IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

UNITED STATES OF AMERICA,	)	CRIM. NO. 13-00573 SOM
	)	
Plaintiff,	)	ORDER AFFIRMING MAGISTRATE
	)	JUDGE'S ORDER DENYING
vs.	)	DEFENDANTS' MOTION TO UNSEAL
	)	GRAND JURY TRANSCRIPTS
XANYA SOFRA-WEISS,	)	
	)	
Defendant.	)	
_____	)	

ORDER AFFIRMING MAGISTRATE JUDGE'S ORDER DENYING DEFENDANTS' MOTION TO UNSEAL GRAND JURY TRANSCRIPTS

I. INTRODUCTION.

Defendant Xanya Sofra-Weiss appeals an order by the Magistrate Judge denying her motion to unseal grand jury transcripts. Sofra-Weiss contends the transcripts will reveal prosecutorial misconduct that would be grounds for dismissing the indictment. Because Sofra-Weiss's assertion of prosecutorial misconduct is wholly speculative, she does not demonstrate the particularized need required to overcome the presumption of secrecy that attaches to grand jury proceedings. The Magistrate Judge's order denying Sofra-Weiss's motion is affirmed.

II. BACKGROUND FACTS.

On July 23, 2013, a federal grand jury issued a superseding indictment, charging Sofra-Weiss with four counts of mail fraud and eight counts of introducing adulterated medical devices into interstate commerce, in violation of 21 U.S.C. § 331(a). See Superseding Indictment, ECF No. 12.

Sofra-Weiss is alleged to have manufactured and distributed six devices, all purporting to increase strength and stamina and to have various cosmetic effects. Id. ¶¶ 5-10. These devices are called the "Ion Genius," "Ipico," "Arasys," "Perfector," "Ion Magnum" and "iEllios." Id. The indictment alleges that these are medical "devices" within the meaning of 21 U.S.C. § 321(h). Id. That statute defines a medical device, in relevant part, as "an instrument, apparatus, implement, machine, contrivance, implant . . . or other similar or related article . . . intended for use in the . . . cure, mitigation, treatment or prevention of disease in man or other animals, or intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(h)(2). The indictment states that all "newly marketed medical devices are deemed Class III by the [Federal Food, Drug, and Cosmetic Act] and are required to obtain FDA approval prior to being marketed." Superseding Indictment ¶ 4, ECF No. 12.

A party seeking to market a medical device without first obtaining FDA approval or qualifying for an exemption is considered to be unlawfully distributing "adulterated" medical devices. Id.; 21 U.S.C. § 351 (f)(1)(B). The Government considers the six devices mentioned in the indictment "adulterated" because, the Government alleges, Sofra-Weiss did not receive Pre-Market Approval ("PMA") or an Investigational

Device Exemption ("IDE") from the FDA prior to marketing them. Id. Sofra-Weiss has pled not guilty to the charges in the superseding indictment and awaits trial. ECF No. 17.

III. LEGAL STANDARD.

Pursuant to 28 U.S.C. § 636(b)(1) and Criminal Local Rule 57.3(b), a party may appeal to a district judge any pretrial nondispositive matter determined by a magistrate judge. Under 28 U.S.C. § 636(b)(1)(A), a magistrate judge's order may be reversed by the district court only if it is "clearly erroneous or contrary to law." The threshold of the "clearly erroneous" test is high. United States v. U.S. Gypsum Co., 333 U.S. 364, 395 (1948) ("A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed."); Thorp v. Kepoo, 100 F. Supp. 2d 1258, 1260 (D. Haw. 2000) (the clearly erroneous standard is "significantly deferential, requiring a definite and firm conviction that a mistake has been committed").

IV. ANALYSIS.

"[T]he proper functioning of our grand jury system depends upon the secrecy of grand jury proceedings." Rehberg v. Paulk, 132 S. Ct. 1497 (2012) (internal quotation omitted). Secrecy is of paramount importance because it "encourag[es] witnesses to come forth voluntarily and to testify fully and

frankly, reduc[es] the possibility that those under investigation will flee or attempt to influence grand jurors' votes, and protect[s] accused, but exonerated individuals from public ridicule." United States v. Plummer, 941 F.2d 799, 806 n.4 (9th Cir. 1991).

"Parties seeking grand jury transcripts under Rule 6(e) [of the Federal Rules of Criminal Procedure] must show that the material they seek is needed to avoid a possible injustice in another judicial proceeding, that the need for disclosure is greater than the need for continued secrecy, and that their request is structured to cover only material so needed." United States v. Caruto, 627 F.3d 759, 768 (9th Cir. 2010) (quoting Douglas Oil Co. v. Petrol Stops Northwest, 441 U.S. 211, 222 (1979)). In particular, a "trial judge should order disclosure of grand jury transcripts only when the party seeking them has demonstrated that a 'particularized need exists . . . which outweighs the policy of secrecy.'" United States v. Walczak, 783 F.2d 852, 857 (9th Cir. 1986) (quoting Pittsburgh Plate Glass Co. v. United States, 360 U.S. 395, 400 (1959)).

