FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH AS USED BY THE FOOD AND DRUG ADMINISTRATION" (0910-0847)

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TITLE OF INFORMATION COLLECTION: Health Care Providers' Understanding of Opioid Analgesic Abuse-Deterrent Formulations: Focus Groups

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of Need:

Every day in the United States, more than 3,900 people initiate the nonmedical use of a prescription opioid, putting them at risk of developing a physical dependence on their medications, which can lead to misuse, abuse, and addiction (SAMHSA, 2017; Turk et al., 2014). Furthermore, evidence suggests prescription opioid-involved deaths have been "alarmingly high" in the United States in recent years (Seth et al., 2018, p. 501). Recognizing their potential to help combat the opioid epidemic, the Food and Drug Administration's (FDA's) (2017) Opioids Action Plan calls for expanding access to abuse-deterrent formulations, or ADFs, which are opioid analgesics with properties that are expected to meaningfully deter certain types of abuse or make abuse more difficult or less rewarding by blocking common forms of recreational and nonmedical consumption, such as chewing, inhaling, and injecting an opioid analgesic for its euphoric effect. Although ADF prescribing presents opportunities for healthcare providers (HCPs) to prevent opioid abuse and addiction, little is known about their attitudes, perceptions, and behaviors related to these medications, and evidence suggests considerable variability in their knowledge about them (e.g., Hwang et al., 2016).

Given the magnitude and scope of the opioid crisis, and FDA and Congressional concerns about HCPs' understanding and perceptions of ADF products and terminology, FDA Commissioner Dr. Scott Gottlieb requested research be undertaken that would provide comprehensive evidence to inform the FDA's ADF policy, regulatory, and communication decisions, including alternative language to describe and explain ADF products. This work aligns with Priority 1 of the FDA Commissioner's Strategic Policy Roadmap (2018), and the Department of Health and Human Services and the White House have both placed a high priority on addressing the epidemic of misuse and abuse of opioid drugs harming U.S. families.

As a result, the purpose of the first phase of this project and which is the subject of this information collection is to conduct focus groups with HCPs to explore their knowledge, attitudes, perceptions, and behaviors related to ADF opioid analgesics. This will include their perceptions of the terminology and information used to describe these drugs and to solicit input on other language that may better describe ADF products that hold potential for decreasing the nation's serious opioid epidemic.

This focus group study is the first exploratory phase of a three-phase comprehensive, systematic, mixed-method study FDA is undertaking to achieve the goals outlined in the Strategic Policy Roadmap and Opioid Action Plan and which will provide the foundation for the subsequent phases. The first of these two phases will allow FDA to determine the prevalence of various opinions and beliefs about ADFs among different types of HCPs through a survey, and the third and final phase will allow FDA to optimize the information it provides to HCPs about opioid

ADFs, potentially through drug labeling, by using experimental manipulation of terminology and content, and comparing responses from participants. FDA has contracted and is working with RTI International to carry out this study.

2. Intended Use of Information:

The Phase 1 focus groups are intended to be exploratory, offering HCPs the opportunity to provide diverse and in-depth input and reactions in their own language, which will help FDA identify trends and consistencies in participants' knowledge and decision-making processes, and help ensure that we have elicited an appropriate range of beliefs and perceptions about opioid ADFs, prescribing behavior and terminology. The findings from this qualitative phase will be used to inform the phases that follow. Specifically, learnings from the focus groups will be used to develop the Phase 2 survey questionnaire, ensuring that it includes questions that can appropriately measure the prevalence of HCP knowledge of, experience with, behaviors, perceptions, and opinions on ADF opioid analgesics and abuse deterrence that we learned about through the focus groups. Phases 1 and 2 will be used to inform Phase 3, which employs a randomized experiment to test wording and content. This first phase of the overall project is only to gain broad understanding related to the ADF issues of FDA interest, and as such, the findings will not be used for the purposes of making policy or regulatory decisions.

3. Description of Respondents:

We will conduct 16, 90-minute focus groups with HCPs who prescribe opioids (n=14) and pharmacists who dispense opioids (n=2). For each of the focus groups, we will recruit 12 participants to achieve a desired turnout of nine participants (N=144). The focus groups will be segmented by provider type and field of practice as shown in **Exhibit 1**. Each specialty focus group will consist of a mix of three different specialties (e.g., rheumatologists, surgeons, orthopedists, etc.). For each group, we will ensure a reasonable degree of geographic and demographic diversity, including years of practice, race/ethnicity, and age.

