THE GRANSTON MEMO'S EFFECT: THE DOJ IS DISMISSING MERITLESS AND FRIVOLOUS ACTIONS

The DOJ plans to dismiss 11 FCA lawsuits involving the new theory that patient assistance services supplied by drugmakers are unlawful kickbacks.[1] These lawsuits were brought by shell company whistleblowers backed by the National Healthcare Analysis Group ("NHCA"), a company that specializes in generating FCA cases. The 11 cases were essentially the same complaints with a different defendant.

The dismissals stem from the DOJ's Granston Memo, which directed federal attorneys to be more aggressive about ending flimsy FCA suits that are causing the government to incur substantial costs to litigate. It also hints that the DOJ is casting doubt on a theory that drugmakers have provided kickbacks to prescribers by assisting with prior authorizations and arranging for nurses to educate patients on proper drug use. Although the NHCA's reaction accused the government of having a "disturbing alignment with Big Pharma," the government contends that its high spending on prescription drugs creates a strong interest in making sure patients have basic product support in relation to those medications. These lawsuits "would undermine common industry practices the federal government has determined are, in this particular case, appropriate and beneficial to federal health care programs and their beneficiaries." The cases also involved allegations of "white coat marketing," which entails hiring contracted nurses to act as undercover sales reps who engage in prohibited marketing activities. However, the DOJ overlooked those claims and still wants to dismiss these lawsuits.

The DOJ also accused the NHCA of dishonesty by saying that the transcripts from the "witness interviews reveals the false pretenses NHCA uses to obtain information." Even with the government's actions on the suits, NHCA believes that a handful of states will ultimately pursue the kickback claims independently and that the NHCA may choose to challenge the DOJ's dismissal efforts.

The 11 cases are:

- U.S. ex rel. Health Choice Group LLC v. Bayer Corp. et al., case number 5:17-cv-00126;
- U.S. ex rel. Health Choice Alliance LLC v. Eli Lilly & Co., case number 5:17-cv-00123;
- U.S. ex rel. Health Choice Advocates LLC v. Gilead Sciences Inc. et al., case number 5:17-cv-00121;
- U.S. ex rel. Miller v. AbbVie Inc., case number 3:16-cv-02111;
- U.S. ex rel. CIMZNHCA v. UCB Inc., case number 3:17-cv-00765;
- U.S. ex rel. Carle v. Otsuka Holdings Co., case number 17-cv-00966;
- U.S. ex rel. SCEF LLC v. AstraZeneca PLC, case number 17-cv-01328;
- U.S. ex rel. SMSF LLC v. Biogen Inc., case number 1:16-cv-11379;
- U.S. ex rel. SAPF LLC, v. Amgen Inc., case number 16-cv-05203;
- U.S. ex rel. SMSPF LLC v. EMD Serono Inc., case number 16-cv-05594; and
- U.S. ex rel. NHCA-TEV LLC v. Teva Pharmaceutical Products Ltd., case number 17-cv-02040.

CONCLUSION

The government's move to dismiss the NHCA cases is consistent with the trend since the Granston Memo to investigate *qui tam* cases more closely to weed out the frivolous and abusive, both to avoid unnecessary costs to the government and to protect providers from the time and expense of defending against them. It also demonstrates that the government is more willing than ever to consider the validity of novel FCA theories rather than allow relators courts to create new rules for the administration of the federal health care programs.

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[1] https://www.law360.com/health/articles/1112891/doj-aims-torpedo-at-11-fca-kickback-suits?nl_pk=449a8260-92ce-45bc-9ec0-e2a699fdbf17.