IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

FARM-TO-CONSUMER LEGAL DEFENSE FUND, et al.,	)	
Plaintiffs,	)	
v.	)	No. C 10-4018-MWB
KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services, et al.,	)	
Defendants.	)	

DEFENDANTS' BRIEF IN SUPPORT OF RESISTANCE TO PLAINTIFFS' MOTION TO ADMIT NEWLY EVIDENCE

The United States Department of Health and Human Services ("HHS"), Kathleen Sebelius, in her official capacity as Secretary of HHS, and Margaret Hamburg, Commissioner of Food and Drugs, United States Food and Drug Administration ("FDA") (collectively, "defendants") submit this brief in support of their Resistance to plaintiffs' Motion to Admit Newly Discovered Evidence ("Motion to Admit"). Plaintiffs' Motion to Admit should be denied as it is merely a belated bid to file a sur-reply and/or introduce evidence on a motion that has already been briefed, argued, and submitted. Furthermore, the evidence does not materially alter any facts or argument raised by the parties in litigating the Motion to Dismiss, does not entitle plaintiffs to discovery, and does not obviate the need for plaintiffs to file a citizen petition.[1]

[1] Defendants contend that discovery is inappropriate here where plaintiffs appear to seek "judicial review based on an administrative record." See LR 16.d.1. If plaintiffs wish to know what "FDA considers the conduct described by plaintiffs in their amended complaint," they should use the avenue open to them for obtaining such an advisory determination: FDA's citizen petition process. 21 C.F.R. § 10.45(b).

I. PROCEDURAL HISTORY

Defendants filed their Motion to Dismiss on April 26, 2010, (Dkt. No. 10). Plaintiffs filed their Motion for Leave to File Over length Brief in Resistance ("Resistance Brief") on June 14, 2010, (Dkt. No. 15). On June 15, 2010, counsel for plaintiffs were forwarded an email written by an FDA employee at approximately 10:00 AM (the "10:00 AM email") that same day. Motion to Admit, Ex. 1. On June 24, 2010, prior to a conference call arranged by counsel for plaintiffs "to discuss how best to present this newly discovered evidence to the Court," counsel for plaintiffs forwarded the 10:00 AM email to counsel for defendants. See id., Ex. 3. In response shortly thereafter, counsel for defendants forwarded to counsel for plaintiffs an email written at approximately 7:30 PM (the "7:30 PM email") on June 15, 2010, by the same FDA employee who wrote the 10:00 AM email. Id., Ex. 4. On July 15, 2010, this Court ordered a telephonic hearing on the Motion to Dismiss to be held on July 22, 2010, (Dkt. No. 20). At the conclusion of that hearing, this Court reserved judgment and had not yet ruled on the Motion to Dismiss by the time plaintiffs filed their Motion to Admit on July 24, 2010.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 60(b) provides a means to relieve a party from an order or proceeding for several reasons, including, but not limited to, "mistake, inadvertence, surprise, or excusable neglect," and "newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b)." See Fed. R. Civ. P. 60(b)(1), (b)(2); see *O.N. Equity Sales Co. v. Pals*, 551

F. Supp. 2d 821, 828 (N.D. Iowa 2008) (citing *Greyhound Lines, Inc. v. Wade*, 485 F.3d 1032, 1036 (8th Cir. 2007)) (internal citations omitted).

III. ARGUMENT

In their July 24, 2010, Motion to Admit, plaintiffs mischaracterize emails that have been in their possession for over a month as "new" or "newly discovered" in a belated bid to introduce them in resistance to defendants' Motion to Dismiss that was briefed, argued, and submitted on July 22, 2010. By waiting until after the hearing to submit the emails, plaintiffs have deprived defendants of a proper opportunity to respond. Nothing in these emails is material to plaintiffs' resistance to defendants' Motion to Dismiss, and the emails will not produce a different result if admitted.

A. The Emails Are Not Newly Discovered and Plaintiffs Are Not Entitled to Re-Argue Their Resistance to the Motion to Dismiss.