Exhibit 1. Focus Group Segmentation

Provider Segment	Number of Focus Groups		
	Primary Care Practice	Specialty Practice	Total Focus Groups
Physicians	3	3	6
Physician assistants	2	2	4
Nurse practitioners	2	2	4
Pharmacists	N/A	N/A	2
Total	**7**	**7**	**16**

RTI will work with a professional market research firm(s) to recruit focus group participants. The firm(s) will use a structured screener developed by FDA and RTI to identify HCPs who meet the eligibility criteria (See **Attachment A: Focus Group Screening Questionnaire**). Physicians, physician assistants, and nurse practitioners will be eligible if they spend at least 50% of their time per month providing direct patient care and have prescribed opioid analgesics for non-cancer pain in the past 30 days. Pharmacists will be eligible if they have dispensed opioid analgesics in the past 30 days. Individuals who have ever worked for the Department of

Health and Human Services, a pharmaceutical company, a market research firm, or RTI will be ineligible.

4. Date(s) To Be Conducted and Location(s):

Pending all approvals, we plan to conduct the focus groups over a 6-week period starting as soon as possible. In order for the project to progress on the timeframe required by the contract, focus group recruitment would need to occur by April 1, 2019. Focus groups will be held online or, if necessary due to recruitment challenges, in person at market research facilities. RTI will work with FDA to attempt to achieve geographic diversity among participants.

5. How the Information Is Being Collected:

We plan to convene all focus groups online using a video-based platform; however, if we experience recruitment challenges (e.g., high cancellation and/or no-show rates), we may also conduct some focus groups in-person. This strategy will enable us to maximize our response rate and engage a diverse and hard-to-reach population. All the focus groups will be audio and video recorded, and time-stamped verbatim transcripts of each discussion linked to the video recordings will be developed.

The online focus groups will be convened using a video platform that has audio-video recording and streaming capability. Individuals must have access to a computer and webcam to participate. We anticipate that this will not be a barrier for most HCPs as they routinely use computers in their practices. The recruitment firm(s) will email scheduled participants instructions for joining the online focus group prior to the session (see **Attachment D: Follow-up Contact Scripts**, *Script 1*). RTI will work with an online focus group vendor that can ensure that participants have tested the technology, and they will offer technical support during the focus groups in case any issues arise. Additionally, the recruitment firm will monitor the online participant roster to ensure all scheduled participants have joined the session. They will call individuals who have not joined the session to remind them of the focus group and encourage their participation (see **Attachment D: Follow-up Contact Scripts**, *Script 2*). The RTI moderator will also be on a webcam and will be able to be seen by all participants, who will also be able to see each other. Participants will be told both in the informed consent and reminded by the moderator that FDA and RTI observers will be able to observe in real-time, but they will not be able to interact directly with participants. A "chat" feature on the platform will allow observers to send the moderator clarifying questions to be asked at the end of the group.

If in-person focus groups are conducted, they will be convened at professional research facilities. As with the online groups, FDA and RTI team members will be able to observe the in-person focus groups remotely in real time through a secure, password-protected online streaming system (e.g., BlueJeans) or possibly from behind a one-way mirror. Observers will be able to use a chat feature to send the moderator questions to be asked at the end of the group. The focus groups will be audio and video recorded, and time-stamped verbatim transcripts of each discussion linked to the video recording will be developed.

HCPs will be told they must provide consent prior to participation (See **Attachment B: Focus Group Consent Form**). For online groups, HCPs will have a choice of completing an online or hard copy consent form. For the latter, the recruitment firm(s) will email or mail the consent form to scheduled participants (see **Attachment D: Follow-up Contact Scripts**, *Script 3*).

Scheduled participants will be notified at the time of recruitment and in the follow-up correspondence that the signed consent form agreeing to participate must be returned to the recruitment firm(s) prior to participation. When the recruitment firm calls to remind individuals of their upcoming focus group session, they will ask those who have not yet returned the signed consent form to do so prior to the focus group session (see **Attachment D: Follow-up Contact Scripts**, *Script 4*). At this time, they will remind individuals they cannot participate in the focus group if they do not return the form to the recruitment firm prior to the session. If the recruitment firm has not received the consent form within two days of the reminder call, they will call the individual again to request that they return the signed consent form (see **Attachment D: Follow-up Contact Scripts**, *Script 5*). For in-person groups, participants will receive and sign the consent forms at the facilities prior to participation.

