

An Ounce of Prevention: The Role of Compliance Programs in False Claims Act Investigations and Litigation

LENA AMANTI, ASSISTANT UNITED STATES ATTORNEY

SCOTT GRUBMAN, CHILIVIS, COCHRAN, LARKINS & BEVER LLP

LAUREN MARZIANI, SENIOR COUNSEL, OFFICE OF COUNSEL, HHS-OIG

RENÉE BROOKER, FINCH MCCRANIE LLP

ALL VIEWS ARE THE SPEAKERS' OWN VIEWS

Government's Perspective

Q: LENA, WHEN YOU CONDUCT AN FCA INVESTIGATION OF A HEALTH CARE PROVIDER, HOW DO YOU CONSIDER (IF AT ALL) THE PROVIDER'S COMPLIANCE MEASURES? DOES IT PLAY A ROLE IN YOUR EVALUATION OF SCIENTER? DO YOU LOOK AT THEIR WRITTEN POLICIES OR WHAT THEY ARE ACTUALLY DOING? HOW DOES IT MAKE A DIFFERENCE IN THE RESOLUTION OF THE FCA CASE?

Government's Perspective

Q: LENA, WHEN YOU ARE SITTING ACROSS THE TABLE FROM A DEFENDANT AND DISCUSSING ITS COMPLIANCE FAILURES, WHAT DO YOU FIND TO BE AN EFFECTIVE OR INEFFECTIVE RESPONSE? DOES THE SAME ANSWER APPLY TO WHEN YOU ARE INVESTIGATING INDIVIDUALS AT THE PROVIDER?

Government's Perspective

Q: LENA, IN WHAT CIRCUMSTANCES WOULD YOU SEEK TO INTERVIEW OR DEPOSE COMPLIANCE PERSONNEL? WHAT TYPE OF INFORMATION DO YOU SEEK IN THESE INTERVIEWS/DEPOSITIONS?

Government's Perspective

Q: DO YOU HAVE AN ANECDOTAL EXAMPLE (WITHOUT NAMING NAMES) OF HOW A PROVIDER'S STRONG OR WEAK COMPLIANCE PROGRAM FACTORED INTO A RESOLUTION IN ONE OF YOUR CASES?

Government's Perspective

Q: DO YOU EVALUATE THE PROVIDER'S HISTORY OF AUDITS AND WHETHER IT CORRECTED PROBLEMS OR IGNORED AUDIT RESULTS; WHETHER THERE ARE REPEAT AUDIT FINDINGS? HOW SO?

Defense Perspective

Q: SCOTT, TO WHAT EXTENT DO YOU INVOLVE A CLIENT'S COMPLIANCE PERSONNEL IN RESPONDING TO GOVERNMENT ALLEGATIONS AND INVESTIGATIVE REQUESTS? DO YOU INCLUDE COMPLIANCE PERSONNEL IN SETTLEMENT PRESENTATIONS (E.G., ATTEND GOVERNMENT OR CLIENT PRESENTATIONS TO GOVERNMENT, PREPARE RESPONSE TO SETTLEMENT PRESENTATIONS, ACTUALLY PARTICIPATE IN PRESENTING SETTLEMENT RESPONSE)?

Defense Perspective

Q: SCOTT, WHEN YOU ARE REPRESENTING A CLIENT UNDER INVESTIGATION WITH A PARALLEL FCA INVESTIGATION, HOW DO YOU PUT THE CLIENT'S BEST FOOT FORWARD IN THE NEGOTIATIONS LIGHT OF ITS COMPLIANCE PROGRAM? WHAT FACTORS OF COMPLIANCE DO YOU HIGHLIGHT FOR THE GOVERNMENT? DOWNPLAY?

Defense Perspective

Q: SCOTT, HOW FORTHCOMING DO YOU ADVISE THE CLIENT TO BE AT THE SETTLEMENT TABLE ABOUT ITS COMPLIANCE MEASURES? DO YOU HAVE ANY ANECDOTAL STORIES OF A CLIENT THAT FARED POORLY WITH THE DOJ DURING AN FCA INVESTIGATION AS A RESULT OF POOR COMPLIANCE MEASURES?

Defense Perspective

Q: SCOTT, DO YOU THINK COMPLIANCE PROGRAMS ARE EVALUATED DIFFERENTLY BY DOJ IN A CRIMINAL AND CIVIL INVESTIGATION? WHERE THERE'S A PARALLEL ADMINISTRATIVE ACTION? HOW DOES THAT IMPACT THE CLIENT IN A PARALLEL INVESTIGATION?

Defense Perspective

Q: SCOTT, HOW DO YOU PREPARE COMPLIANCE PERSONNEL FOR INTERVIEWS OR DEPOSITIONS WITH THE GOVERNMENT?

Defense Perspective

Q: SCOTT, WHAT IS THE ROLE OF REGULAR COMPLIANCE AUDITS AS PART OF AN ONGOING COMPLIANCE PROGRAM? HOW CAN THOSE AUDITS HELP WHEN IT COMES TO AN FCA INVESTIGATION AND RESOLUTION, AND HOW THEY CAN ALSO HURT? IS THERE ANY WAY TO CONDUCT AUDITS TO PREVENT THEM FROM HURTING THE COMPANY DURING AN INVESTIGATION?

