Framing a Research Question

Name

Institution Affiliation

Framing a Research Question

1. **Bibliographic Citation for the Article**

Treasure, C. L., Avorn, J., & Kesselheim, A. S. (2015). Do March-In Rights Ensure Access to Medical Products Arising From Federally Funded Research? A Qualitative Study. *The Milbank Quarterly*, *93*(4), 761-787. doi:10.1111/1468-0009.12164

2. **Summary of the Research Question**

The increasing costs of new prescription medications is a mounting health policy problem. Most revolutionary medicines were initiated in public sector financing to non-profit study facilities. Even though the Bayh-Dole Act (1980) allows for march-ins that the government can use to have power over patients safeguarding products created via public financing to guarantee the public availability of these drugs, the appropriateness of the stipulation to recent policy programs is not apparent (Treasure, Avorn, & Kesselheim, 2015). The study intends to assess the function of march-in rights in the commercialization and licensing of health care. More specifically, whether applying march-in rights is a feasible approach in tackling the rising costs of specific health care products. The objective of the analysis is to comprehend the subtleties of using march-in rights and their part in the commercialization of pioneering medical technology centered on government-backed research.

3. **Author's rationale for using qualitative methods**

Treasure, Avorn, & Kesselheim performed a primary-source document review of the Bayh-Dole Act, and the trials of former march-in rights appeal to the NIH (National Institutes of Health). Petitions concerning march-in rights are still cited by advocates and filed by policymakers, especially in the setting of expensive new products created through government-financed research. The author's rationale for using qualitative methods is that in reviewing the

specifics of previous march-in rights cases and the perspectives of the interviewees, they discover what seems to be a sound legal foundation for including the extremely high product price to be a legitimate motive to petition march-in rights. Bayh-Dole Act's legislative timeline and the simple language of the statute ascertain that the proper conditions must consider the price, especially when it is manifestly irrational and an essential factor in restricting the product's availability (Treasure, Avorn, & Kesselheim, 2015).

4. ***Data Collection and Analysis***

The data was collected using semi-structured interviews were performed with specialists, incorporating vital participants in the creation of the law and the nature of previous petitions. The interviews probed the aim of the Congress in devising the march-in rights stipulation, the validation for former march-in rights appeals, the responsibility of the NIH in assessing march-in rights appeals, the benchmark used in the evaluation of the march-in rights petitions, and proposals for enhancing the benefit of the march-in rights legislation and the Bayh-Dole Act.

The analysis of data involved establishing themes and keywords concerning the march-in rights procedure. These keywords were then applied to assess the interview transcripts through accepted qualitative coding methods. Using a subset of three randomly chosen interviews, the authors independently created coding structures to arrange the data. The coding structures were then contrasted and merged resulting in a final coding scheme that comprised the choice to rebuff a petition, Congress' objective of the march-in rights stipulations, and the appropriateness of march-in rights to product accessibility. The coding themes also included the suggestions for enhancing the suitability of march-in rights as a public policy instrument and the decision and procedure of filing a march-in rights petition (Treasure, Avorn, & Kesselheim, 2015).

5. *Use of unobtrusive methods*

The qualitative authors did not apply any discreet methods. They established 21 possible applicable specialists in the Bayh-Dole Act and march-in rights from the domains of public health, law, politics, healthcare, and business. Twelve consented to involvement, with at least two subjects signifying each of the four main classes of expertise (Treasure, Avorn, & Kesselheim, 2015).

6. **Achievement of Study Purpose**

Yes, the authors achieved the research purpose of their study as they discovered persuasive contentions from the interviewees regarding a political and regulatory context providing less probability that march-in rights can be summoned to control pricing of a health care product created through government-financing. They also found out that numerous former march-in rights petitions have delineated the adverse impacts of high prices on the economy and US consumers. The researchers also learned that there is a significant consensus on the NIH's reluctance to intercede. They showed that the NIH does not have the capacity to summon a march-in petition and is fearful of the possible adverse implications that the enforcement of march-in rights under Bayh-Dole might have on impending commercialization.

7. **Biases/Assumptions in Author's Approach/Conclusions**

There are no assumptions in the authors' approach or conclusion. To begin with, the authors avoided selection bias by establishing 21 potential relevant specialists in the Bayh-Dole Act and march-in rights from different. Twelve participated, and at least two of them represented the four primary classifications of expertise (Treasure, Avorn, & Kesselheim, 2015). As a result, the method was rigorous since the participants were all experts in the Bayh-Dole Act and march-in rights.