The consent form describes the purpose of the study, how the information will be collected, benefits and risks to participation, plans for observation (in real-time and through audio and video recordings), the right to refuse or withdraw and the voluntary nature of participation, and the amount of the honorarium. Contact information for the RTI Project Director and the RTI Office of Research Protection are also provided. Finally, the form describes the procedures in place to protect confidentiality: Nondisclosure of personally identifiable information (PII), the inability to link individual responses to PII, reporting in aggregate such that individuals cannot be identified by name, storage of study documents and information, and eventual destruction of study files, including audio and video recordings (see *Section 6* for additional details on confidentiality procedures).

All focus groups will be conducted by an RTI moderator, and an additional RTI team member will provide notetaking and logistical assistance. The moderator will use a semi-structured guide developed by FDA and RTI to facilitate the discussions and ensure that all major topics of interest are addressed (See **Attachment C: Focus Group Moderator Guide**). The moderator will start each group by introducing herself, explaining the ground rules, and reviewing key points from the informed consent. For the focus groups with specialists, the moderator will ask participants to identify their specialty on the placard provided to them. After addressing these items, the moderator will move on to the discussion questions.

After each focus group is completed and the participants are released and gone, the moderator will review and add to the focus groups notes as needed. The note taker and moderator will discuss any issues that arise related to logistics, the discussion guide, and/or participant interactions. RTI and FDA will discuss what is learned during these informal debriefs; RTI will not make any process changes unless they are requested by FDA.

6. Confidentiality of Respondents:

We will implement several procedures to protect participants' confidentiality, including the following:

1. In addition to recording answers to screening questions, the research firm(s) will collect names, email addresses, and telephone numbers for eligible individuals who are willing and available to participate in a focus group. The firm(s) will use this contact information to send individuals the consent form, instructions for joining the online focus group, and remind them of their upcoming appointments and to return their signed consent form if they have not already done so (see **Attachment D: Follow-up Contact Scripts,** *1-5*).

This PII will be recorded separately from the screener and stored in a locked file cabinet or on a password-protected computer only at the research firm(s) and will be destroyed after all the focus groups have been conducted. Only the research firm(s) will have access to participant names and contact information; FDA and RTI will have access only to de-identified screening data.

2. As noted previously, the informed consent form covers aspects related to confidentiality. At the beginning of each focus group, the moderator will remind participants of this information and tell them to use only their first names or nicknames in the group. If a participant discloses their last name or other PII, this information will be redacted from the focus groups transcripts and audio and video recordings before they are provided to RTI and FDA.
3. Only staff authorized by the FDA project officer and RTI project director will be provided with instructions for observing the focus groups by video or telephone. For in-person groups, the recruitment firm(s) have procedures in place to prevent unauthorized access to their facilities. Additionally, to help prevent unauthorized people from overhearing the discussion, those in online focus groups will be reminded to make sure they participate where others cannot overhear the conversation. And for the in-person focus groups, RTI will post a do-not-enter sign outside of the room/area in which the group is taking place.
4. There will be no link between the data collected and the participants' identities. FDA and RTI will not have the full names or any contact information for any of the participants.
5. All screener and focus group data will be analyzed and reported in aggregate.
6. At both FDA and RTI, access to project data and materials will be limited to only research staff working on the project who have been granted access by the FDA project officer or RTI project director.
7. All study files, including video and audio recordings, will be stored on password-protected computers at both FDA and RTI and destroyed within 5 years of the study's end date.

7. Amount and Justification for Any Proposed Incentive

Recognizing the significant time and other burdens involved with participation in research and to convey the importance of the research to participants, honorariums are intended to help defray these "costs" in order to encourage individuals to participate (Klabunde et al., 2012). Numerous empirical studies have established that an honorarium can significantly increase participation rates (Abreu & Winters, 1999; Aikin et al., 2016; Dykema et al., 2011; Greenbaum, 2000; Martins et al., 2012; Medway & Tourangeau, 2015; Mercer et al., 2015; Shettle & Mooney, 1999; Thorpe et al., 2008; VanGeest et al., 2007). This is particularly true for HCPs who are more difficult to recruit as study participants than members of the general population (Asch, Connor, Hamilton, & Fox, 2000; Cummings et al., 2001).

