

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Kesselheim AS, Studdert DM, Mello MM. Whistle-blowers' experiences in fraud litigation against pharmaceutical companies. *N Engl J Med* 2010;362:1832-9.

APPENDIX

Experiences of Whistleblowers in Major Fraud Litigation Against Pharmaceutical Manufacturers

Qualitative Analysis Study Methodology

Study Design

We conducted semi-structured interviews with a sample of relators involved in health care fraud litigation against pharmaceutical manufacturers and analyzed the interview data using qualitative methods. A qualitative approach provides a rigorous way of investigating personal motivations, reflections, and outcomes among a small cohort of subjects who share a common experience.¹ Qualitative methods are also appropriate for exploratory research and hypothesis generation, which were both relevant considerations given the paucity of published data about the qui tam process for investigating health care fraud.² The study was approved by ethics review boards at Brigham and Women's Hospital and the Harvard School of Public Health.

Sample Construction

Officials in the US Department of Justice (DOJ)-Civil Division provided us with a full list of settled pharmaceutical-related qui tam cases, together with copies of the unsealed complaints filed by the relators in most of those cases (a relator's name remains under seal until the case is settled). The rest of the complaints were obtained from on-line searches of archives of US federal court filings³ and direct approaches to lawyers involved in the litigation. We also obtained copies of the final settlement agreements in each case through searches of DOJ Internet archives.⁴ The settlement agreements list the names of all the parties to the final settlement, including relators and their lawyers.

This process identified 17 federal qui tam cases against pharmaceutical manufacturers that were settled by the DOJ between January 2001 and March 2009; collectively, these cases accounted for \$6.8 billion in total recoveries (2009 dollars) (Table 1). The forms of fraud alleged in the cases included improper billing, kickbacks, off-label promotion, failure to disclose side effects, and falsification of documents. The settlement agreements from these cases named 47 relators, 3 of whom were involved in more than 1 case, leaving 44 unique relators. These individuals constituted our study sample.

Recruitment

Relators for whom contact information was available were approached directly via email and/or telephone and invited to participate in the study; for the others, the invitation to participate was passed through their lawyers. Twenty-six relators agreed to participate, 16 declined, 1 had died, and 1 could not be contacted—a response rate of 62% (26/42). Among the 26 was 1 of the 3 repeat pharmaceutical relators. Relators who declined cited a concern that their responses could be linked to them (despite undertakings of confidentiality), lack of interest in revisiting this difficult episode in their lives, and ongoing secondary litigation related to the case at issue. At least 1 relator participated from 15 of the 17 cases in the sample.

Data Collection

One investigator (ASK) conducted in-depth telephone interviews with the relators who agreed to participate between January and September, 2009. Median interview time was 40 minutes (interquartile range, 31-49 minutes). All but one interview was recorded (the interviewee was uncomfortable with being audiotaped) and fully transcribed by an independent professional transcriptionist. The interviewer also kept written notes.

The interviewer used a written guide that contained a list of key thematic areas to be probed for clarification and additional detail if a relator's own "story" did not address them. Five relators requested and were forwarded a copy of the written guide prior to the interview.

The interview began by obtaining informed consent, followed by background demographic and professional information on relators. Next, we elicited information on the nature of their work leading up to the litigated events, their connection with the defendant company, and when and how they first noticed the alleged fraudulent activities. Interviews then proceeded chronologically through the following topics: initial attempts to address the concerning activities; the decision to pursue a qui tam action; experiences during the DOJ investigations and settlement of the case; and life after the settlement. Finally, relators were asked to verify published reports of their gross financial recovery and provide an estimate of the net recovery, after taxes and attorneys' fees.

Data Analysis

Interview notes and transcriptions were analyzed using standard coding techniques⁵ and the constant comparative method of qualitative data analysis.⁶ The 3 investigators independently analyzed 5 (19%) randomly selected interviews and developed separate coding schemes for organizing the data.⁷ The coding schemes were then compared, discussed and reconciled to produce a final coding structure which consisting of 12 broad themes covering 73 specific codes. One investigator (ASK) then used the final coding scheme to code all of the transcripts and interview notes using the NVIVO 8 software package (QSR International, Melbourne, Australia).⁸ The software was also used to perform the content analysis. The analysis focused on organizing and describing themes, including distinctions among whistleblowers based on the nature of their relationship with the defendant company (internal employee vs. external observer), employee type (entry-level vs. executive), and financial recovery (<\$1 million, \$1-\$5 million, >\$5 million).

Appendix References

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