A motion pursuant to Rule 60 "is not a vehicle for simple re-argument on the merits." *Broadway v. Norris*, 193 F.3d 987, 990 (8th Cir. 1999). Rule 60(b) "authorizes relief based on certain enumerated circumstances (for example, fraud, changed conditions, and the like)." Id. None of those circumstances are present here.

By July 15, 2010, the date the time this Court set a hearing on defendants' Motion to Dismiss, plaintiffs had been aware of the 10:00 AM email for thirty-one days and of the 7:30 PM email for twenty-two days. During that time, plaintiffs' counsel arranged a telephone conference with defendants' counsel to discuss the emails, but did not amend their Resistance Brief or pleadings. And despite being given seven days of notice by the Court that a hearing on the matter was to take place, plaintiffs did not avail themselves of that time to supplement their papers. Plaintiffs also had an

opportunity to bring these emails to the Court's attention during the hour-and-one-half-long hearing on defendants' Motion to Dismiss, but plaintiffs failed to do so.[2] By waiting until now to raise this issue and denying defendants a proper opportunity to respond, plaintiffs have hardly made an "adequate showing of exceptional circumstances" needed to justify the "extraordinary relief" they seek under Rule 60. *See O.N. Equity Sales Co.*, 551 F. Supp. 2d at 828 (citing *Jones v. Swanson*, 512 F.3d 1045, 1047-48 (8th Cir. 2008)).

B. The Emails Will Not Produce a Different Result Because They Neither Constitute Official FDA Policy Nor Bind the Agency.

Taken together, these emails clearly do not articulate some official policy regarding the transportation of raw milk by consumers who purchase raw milk in a state where such sales are legal and take it to another state, where the sale of raw milk is not legal, for their personal consumption. Nor do these emails establish that FDA has taken or intends to take enforcement action against individuals so situated. The substance of the emails is ambiguous, if not absolutely contradictory.

Moreover, FDA regulations clearly state that communications like these emails are not official policy statements of the agency. Title 21, Code of Federal Regulations, Section 10.85(k) provides, in part: "A statement or advice given by an FDA employee orally, or given in writing but not under this section or §10.90, is an informal communication that represents the best judgment of that employee at that time but . . . does not necessarily represent the formal position of FDA, and does not bind or

[2] Had plaintiffs offered the emails at the hearing, they had an additional three days to file them with the Court as exhibits. See Hearing Minutes (Dkt. No. 23).

otherwise obligate or commit the agency to the views expressed." Even if the emails could be construed as an interpretation of law by this FDA employee, it is well-settled that the government is not bound by the unauthorized acts of its agents or by acts that exceed the scope of an agent's authority. *Fed. Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 384 (1947); *DeVilbiss v. Small Bus. Admin.*, 661 F.2d 716, 718 (8th Cir.1981). Both emails were written by an FDA press office employee who has not been delegated decision-making authority by statute or regulation.[3] See FDA, *Staff Manual Guides, Vol. II,* § 1410.21 (listing a discrete number of officials—none of whom are press office employees—who are "authorized to perform all delegable functions of the Commissioner [but] may not further redelegate this authority, or any part of this authority, except as elsewhere specified") (available at: http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm049543.htm). Thus, neither email can advance plaintiffs' resistance to the Motion to Dismiss.

IV. CONCLUSION

For all of the foregoing reasons, plaintiffs' Motion to Admit Newly Discovered

[3] Nor is this employee an attorney. It is clearly not within the scope of a press office employee's duties to provide legal advice to the public about the Public Health Service Act and the regulations promulgated pursuant to same.

Evidence is without legal basis. Defendants respectfully request that this Court decline to grant the relief requested by plaintiffs in their motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 30, 2010, I electronically filed the foregoing with the Clerk of the Court using the ECF system which will send notification of such filing to the parties or attorneys of record.

BY: /s/ D. Nash