There are many reasons why HCPs are difficult to engage in research, most of which are related to their professional demands and time constraints (Asch, Connor, Hamilton, & Fox, 2000). For example, many HCPs work irregular hours and must respond to clinical emergencies, making them less available to participate in research that must be scheduled in advance (Asch, Connor, Hamilton, & Fox, 2000). Relatedly, focus groups must be scheduled to accommodate the needs of a diverse group of eight to 10 participants. Although researchers try to accommodate HCPs' demanding schedules (e.g., offer multiple timeslots, conduct groups early or late in the day, etc.), it is challenging to find times that do not interfere with their patient care and other required

activities (Bakken, Lantigua, Busacca, & Bigger, 2009). The amount of time required for data collection is another factor that limits HCPs' participation in research. High patient-volume, back-to-back scheduling, and the need to respond to patient emergencies leaves little time in the day to participate in nonessential activities (Capko, 2015). For example, a 2015 study found that burden was the primary reason for nonresponse in a study involving a web-based survey, with 60% of physicians saying they had insufficient time to complete the survey requests (Cunningham et al., 2015). Building on these earlier findings, a recent survey conducted by The Physicians Foundation (2018) found that physicians saw an average of 20 patients per day, and about 80% said they were overworked/overextended or at capacity. These time constraints are particularly salient for qualitative data collections like focus groups because they tend to be more time consuming than surveys and may require travel to an offsite location (typically 60-90 minutes).

Studies with HCPs have shown that participation rates vary by specialty, gender, and other factors (Cunningham et al., 2015; Martins et al., 2012). For example, a recent found that general surgeons (29.6%), pediatricians (29.2%), and psychiatrists (27.1%) were less likely to participate in a web-based survey than neurologists or neurosurgeons (46.6%) and internists (42.9%) (Cunningham et al., 2015). Furthermore, Juster and Suzman (1995) found that high incentives reduced nonresponse bias for people with high incomes. These findings are particularly relevant for our study because we intend to recruit physicians from a variety of specialties, including general surgeons and psychiatrists as well as others that are even less common, such as pain management specialists and rheumatologists.

For this study, we will provide all focus groups participants with a $300 honorarium which OMB approved for the previous FDA research project titled Testing Communications on Biological Products [REMOVE: *Focus Group Study of Healthcare Provider Knowledge of Biosimilar Biological Products]* approved in 2014 under generic clearance 0910-0687. Only if specialists decline to participate based on their stated reason that the $300 incentive is too low, we will reserve the option to offer them an additional $100 in an attempt to convert these refusals to willingness to participate ($400 maximum). This option will enable FDA to address costs that have risen over the past 5 years and better ensure recruitment of the very specialized and difficult-to-recruit populations necessary for this high-profile project of Dr. Gottlieb's. A similar tiered strategy was approved by OMB in 2017 for the Centers for Disease Control and Prevention's *Formative Research to Develop HIV Social Marketing Campaigns for Healthcare Providers* (OMB No. 0920-1182). As noted above, if we are not successful in recruiting enough participants for online groups, we will arrange in-person groups and those who attend these groups would be provided an additional $75 to cover travel-related costs (e. g., travel time, mileage, and parking).

Several studies have explored strategies to improve recruitment of HCPs, and some have examined participation rates by incentive amount and/or type (Asch et al., 1998; Deehan et al., 1997; Pit, et al., 2015; Thomson et al., 2004; Young et al., 2011). This research shows that monetary incentives resulted in higher survey response rates compared to nonmonetary incentives and that the value (or perceived value) of the incentive matters, with higher incentives yielding greater participation than lower incentives (Pit et al., 2015; Young et al., 2011). Although the incentives in this literature were lower than those proposed here, they involved significantly shorter survey participation and often from many years ago however, provision of high-value honorariums is supported by leading qualitative researchers who suggest that focus groups with physicians may require amounts up to or exceeding $500 (Krueger and Casey,

