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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF WYOMING

CODY LABORATORIES, INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil No. 2:10-cv-00147-ABJ
	)	
THE HONORABLE KATHLEEN SEBELIUS, Secretary of Health and Human Services, et al.,	)	
	)	
Defendants.	)	

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR CLARIFICATION, AMENDMENT, OR RECONSIDERATION OF ORDER

INTRODUCTION

In their motion for clarification, amendment, or reconsideration of this Court's July 26, 2010, Order, plaintiffs seek to clarify whether the Court actually intended to dismiss the case and, if so, to clarify the basis for the dismissal. Pl. Motion at 2 and ¶¶ 13-16. Plaintiffs also seek reconsideration if the Court intended to dismiss the case. *Id.*

Plaintiffs' motion should be denied because the Order makes clear that the Court intended

to dismiss the case and also makes clear the basis for the dismissal. Contrary to plaintiffs' suggestion, *id.* at 5 (¶ 12), the dismissal of this case did not require reliance on "new legal ground," nor anything controversial, and reconsideration is not necessary.

ARGUMENT

I. THE COURT INTENDED TO DISMISS THE ACTION

The Order states: "[I]t is hereby ORDERED that Plaintiffs' Complaint, and this action are DISMISSED." Order at 37.[1] It could not be more plain that the Court intended to dismiss the case in its entirety. Although plaintiffs suggest that this was somehow improper because a motion to dismiss was not filed, Pl. Motion ¶¶ 11-12, this is not correct. After determining that it lacked jurisdiction, the Court was not required to await a motion to dismiss from defendants, hold a hearing, or follow any other set procedure. In fact, Federal Rule of Civil Procedure 12(h)(3) provides: "If the court determines *at any time* that it lacks subject-matter jurisdiction, the court *must* dismiss the action." (emphasis added). *See also Ins. Corp. of Ireland, Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982) (holding that a court can "raise lack of subject-matter jurisdiction on its own motion" and "the consent of the parties is irrelevant"); *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 551 n.1 (10th Cir. 1992) ("Because there is no statutory direction for procedure upon an issue of jurisdiction, the mode of its determination is left to the trial court.") (citation and quotation marks omitted);

[1] In this memorandum, citations are to the numbering at the top of the pages of the Court's Order.

Basso v. Utah Power & Light Co., 495 F.2d 906, 909 (10th Cir. 1974) ("A court lacking jurisdiction cannot render judgment but must dismiss the cause at any stage of the proceedings in which it becomes apparent that jurisdiction is lacking. . . . If the parties do not raise the question of lack of jurisdiction, it is the duty of the federal court to determine the matter *sua sponte*.").

Moreover, the issue of the Court's jurisdiction was addressed extensively in the government's opposition to the motion for preliminary injunction and at oral argument (at which time plaintiffs' counsel had ample opportunity to respond to the issue). It is clear that the Court intended to dismiss the case, and the Court was not required to await a motion to dismiss or to undertake any other type of procedure.

II. THE COURT STATED THE GROUNDS FOR DISMISSAL

Plaintiffs also argue that, if the Court did intend to dismiss the case, "it is not clear to Cody/Lannett from the Order whether the basis (or bases, if alternative grounds exist) for such dismissal was jurisdictional, justiciability, failure to state a claim, or some other grounds." Pl. Motion ¶ 13. In its detailed 37-page Order, however, the Court explicitly stated that it lacked jurisdiction:

> Plaintiffs have no likelihood of success on the merits. Indeed, this court has no jurisdiction to grant the relief requested by plaintiffs. Plaintiffs seek declaratory and injunctive relief to prevent FDA from taking any enforcement action to remove their unapproved morphine sulfate solution from the market. Compl. ¶ 1. It has long been established that courts lack jurisdiction to enjoin FDA from initiating enforcement proceedings under the FDCA. *See Ewing [v. Mytinger & Casselberry]*, 339 U.S. 594 [1950].

Order at 16; *see also id.* at 19 ("Because the relief sought by plaintiffs is clearly foreclosed by *Ewing* and its progeny, plaintiffs' complaint must be dismissed."). Further:

> To date, FDA has taken no action against plaintiffs that constitutes final agency action. Because FDA's warning letters do not represent the consummation of FDA's process, determine any legal rights or obligations, or affect plaintiffs' legal rights, plaintiffs' claims are not ripe for review. For these reasons, the Court has no jurisdiction over plaintiffs' claims, and thus they have no likelihood of success.

Order at 25; *see also id.* at 21 (the fact that FDA has not issued a final decision "'[w]eighs strongly in favor of dismissal'"); 22 (noting that plaintiffs "have the burden of identifying . . . 'final agency action'" and that "[p]laintiffs have not met, and cannot meet, that burden here.").

The Court made clear that it did not reach the merits of plaintiffs' claims:

> By their very nature, plaintiffs' claims cannot be evaluated as a question of pure law. An enforcement action brought on behalf of FDA by the United States Department of Justice . . . would provide the appropriate forum to resolve the factual basis for plaintiffs' dispute.

Order at 20. Also,

> If this Court were to become involved in this matter now, it would need to apply the criteria in FDA's regulations to plaintiffs' drug and undertake an evaluation to determine whether plaintiffs' have produced sufficient evidence in support of their claim that their drug meets the requirements of the 1938 grandfather clause and is not a "new drug."

Order at 20-21. *See also Brereton v. Bountiful City Corp.*, 434 F.3d 1213, 1218 (10th Cir. 2006) ("[T]he court, having determined that it lacks jurisdiction over the action, is incapable of reaching a disposition on the merits of the underlying claims.").

Thus, the Court did not reach the "ultimate issues" regarding whether plaintiffs' product is a new drug or whether it is grandfathered. *See* Pl. Motion ¶ 15. The Court's statements on these issues, *see id.* at 5 n.4, pertained to whether plaintiffs had a likelihood of success on the merits, but were not a ruling on the merits. *See* Order at 25-30.

It is unclear what further "clarification" could possibly be necessary in order for plaintiffs "to evaluate [their] options moving forwarding [sic]." Pl. Motion ¶ 13. The Court's July 26 Order of dismissal is a final, appealable order that needs no clarification or reconsideration. *See Moya v. Schollenbarger*, 465 F.3d 444, 450 (10th Cir. 2006) (dismissal of action is a final, appealable order).

CONCLUSION

For the foregoing reasons, plaintiffs' motion for clarification, amendment, or reconsideration of the Court's July 26, 2010, Order should be denied.

DATED this 6th day of August, 2010.

Respectfully submitted,

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CERTIFICATE OF SERVICE

IT IS HEREBY CERTIFIED that on August 6th, 2010, a true and correct copy of the foregoing *Memorandum in Opposition to Plaintiffs' Motion for Clarification, Amendment, or Reconsideration of Order* was electronically filed and consequently served upon all counsel of record.

Melody Morse
Office of the United States Attorney