Sofra-Weiss claims that she has a particularized need to obtain the transcripts, because she contends they will reveal prosecutorial misconduct before the grand jury. She argues that prosecutors must have incorrectly identified her products as "Class III" devices rather than "Class II," thereby suggesting to

the grand jury that they carried a higher degree of consumer risk than they in fact did.[1] Memo in Support at 12-13, ECF No. 36-1. Sofra-Weiss further claims that one of the devices mentioned in the indictment--the "Ion Genius"--does not actually exist, and therefore its presence in the indictment must have been the product of misinformation. Id. at 12. Sofra-Weiss next contends that the grand jury was falsely told that the FDA regulates international sales when, she maintains, it does not. Id. Finally, Sofra-Weiss claims that it is "highly likely that the Government misled the [g]rand [j]ury into believing that the FDA had provided notice [to her] that her devices lacked requisite approvals," when in fact, she contends, no notice was given. Id. at 6.

"[A]lleged instances of prosecutorial and grand jury misconduct . . . do not amount to the particularized need required to outweigh the secrecy of [] grand jury proceedings . . . [unless t]he claimed misconduct would . . . compel[] the dismissal of the . . . indictment" United States v. Murray, 751 F.2d 1528, 1533 (9th Cir. 1985). Sofra-Weiss, therefore, must show not only that impropriety possibly occurred before the grand jury, but that this impropriety was so severe as to require the "drastic [and] disfavored remedy" of dismissal. United States v.

[1] The Government responds that all medical devices are considered Class III devices until the FDA grants them approval or exemption. Government Response in Opp. at 2, ECF No. 32.

Rogers, 751 F.2d 1074, 1076 (9th Cir.1985). In other words, Sofra-Weiss must present some reason to believe that "the conduct of the prosecuting attorney was flagrant to the point that the grand jury was deceived in some significant way." United States v. Wright, 667 F.2d 793, 796 (9th Cir. 1982).

Sofra-Weiss' argument appears to be that, because the charges against her are allegedly false, they must necessarily have resulted from misconduct. Sofra-Weiss has no affirmative evidence of misconduct, or even any reason to believe misconduct occurred, aside from what she sees as the sheer implausibility that a grand jury would return an indictment against her.

It is not entirely clear from her motion whether Sofra-Weiss is arguing that the evidence presented to the grand jury was insufficient to obtain an indictment, or whether she is claiming that the Government wilfully lied before the grand jury, and presented evidence it knew to be false. Sofra-Weiss elides the distinction between these two claims by simply alleging repeatedly that the grand jury was "misinformed." As presented by Sofra-Weiss, the alleged instances of prosecutorial "misinformation" are indistinguishable from a good-faith attempt by the Government to present matters to the grand jury.

A grand jury proceeding is not a mini-trial in which the Government must play the role of prosecution and defense. The Government appears to have conveyed to the grand jury its

belief that Sofra-Weiss had marketed adulterated medical devices, and to have provided supporting evidence for this belief. Sofra-Weiss's assertions that she had FDA approval for her products, or that she had the lawful right to market her products internationally, are the very questions a jury must resolve at trial, not reasons to believe the indictment itself should be dismissed for misconduct. It is well settled that a defendant cannot demonstrate prosecutorial misconduct simply by arguing "that there was inadequate or incompetent evidence before the grand jury." Costello v. United States, 350 U.S. 359, 402 (1956). Nor is Sofra-Weiss entitled to relief because she recasts her adequacy-of-the-evidence challenge as prosecutorial "misinformation." See United States v. Williams, 504 U.S. 36, 54 (1992) ("A complaint about the quality or adequacy of the evidence can always be recast as a complaint that the prosecutor's presentation was 'incomplete' or 'misleading.'").

Sofra-Weiss provides almost nothing to the court in support of the separate argument that the Government knowingly lied to or doctored evidence before the grand jury, or, in fact, did anything other than present its accusations in good faith. See, e.g., United States v. Samango, 607 F.2d 877, 882 (9th Cir. 1979) ("[D]eliberate introduction of perjured testimony is perhaps the most flagrant example of misconduct."). Sofra-Weiss's principal evidence is a letter dated June 21, 2013, which

appears to grant her FDA approval to prospectively market the "Ion Magnum Genius" in the United States. Defendant's Exhibit 6, ECF No. 36-9. Sofra-Weiss argues that this letter demonstrates that prosecutors must have misinformed the grand jury, because she "had FDA approval to sell [the Ion Magnum] as a Class II device prior to the issuance of the Superseding Indictment." Memo. in Support at 12, ECF No. 36-1. However the June 21 letter, far from supporting Sofra-Weiss's claim, actually undermines it. The letter appears to show that Sofra-Weiss did *not* have permission to market the "Ion Magnum" *before* June 21, 2013. The indictment alleges that Sofra-Weiss has been marketing six adulterated devices since 2006, and charges her based on conduct that preceded the issuance of the indictment. The FDA letter shows, at most, that Sofra-Weiss had approval to market one of her devices after June 21, 2013, not that she has had approval for all six products since 2006. In other words, the letter does not even support Sofra-Weiss' claim of innocence, let alone provide affirmative evidence of egregious prosecutorial misconduct.