2015). In addition, past experience on other projects our contractor RTI has conducted, and their recent consultation with two national research firms (Schlesinger Group and L&E Research), show that the amounts offered are consistent with what specialized HCPs such as those we are targeting for this project require to take time out of their already time-constrained clinical practices to participate in these types of research projects. For example, in line with the $300 incentives for the 90-minute focus group participation in the FDA biological products study mentioned above, RTI also paid specialists incentives of $250 for participating in interviews that were substantially shorter (60 minutes) as part of the same project (OMB No. 0910-0687 approved in 2015). Similarly, specialists received $250 incentives for participating in a one-hour focus group as part of FDA's *Generic Drug Substitution in Special Populations* study (OMB No. 0910-0677; 2017) and in 60-minute telephone interviews for *Studies to Enhance FDA Communications Addressing Opioids and Other Potentially Addictive Pain Medications* (OMB No. 0910-0695; 2016), an incentive rate that would have amounted to $375 for 90 minutes.

The decision to provide the proposed honorarium amounts is based on the principles set forth in OMB's guidance on factors that may justify provision of an incentive (Office of Management and Budget, 2006):

- *Data quality:* The findings from the Phase 1 focus groups will directly inform research activities in subsequent phases (i.e., the Phase 2 survey and Phase 3 experiment and stimuli). Therefore, the integrity of the entire study rests on the quality of the focus group data. One strategy we will implement to improve the quality and robustness of the data is to recruit HCPs with wide-ranging behaviors, specialties, and sociodemographic characteristics. Offering less than the proposed amounts, however, is likely to limit our ability to recruit the diversity of the desired subgroups and provide the breadth of the expertise, experience, and prescribing practices necessary for this project. Prior studies have shown variations in participation rates by medical specialty, age, and race/ethnicity. Furthermore, the difficulties engaging HCPs for research studies have been well-documented. Numerous studies have shown that honorariums can reduce sample bias which occurs when research participants do not represent the diversity of the intended audience (Griffin et al., 2011; Lesser et al., 2001; Singer & Kulka, 2002). A biased sample will compromise the usefulness and validity of the findings.
- *HCP participant burden.* Lack of time and competing demands are significant barriers to research participation among HCPs. Although we will aim to limit burden to the extent possible, the study design requires participation in a 90-minute prescheduled focus group session (and for individuals who attend in-person focus groups, time and travel to an offsite location). Participants may need to find coverage for their patients to attend the session and/or work longer days to complete paperwork or follow up with patients. Burden concerns are a common deterrent to participation, particularly among high-volume HCPs or high-demand and/or uncommon specialists, which would lead to sample bias and affect data quality (see above). The honorarium will help offset or reduce concerns about time and other burdens, such as disruptions to patient flow, inconvenience, financial loss, and the need to limit or reschedule patient appointments.
- *Past experience:* As described previously, the study team has conducted numerous qualitative studies with HCPs, and our experience confirms that they are a very challenging population to recruit. The requested amount is consistent with the amounts provided for the prior FDA-RTI studies that involved qualitative research methods with similar populations (see above).

- *Improved coverage of specialized respondents or rare groups*: The HCP participants in this study are considered specialized because they have specific knowledge and experience related to the topic area. Although the number of professionally active primary care and specialty physicians in the United States are similar, the latter are distributed across multiple specialty types, increasing specialists' rarity (Kaiser Family Foundation, 2018). In 2018, for example, the proportion of specialists representing each area ranged from 2% (endocrinologists) to 11% (psychiatrists and emergency medicine specialists) (Kaiser Family Foundation, 2018). These data demonstrate that the pool of potentially-eligible HCPs is limited, and our eligibility criteria impose further eligibility restrictions. Rarity coupled with barriers related to time and other burdens make specialists particularly hard-to-recruit.

8. Questions of a Sensitive Nature

We do not anticipate asking any sensitive questions during screening or the focus groups. Nevertheless, participants will be told that they may skip any screener or focus group question that they do not want to answer or stop participating at any time.

9. Description of Statistical Methods

After completing the interviews, RTI will analyze the data using NVivo, a qualitative data analysis computer software package produced by QSR International. NVivo is ideal for managing large amounts of data and allows analysts to link external information, such as participant characteristics obtained through screeners, to qualitative data. We will begin by obtaining verbatim transcripts of the sessions based on the audio and video recordings. We will then review each transcript, have two team members independently code participant responses, and organize responses by question topic and HCP segment (e.g., knowledge of ADF opioid analgesics among primary care physicians, physician specialists, or other HCP types). This step serves to reduce or summarize the data, while also facilitating the recognition of patterns within it (Gale, Heath, Cameron, Rashid, & Redwood, 2013).

