ensuring patients get needed treatments**: Marketing research studies with prescribers about their patients' compliance with treatment regimens help determine what causes patients to avoid or cease treatment and how to encourage compliance – which in turn promotes health and longer life, as well as reduced waste of medical resources.
- **Improving acceptance and adoption of needed drugs**: Marketing research studies of how prescribers will accept and adopt new drugs are crucial to the development of new lifesaving products. If a medication has poor odds of acceptance or adoption, the manufacturer may not invest in producing it, but may learn from the research how to counteract those deficiencies with an improved product.
- **Role-playing research yields results**: Marketing research studies involving doctor-patient role playing can garner unexpected findings vital to more than just the studies' sponsors. For example, studies have discovered that physicians often don't describe all available options to patients, even though they claim to do so in conventional research surveys.
- **Simulations are safer**: The best way that medical device manufacturers can evaluate if healthcare providers are using their equipment correctly is a simulation – a form of marketing research. It allows a full test of equipment without endangering a patient
- **Eliminating side effects for patients**: In one case example, marketing research with doctors directly led to the reformulation of a drug to deal with its side effects. The drug fights blindness, but resulted in burning red eyes for some users. Marketing research revealed that these side effects, which were not being perfectly reported, were keeping many patients from taking the drugs (on the required schedule, or sometimes at all). Reformulation removed the side effects, saved the drug, and saved many people's sight.
- **Improving public health in the Latino community**: Focus groups and in-depth interviews (IDIs) conducted with doctors on issues related to Type 2 diabetes in the Latino community helped manufacturers of diabetes medications and devices better tailor their communications and educational materials to make them understandable, clear, and free from dangerous mis-interpretations.[1]

Bill status

Rep. Mike Zabel (D-163) introduced H.B. 2643, cosponsored by Reps. Carol Hill-Evans (D-95), Joe Webster (D-150), Robert D. Freeman (D-136), Kristine Howard (D-167), Rosita Youngblood (D-198), Wendy Ullman (D-143), Tina Davis (D-141), Thomas Murt (R-152), Liz Hanbidge (D-61), Christopher Rabb (D-200), Elizabeth Fiedler (D-184), Greg Vitali (D-166), Joanna McClinton (D-191), Anthony DeLuca (D-32), Ed Neilson (D-174), and Maria Donatucci (D-185). It awaits action in the House Health Committee.

[1] "Public Health Benefits of Marketing Research with Doctors: A case study from California." By Carlos Garcia. June 22, 2017. http://www.insightsassociation.org/article/public-health-benefits-marketing-research-doctors-case-study-california