In addition to her claims regarding prosecutorial "misinformation," Sofra-Weiss asserts that the Government is likely to have presented testimony to the grand jury from a business rival and an ex-employee of hers--both of whom are involved in separate civil litigation against her--without

revealing their potential bias. Sofra-Weiss also speculates that the Government failed to reveal to the grand jury that some of her employees incriminated her because, she alleges, "they faced potential prosecution themselves if they failed [to do so]." Memo in Support at 9-10, ECF No. 36-1.

The Government contends that none of the witnesses Sofra-Weiss suspects of bias even appeared before the grand jury. See Gov't. Resp. in Opp. at 4-5, ECF No. 32. Sofra-Weiss presumably believes that the Government is lying in its submissions to this court, that these individuals did in fact testify, and, further, that the Government mischaracterized them as impartial when presenting them to the grand jury. Even making these unlikely assumptions, however, a "prosecutor has no duty to present to the grand jury all matters bearing on credibility of witnesses or any exculpatory evidence." United States v. Al Mudarris, 695 F.2d 1182, 1185 (9th Cir. 1983). See also United States v. Tham, 665 F.2d 855, 863 (9th Cir. 1981) ("[A] grand jury need not be advised of all matters concerning credibility.").

Sofra-Weiss likens this case to United States v. Samango, 607 F.2d 877 (9th Cir. 1979), which involved a litany of prosecutorial "errors and indiscretions," including the use of witnesses whose credibility was mischaracterized to the grand jury. Id. at 884. However, the court in Samango was clear that

"none of [the errors] alone might have been enough to tip the scales," and it was only their "cumulative effect [that] . . . produc[ed] a biased grand jury." Id. Nothing in the record before the court in this case suggests anything close to the catalogue of errors present in Samango, and Sofra-Weiss is not entitled to go on a "fishing expedition[]" to discover potential impropriety. United States v. Kim, 577 F.2d 473, 478 (9th Cir. 1978).

Moreover, the evidence Sofra-Weiss herself submits suggests that the Government relied on far more than the allegations of her rivals in deciding to pursue an indictment. For example, the affidavit of FDA Special Agent John Liam Gimon states that, acting in an undercover capacity, he had conversations with individuals in Sofra-Weiss's company who agreed to sell him the allegedly adulterated devices and misrepresented the status of their FDA approval. See Defendant's Exhibit 4 ¶ 31, ECF No, 36-7. To justify the dismissal of an indictment, "prosecutorial misconduct must (1) be flagrant and (2) cause 'substantial prejudice' to the defendant." United States v. Ross, 372 F.3d 1097, 1110 (9th Cir. 2004). Even if the Government omitted information about witnesses in its presentation before the grand jury that would not amount to flagrant prosecutorial misconduct, nor cause Sofra-Weiss "substantial prejudice," given the apparent presence of

significant other evidence.

Because Sofra-Weiss's speculative allegations, even if true, would likely be insufficient to justify the dismissal of the indictment, she cannot be deemed to have demonstrated the particularized need required to overcome the presumption of grand jury secrecy.

V. CONCLUSION.

To the extent Sofra-Weiss accepts that the Government's presentation of evidence to the grand jury was done in good faith, she is not entitled to challenge the validity of the indictment--and therefore not entitled to obtain the grand jury transcripts--simply because she disputes the adequacy of the evidence. To the extent Sofra-Weiss contends that the Government wilfully and in bad faith introduced false evidence, her claim is nothing more than speculation. See United States v. Ferreboeuf, 632 F.2d 832, 835 (9th Cir. 1980). ("Mere unsubstantiated, speculative assertions of improprieties do not supply the particular need required to outweigh the policy of grand jury secrecy.").

Sofra-Weiss's assertion that she requires the grand jury transcripts to uncover prosecutorial misconduct would be unpersuasive even under de novo review, let alone the deferential standard applicable to an appeal from a Magistrate Judge's nondispositive order. See Osband v. Woodford, 290 F.3d 1036,

1041 (9th Cir. 2002) ("A district judge may reconsider a magistrate's order in a pretrial matter if that order is 'clearly erroneous or contrary to law.'").

The Magistrate Judge's Order denying Defendant's motion to unseal grand jury transcripts is affirmed.

IT IS SO ORDERED.

DATED: Honolulu, Hawaii, January 23, 2013.

/s/ Susan Oki Mollway
Susan Oki Mollway
Chief United States District Judge