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FROM

Howard Fienberg, PPC, PLC -- Director of Government Affairs for the Insights Association

TO

Office of the New Jersey Attorney General, Consumer Affairs Division

ABOUT

"Limitations on and Obligations Associated with Acceptance of Compensation from Pharmaceutical Manufacturers by Prescribers" (N.J.A.C. 13:45J)

Thank you for allowing me to testify today at this important hearing on behalf of the Insights Association,[1] the leading nonprofit trade association for the marketing research and analytics industry, and our more than 210 members in New Jersey.

I am here today to urge you to exempt from these regulations any incentive payments to prescribers participating in marketing research. There is ample precedent for such an exemption at the state and federal level.

Without an exemption, these regulations, restricting a variety of gifts and payments from pharmaceutical manufacturers to any medical professionals licensed to prescribe drugs in New Jersey, will raise costs and hurt respondent cooperation in pharmaceutical marketing research.

While incentives to prescribers for participation in pharmaceutical marketing research might still be allowed by the proposed rules,[2] the payments would presumably be counted towards the annual cap on each prescriber's annual consulting earnings,[3] and research relationships with prescribers would be

[1] The Insights Association's membership includes both marketing research and analytics companies and organizations, as well as the researchers and research departments inside of non-research companies and organizations. The Insights Association helps empower intelligent business decisions as a voice, resource, and network for the companies and individuals engaged in this important work. http://www.insightsassociation.org

[2] "Compensation, based on fair market value, for participation on advisory bodies or under consulting arrangements," as long as it is consistent with the cap on earnings, would fall under "permitted gifts and payments" in the proposed regulations. http://www.njconsumeraffairs.gov/Proposals/Pages/DCA-10022017-proposal.aspx

[3] According to the proposed regulations, "A prescriber shall not accept more than $ 10,000 in the aggregate from all pharmaceutical manufacturers in any calendar year for the bona fide services of presentations as speakers at promotional activities, participation on advisory boards, and consulting arrangements."

INSIGHTS ASSOCIATION
1156 15TH ST, NW, SUITE 302, WASHINGTON, DC 20005 • PH: (202) 570-7312
WEBSITE: www.InsightsAssociation.org • EMAIL: howard.fienberg@insightsassociation.org

subject to a lot more legal paperwork. The ban on "modest meals"[4] would also presumably mean that providing food as part of an hours-long in-depth interview or focus group with prescribers would be verboten, since marketing research participation would not qualify for either exemption from the ban.

All this would be the case, even though such incentives are, for all practical purposes, always offered by independent marketing research companies and the sponsoring manufacturers are typically not aware of which practitioners participated.

What is marketing research?

Marketing research is not marketing – it is the systematic, objective investigation and analysis of people's opinions, attitudes and behavior.[5]

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 those applying to Insights Association members) forbid researchers and their clients from marketing to research study respondents.[6]

Incentives for marketing research participation

The Insights Association understands and appreciates New Jersey's concerns about pharmaceutical manufacturers pursuing influence with prescribers, but respondent incentives solely encourage participation in research by a highly important and difficult to reach community.

What have other authorities done with respect to health care research and the payment of incentives to participating prescribers? Except for two states (Vermont and Maine), all permit such research and have little to no restrictions on marketing research incentive payments to these prescribers.

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[4] The proposed regulations would prohibit "modest meals," unless they are "provided through the event organizer at a continuing education event, provided the meals facilitate the educational program to maximize prescriber learning," or "through promotional activities no more than four times in a calendar year from the same manufacturer." "Modest meals" means "a food and/or refreshment, where its fair market value does not exceed $15.00 for each prescriber."

[5] Marketing researchers perform critical research to deliver insights to their clients; in the process, they sell nothing to research participants. Marketers, on the other hand, advertise and sell properties, goods or services directly to participants. These two functions are distinct and separate.

[6] Until the Insights Association publishes a new code of ethics, expected in late 2017, the legacy MRA code applies to individual members and the legacy CASRO code applies to company members. The MRA code, available at http://www.insightsassociation.org/sites/default/files/misc_files/mra_code.pdf , states specifically: "Conducting commercial or political activities under the guise of opinion and marketing research undermines public trust in the profession and erodes the goodwill that makes research possible. Our industry works hard to guard its reputation. These non-research activities include, but are not limited to . . . [s]ales or promotional approaches to the respondent." The CASRO code, available at http://www.insightsassociation.org/sites/default/files/misc_files/casro_code_of_standards.pdf , provides that "[d]eceptive practices and misrepresentation, such as using research as a guise for sales or solicitation purposes, are expressly prohibited."