Interview bias was avoided by conducting telephone interviews with the experts and asking them the same questions (Pannucci & Wilkins, 2010). These issues included the aim of the Congress in devising the march-in rights stipulation, the validation for former march-in rights appeals, the responsibility of the NIH in assessing march-in rights requests, the benchmark used in the evaluation of the march-in rights petitions, and proposals for enhancing the benefit of the march-in rights legislation and the Bayh-Dole Act.

The authors avoided chronology bias by using prospective studies that included documents associated with the Bayh-Dole Act and the records of previous hearings for march-in rights summons.

8. ***Would another qualitative or quantitative method have worked?***

A different qualitative or quantitative method would not be appropriate in tackling the research question. The semi-structured interviews that were used allowed the researchers to devise a map for the themes to be covered. Still, the responses of the interviewee guide the direction of the interview. This qualitative method enabled the authors to elicit responses for the relevant established queries. Moreover, the semi-structured interview offered reasonable instructions for the interviewers and provided relative, reliable qualitative data.

9. *Overall evaluation of the study*

The study was comprehensive in analyzing the different data sources and interview responses to make a valid finding. The authors appraised the Bayh-Dole Act and the trials of former march-in rights pleas to the NIH. This was followed by semi-structured interviews of twelve vital professionals in the march-in rights of the Bayh-Dole Act to establish the cause of the disagreements and the original premises in the policy's enforcement. Moreover, the authors assess the interview transcripts utilizing standard qualitative approaches avoiding bias. The

findings of the study were also inclusive as they revealed the NIH's reluctance to apply its march-in rights focusing on its refusal of the petitions.

10. **Weak Areas**

There is a possibility that the age, race, and sex of the interviewers influenced the level of information that the participants were ready to reveal and their sincerity regarding the information they divulge. This issue greatly relied on the kind of themes in the interviews. Furthermore, the interviews depended on the capacity of the interviewees to duly and sincerely remember details concerning their opinions are being queried. Another issue is that the interviewing might have been expensive and time intensive.

Qualitative interviewing encompasses devising a guide, establishing a sample, and performing the interviews (McLeod, 2014). However, the transcription and coding of the interviews may have been labor intensive. The interviews might have been expensive, as the researchers might have provided the interviewees with financial incentives for participating. This is justified since they are requesting the respondents to sacrifice their time to be involved in the study (McLeod, 2014).

Even though the telephone interviews enabled the researchers to interview individuals that are rarely available, a shortcoming of the technique is that there is a decline in the social cues. Since the interviewer cannot see the interviewee, it becomes pointless to utilize body language as a source of additional information. However, it is significant to note that the interviewer could access the intonation and voice of the interviewees.

Also, in the telephone interviews, the interviewer does not have a clue of the circumstance in which the respondent is positioned. Due to this, the interviewer has reduced opportunities to enable a conducive interview atmosphere. Face-to-face interviews have the

ability to standardize the scenario (McLeod, 2014). Because of the reduced opportunity to allow a normalization of the setting with telephone interviews, the interviewee is still seen by other individuals around him. This might imply that the discussion is interrupting the work of other and may result in its termination (McLeod, 2014).

11. **Strong Areas**

It is apparent that the qualitative telephone interviews were an effective means of collecting detailed information. Irrespective of the subject being studied, the application of interviews can be explored extensively than any other method. The participants of the investigation were allowed to explain themselves in a manner that might not be achievable with other approaches such as survey studies. The responded also have the opportunity to share information with the interviewers in their way and from their viewpoints instead of being instructed to place those standpoints into restricted responses offered by the researcher. Furthermore, the telephone interviews were useful since the interview could be recorded on a tape. Still, this might be time intensive since the tape needs to be transcribed to be helpful.

References

McLeod, S. (2014). Structured and unstructured interviews. Retrieved from https://www.simplypsychology.org/interviews.html

Pannucci, C. J., & Wilkins, E. G. (2010). Identifying and Avoiding Bias in Research. *Plastic and Reconstructive Surgery*, *126*(2), 619-625. doi:10.1097/prs.0b013e3181de24bc

Treasure, C. L., Avorn, J., & Kesselheim, A. S. (2015). Do march-in rights ensure access to medical products arising from federally funded research? A Qualitative Study. *The Milbank Quarterly*, *93*(4), 761-787. doi:10.1111/1468-0009.12164