At this point in the analysis, the research team will note regularities, patterns, and other explanations in the data (Miles & Huberman, 1994). This analytic approach will allow us to determine what knowledge, attitudes, perceptions, decision processes, language and terminology, etc. are consistent across HCPs and to identify whether any of these elements differ by medical specialty or other factors. The findings will be summarized in a report at the conclusion of the focus groups.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screening (HCPs)	240*	10	40
Focus Group (HCPs)	144	90	216
TOTAL			**256**

*Based on the incentive amounts cited in Section 7 above.

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References

Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section of the American Statistical Association*. 533-538.

Asch, D.A., Christakis, N.A., & Ubel, P.A. (1998). Conducting physician mail surveys on a limited budget: a randomized trial comparing bill versus $5 bill incentives. *Medical Care, 36*(1):95–99.

Asch S., Connor S.E., Hamilton E.G., & Fox S.A. (2000). Problems in recruiting community-based physicians for health services research. *Journal of General Internal Medicine, 15*(8):591-599.

Aikin, K., Betts, K., Boudewyns, V., Stine, A., & Southwell, B. G. (2016). Physician responsiveness to survey incentives and sponsorship in prescription drug advertising research. *Annals of Behavioral Medicine, 50*(Suppl.), s251.

Bakken S, Lantigua RA, Busacca LV, & Bigger JT. (2019). Barriers, enablers, and incentives for research participation: a report from the Ambulatory Care Research Network (ACRN). J *Journal of the American Board of Family Medicine, 22*(4):436–45.

Capko, J. *To improve practice work flow, tackle patient scheduling*. Retrieved from http://www.physicianspractice.com/scheduling/improve-practice-work-flow-tackle-patient-scheduling. Accessed January 17, 2019.

Cummings, S.M., Savitz, L.A., & Konrad, T.R. (2001). Reported response rates to mailed physician questionnaires. *Health Services Research, 35*(6), 1347-1355.

Cunningham, C.T., Quan, H., Hemmelgarn, B., Noseworthy, T., Beck, C.A., Dixon, E., … (2015). Exploring physician specialist response rates to web-based surveys. *BMC Medical Research Methodology, 15*(32). doi: 10.1186/s13104-014-0969-8.

Deehan, A., Templeton, L., Taylor, C., Drummond, C., & Strang, J. (1997). The effect of cash and other financial inducements on the response rate of general practitioners in a national postal study. *British Journal of General Practice, 47*(415):87–90.

Dykema, J., Stevenson, J., Day, B., Sellers, S., & Bonham, V. (2011). Effects of incentives and prenotification on response rates and costs in a national web survey of physicians. *Evaluation and the Health Professions, 34*(4): 434–447.

Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology, 13*(1), 117.

Greenbaum, T. L. (2000). *Moderating focus groups: A practical guide for group facilitation*. Thousand Oaks, CA: Sage Publications, Inc.

Griffin, J., Simon, A. B., Hulbert, E., Stevenson, J., Grill, J., Noorbaloochi, S., & Partin, M. (2011). A comparison of small monetary incentives to convert survey non-respondents: a randomized control trial. *BMC Medical Research Methodology, 11(*81). doi: 10.1186/1471-2288-11-81.

Hwang, C. S., Turner, L. W., Kruszewski, S. P., Kolodny, A., & Caleb, A. G. (2016). Primary care physicians' knowledge and attitudes regarding prescription opioid abuse and diversion. *The Clinical Journal of Pain, 32*(4), 279–284.

Juster, F. T. & Suzman, R. (1995). An overview of the health and retirement study. *Journal of Human Resources, 30*, S7-S56.

Kaiser Family Foundation. (2018a). *Professionally Active Specialist Physicians by Field.* Retrieved from https://www.kff.org/other/state-indicator/physicians-by-specialty-area/?dataView=1&currentTimeframe=0&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22All%20Other%20Specialties%22,%22sort%22:%22asc%22%7D

Klabunde, C. N., Willis, G. B., McLeod, C. C., Dillman, D. A., Johnson, T. P., Greene, S. M., & Brown, M. L. (2012). Improving the quality of surveys of physicians and medical groups: A research agenda. *Evaluation and the Health Professions, 35*(4), 477–506.