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And, absent a clear exclusion for bona fide marketing research (as has been granted before in the District of Columbia,[7] Massachusetts,[8] Minnesota,[9] in the federal Physician Payments Sunshine Act,[10] and most recently in California S.B. 790[11]), these regulations could severely limit marketing research

[7] In 2007, Title III of the AccessRx Act (Chapter 18, Title 22) required payment reporting. In 2011, the DC Board of Pharmacy approved a marketing research exclusion, if: "(i) the market research is conducted by an independent survey research organization; (ii) the pharmaceutical client does not know the identity of the practitioners who participate in the research; and (iii) the payments are determined and made directly by the survey research organization."

[8] In 2009, the Massachusetts Department of Public Health excluded respondent incentives from their state's reporting requirements. From the FAQs: "If a PMDMC [Pharmaceutical or Medical Device Manufacturing Company] hires a market research company to conduct a double-blind study of health care practitioners, where the health care practitioners are paid an honorarium by the market research company, but the PMDMC does not know which health care practitioners participated in the study and the health care practitioners who participated does not know what pharmaceutical or medical device manufacturing company was involved, is the information subject to disclosure? Answer: No. The regulations seek to create transparency around payments to health care practitioners by PMDMCs that may influence prescriber behavior. Where the health care practitioner participates in a market research study, but is not paid by the PMDMC and is not aware of the PMDMC involved, the payment need not be reported." See http://www.mass.gov/eohhs/docs/dph/quality/healthcare/pharm-medical-device-conduct-faq.pdf at p. 14.

[9] In 2010, the Minnesota Board of Pharmacy rescinded their long-standing ban on marketing research incentives, having determined that marketing research constituted a "genuine research project." From the FAQs: "Q. Under Minnesota law, is it appropriate to make cash payments to practitioners for participation in so-called "surveys" that are intended by pharmaceutical manufacturers to promote, market or sell a drug directly to those practitioners? A. No. Such practices would be considered commercial marketing activities, rather than bona fide market research (i.e. a "genuine research project") conducted by independent survey research organizations. Participation in marketing activities is not a "substantial service," nor does it involve a "genuine research project" as intended by the legislature. Therefore, cash payments to practitioners who participate in marketing activities are prohibited under the no gifts to practitioners statute." See https://mn.gov/boards/assets/FAQ%20Payments%20to%20Practitioners_tcm21-29333.pdf at p. 1.

[10] In 2010, the federal Physician Payments Sunshine Act (part of the Affordable Care Act) excluded incentives from reporting requirements, and the exclusion was drafted specifically to pertain to blinded market research. Sec. 6002 of the Patient Protection and Affordable Care Act: "The term `payment or other transfer of value' means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient." See https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf at p. 695.

[11] In 2017, California S.B. 790 was amended to exempt respondent incentives to doctors for participating in pharmaceutical marketing research studies from the bill's proposed ban on payments, as long as the studies are conducted by a third party research company and the sponsoring manufacturers are not aware of which providers participated: From 150300 (a)(7): "A payment to a health care provider for participation in bona fide marketing research conducted by a third party, only if the payments are made by that third party and the sponsoring manufacturer is not informed of the identity of the participating health care provider." And 150300 (c): "Bona fide marketing research" means the collection and analysis of data regarding opinions, needs, awareness, knowledge, views, experiences, and behaviors of a population, through the development and administration of surveys, interviews, focus groups, polls, observation, or other research methodologies, in which no sales, promotional, or marketing efforts are involved and through which there is no attempt to influence a participant's attitudes or behavior." http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180SB790

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studies of New Jersey's prescribers, whose participation is routinely tied to respondent incentives because of the high demands on and value of their time.

Such 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 no more than a few hundred per study) paid to compensate the practitioners 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 pharmaceutical manufacturers' marketing research staff and their outside research company partners.