Defense Perspective

Q: SCOTT, CAN YOU DESCRIBE AT A HIGH LEVEL, THE DOJ'S RECENT CRIMINAL COMPLIANCE GUIDANCE AND HOW IT COULD COME INTO PLAY IN A PARALLEL PROCEEDING/INVESTIGATION?

Defense Perspective

Q: SCOTT, HOW DO YOU PREPARE COMPLIANCE PERSONNEL FOR INTERVIEWS OR DEPOSITIONS WITH THE GOVERNMENT?

Defense Perspective

Q: SCOTT, HOW DO YOU PREPARE COMPLIANCE PERSONNEL FOR INTERVIEWS OR DEPOSITIONS WITH THE GOVERNMENT?

Plaintiff's Perspective

Q: RENEE, THERE IS A LOT OF TALK ABOUT THE GOLD STANDARD COMPLIANCE PROGRAM. DO YOU THINK GIVING CREDIT IN THE FORM OF A REDUCED MULTIPLIER TO A COMPANY WITH A SO-CALLED GOLD STANDARD COMPLIANCE PROGRAM IS A GOOD IDEA?

Plaintiff's Perspective

Q: RENEE, WHEN YOU REPRESENT A WHISTLEBLOWER, WHAT QUESTIONS DO YOU ASK THEM ABOUT COMPLIANCE TO EVALUATE THEIR CLAIMS?

Plaintiff's Perspective

Q: RENEE, AS COUNSEL FOR WHISTLEBLOWERS, DO YOU EVALUATE A CASE DIFFERENTLY IF THE WHISTLEBLOWER REPORTED (OR DID NOT REPORT) COMPLIANCE CONCERNS TO THE WHISTLEBLOWER'S EMPLOYER?

Resolving the Administrative Case

Q: LAUREN: WHEN YOU ARE RESOLVING A PROVIDER'S ADMINISTRATIVE LIABILITY, ALONG WITH A PARALLEL FALSE CLAIMS ACT RESOLUTION, HOW DOES THE PROVIDER'S COMPLIANCE PROGRAM GET EVALUATED?

Resolving the Administrative Case

Q: LAUREN, HOW DO YOU EVALUATE A PROVIDER'S COMPLIANCE PROGRAM WHEN TAKING INTO ACCOUNT PERMISSIVE EXCLUSION? WHAT FACTORS ARE YOU LOOKING AT?

Resolving the Administrative Case

Q: LAUREN, DO YOU EVER SPEAK DIRECTLY WITH COMPLIANCE PERSONNEL WHEN DETERMINING A PROVIDER'S ADMINISTRATIVE LIABILITY? IF SO, WHAT INFORMATION DO YOU SEEK?

Defense Perspective

Q: SCOTT, WHEN NEGOTIATING WITH OCIG REGARDING WAIVER/RESERVATION OF ADMINISTRATIVE REMEDIES, WHAT TACTICS DO YOU CONSIDER IN REPRESENTATIVE COMPANIES AND INDIVIDUALS?

Relevant links for compliance program documents

- CRITERIA FOR IMPLEMENTING 1128(B)(7) EXCLUSION AUTHORITY (2016 UPDATED DISCUSSION)-
[HTTPS://OIG.HHS.GOV/EXCLUSIONS/FILES/1128B7EXCLUSION-CRITERIA.PDF](https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf)

- ORIGINAL OIG CRITERIA FOR 1128(B)(7) (ORIGINAL FEDERAL REGISTER NOTICE)-
[HTTPS://OIG.HHS.GOV/EXCLUSIONS/FILES/CRITERIA_B7.PDF](https://oig.hhs.gov/exclusions/files/criteria_b7.pdf)

- CRIMINAL FRAUDS- EVALUATION OF CORPORATE COMPLIANCE PROGRAMS-
[HTTPS://WWW.JUSTICE.GOV/CRIMINAL-FRAUD/PAGE/FILE/937501/DOWNLOAD](https://www.justice.gov/criminal-fraud/page/file/937501/download)

- MEASURING COMPLIANCE PROGRAM EFFECTIVENESS (OIG AND HCCA DOCUMENT)-
[HTTPS://OIG.HHS.GOV/COMPLIANCE/101/FILES/HCCA-OIG-RESOURCE-GUIDE.PDF](https://oig.hhs.gov/compliance/101/files/hcca-oig-resource-guide.pdf)

- BACKGROUND ARTICLES

[HTTPS://WWW.LILESPARKER.COM/2017/04/14/OIG-DOJ-ISSUE-IMPORTANT-NEW-COMPLIANCE-GUIDANCE/](https://www.lilesparker.com/2017/04/14/oig-doj-issue-important-new-compliance-guidance/)

[HTTPS://CORPGOV.LAW.HARVARD.EDU/2017/03/19/DOJS-NEW-GUIDANCE-FOR-COMPLIANCE-PROGRAMS/](https://corpgov.law.harvard.edu/2017/03/19/dojs-new-guidance-for-compliance-programs/)