Krueger, R.A., & Casey, M.A. (2015). *Focus Groups: A practical guide for applied research*. Thousand Oaks, CA: Sage Publications, Inc.

Lesser, V.M., Dillman, D.A., Carlson, J., Lorenz, F., Mason, R., & Willits, F. (2001) *Quantifying the Influence of Incentives on Mail Survey Response Rates and Nonresponse Bias*. Paper presented at the annual meeting of the American Statistical Association, Atlanta, GA.

Martins, Y., Lederman, R.I., Lowenstein, C.L., Joffe, S., Neville, A., Hastings, B.T., & Abel, G.A. (2012). Increasing response rates from physicians in oncology research: a structured literature review and data from a recent physician survey. *British Journal of Cancer, 106*(6), 1021-1026.

Medway, R. L., & Tourangeau, R. (2015). Response quality in telephone surveys: Do prepaid cash incentives make a difference? *Public Opinion Quarterly, 79*(2), 524-543.

Mercer, A., Caporaso, A., Cantor, D., & Townsend, R. (2015). How much gets you how much? Monetary incentives and response rates in household surveys. *Public Opinion Quarterly*, *79*(1), 105-129.

Miles, M. B., & Huberman, A.M. (1994). *Qualitative data analysis*. Thousand Oaks, CA: Sage Publications.

Office of Management and Budget, Office of Information and Regulatory Affairs. (2006). *Questions and answers when designing surveys for information collection.* Retrieved from https://www.cio.noaa.gov/itmanagement/pdfs/OMBSurveyGuidance_0106.pdf

Physicians Foundation, The. (2018). *2018 survey of America's physicians—Practice patterns and perspectives.* Retrieved from https://physiciansfoundation.org/wp-content/uploads/2018/09/physicians-survey-results-final-2018.pdf

Pit, S.W., Vo, T., & Pyakurel, S. (2014). The effectiveness of recruitment strategies on general practitioner's survey response rates - a systematic review. *BMC Medical Research Methodology, 6*(14). doi: 10.1186/1471-2288-14-76

Singer, E. & Kulka, R. A. (2002). Paying Respondents for Survey Participation. In M. Ver Ploeg, R. A. Moffitt, & C. F. Citro (Eds.), *Studies of Welfare Populations: Data Collection and Research Issues*, Washington, D.C.: National Academy Press.

Seth, P., Rudd, R. A., Noonan, R. K., & Haegerich, T. M. (2018). Quantifying the epidemic of prescription opioid overdose deaths. *American Journal of Public Health, 108*(4), 500–502.

Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics, 15*(2), 231–250.

Substance Abuse and Mental Health Services Administration. (2017). *Key substance use and* mental health indicators in the United States: Results from the 2016 National Survey on *Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52)*. Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/

Thomson, C.E., Paterson-Brown, S., Russell, D., McCaldin, D., & Russell, I.T. (2004). Short report: encouraging GPs to complete postal questionnaires - one big prize or many small prizes? A randomized controlled trial. *Family Practice, 21*(6):697–698.

Thorpe, C., Ryan, B., McLean, S.L., Burt, A., Stewart, M., Brown, J.B., … (2009). How to obtain excellent response rates when surveying physicians. *Family Practice, 26*(1), 65-68.

Turk, D., Dansie, E., Wilson, H., Moskovitz, B., & Kim, M. (2014). Physicians' beliefs and likelihood of prescribing opioid tamper-resistant formulations for chronic noncancer pain patients. *Pain Medicine, 15*(4), 625–636.

U.S. Food and Drug Administration. (2017). *FDA opioids action plan*. Retrieved from https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm484714.htm

U.S. Food and Drug Administration. (2018). *Health innovation, safer families: FDA's 2018 strategic policy roadmap*. Retrieved from https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM592001.pdf

VanGeest, J. B., Johnson, T. P., & Welch, V. L. (2007). Methodologies for improving response rates in surveys of physicians: A systematic review. *Evaluation of Health Professionals, 30*(4), 303–321.

Young, R.A., Fulda, K.G., Suzuki, S., Hahn, K.A., Espinoza, A.M., Marshall, J.D., … (2011). The influence of research compensation options on Practice-based Research Network (PBRN) physician participation: A North Texas (NorTex) PBRN study. *Journal of the American Board of Family Medicine, 24*(5), 562-568.