A 2009 study of doctors found 9-in-10 physicians (92% of general practitioners and 93% of specialists) indicated that incentives play at least some part in motivating them to participate in marketing research. Less than 1-in-10 physicians (6% of general practitioners and 5% of specialists) said that they would participate in marketing research absent an incentive.[12]

Restricting research studies

Even in the best scenario, where pharmaceutical compliance departments would assume that marketing research studies with prescribers would count as consulting arrangements providing "bona fide services"[13]:

- Research engagements would require more time-consuming paperwork, attestations, and legalistic formal contracts than may be typical right now, especially for low-dollar compensation arrangements, which will raise the cost of the research and make prescribers less likely to participate;
- Since the total incentive payments would count against an individual prescriber's total allowed compensation for the year, prescribers would be less likely to participate in research studies, and manufacturers less likely to want to sponsor research studies;
- Research companies would face yet another hurdle to respondent cooperation, since they wouldn't be able to know which respondents had received how much in total compensation for the year, and thus who would still be available for research participation; and
- Prescribers also might be deterred from participating because of the sensitivity in having to publicly disclose having received payments from the sponsor when they speak at an event, no matter how nominal, even though they did not learn the sponsor's identity until later.[14]

[12] http://www.insightsassociation.org/article/respondent-cooperation-how-big-impact-will-government-legislation-have-physician-surveys-us

[13] According to the proposed regulations, "bona fide services" means "those services provided by a prescriber pursuant to an arrangement formalized in a written agreement including, but not limited to, presentations as speakers at promotional activities and continuing educational events, participation on advisory boards, and consulting arrangements." Most pharmaceutical marketing research participation would presumably fall under this definition as "consulting arrangements."

[14] The rules would require a "prescriber serving as a speaker at a continuing education event or for a promotional activity" to "directly disclose to attendees either orally or in writing at the beginning of the presentation that the prescriber has accepted payment for bona fide services from the sponsoring pharmaceutical manufacturer within the preceding five years."

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Shaming research participants

That last point is key, since researchers would have to inform participating prescribers about who sponsored the research studies in which they participate, at least at the end, so that the prescribers could keep track of their payments, *even though most studies specifically avoid such disclosure to avoid biasing the resulting insights*. With so much research being double-blind, for compliance purposes and to minimize bias, New Jersey's proposed regulations will make the research process more complicated and possibly make marketing research incentive payments to prescribers *more* likely to influence their prescribing behavior, not less.

Marketing research benefits patients and the public

Marketing research provides benefits far beyond just the insights delivered to clients. For example:

- **Controlling health care 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" (adverse events).
- **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.
- **Getting results from role-playing research**: 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 prescribers often don't describe all available options to patients, even though they claim to do so in conventional research surveys.
- **Eliminating side effects for patients**: The reporting of adverse events in pharmaceutical marketing research is an every-day reality. Nearly every pharmaceutical company provides adverse event training to marketing researchers to ensure prompt reporting of adverse drug reactions when they are disclosed by patients and prescribers.
- **Preventing blindness**: In one case example of adverse event reporting, marketing research with prescribers 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 well-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.

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- **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 misinterpretations.[15]

Solution: Exempt bona fide marketing research

Therefore, these regulations should exempt prescriber compensation for participation in "bona fide marketing research" conducted by a third party, where such payments are made by that third party. This would affirmatively exclude payments for marketing research conducted by independent marketing researchers.

"Bona fide marketing research" means "the collection and analysis of data regarding opinions, needs, awareness, knowledge, views, experiences and behaviors of a population, through the development and administration of surveys, interviews, focus groups, polls, observation, or other research methodologies, in which no sales, promotional or marketing efforts are involved and through which there is no attempt to influence a participant's attitudes or behavior."[16]

Conclusion

Marketing research delivers insights to drive good decisions that fuel New Jersey's economic welfare and public health.

On behalf of the Insights Association, the marketing research and analytics industry, and the public, I urge you to adopt these recommendations or work with us on other potential solutions. If you do not, prescribers in New Jersey may not be properly represented in research, leading to an inaccurate view of their and their patients' needs, which will hinder the development and delivery of medicines and services to address unmet patient needs.

Thank you again for your time and attention. We look forward to working with you.

[15] "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

[16] This definition has been used at the federal level in the Research Fairness Act (H.R. 5915, proposed in 2012), available at https://www.congress.gov/bill/112th-congress/house-bill/5915 , in amendments passed to a New Hampshire statute in 2014 on push polling (Title LXIII, Section 664:2 (XVII and XVIII)), available at http://www.gencourt.state.nh.us/rsa/html/LXIII/664/664-2.htm , and in California 2017 pharma bill S.B. 790, available at http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180SB790 .

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