

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

<b>Farm-to-Consumer</b>	:	<b>Case No. 5:10-cv-4018</b>
<b>Legal Defense Fund, et al.</b>	:	
	:	
<b>Plaintiffs</b>	:	<b>Judge Mark W. Bennett</b>
	:	
<b>v.</b>	:	
	:	
<b>Sebelius, et al.</b>	:	
	:	
<b>Defendants</b>	:	

**PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY  
JUDGMENT**

Defendants make a fundamental mistake in resisting Plaintiffs' summary judgment motion and also mischaracterize Plaintiffs' arguments to avoid addressing the merits of Plaintiffs' claims. For these reasons, Defendants' arguments are not well taken and Plaintiffs' motion for summary judgment should be granted.

**I. FDA's reliance on an administrative record is misplaced.**

This is not an administrative record case; this is a declaratory judgment action presenting as-applied challenges to FDA regulations. Plaintiffs pointed this out to the Court when they filed their Rule 16 Statement on April 12, 2011. *See also Minnesota Citizens Concerned for Life v. Federal Election Com'n.*, 113 F.3d 129, 130 (8th Cir. 1997) (noting that the District Court, in a declaratory judgment action, properly denied discovery below because "only the regulation's facial validity [was] at issue."). Defendants did not object to this issue when the Court issued its Minute Entry and Order on April 15, 2011. *See* Doc. Nos. 47 and 48.

The seminal case on this issue is the line of cases that culminated with the United Supreme Court's decision in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 87 S.Ct. 1507 (1967).<sup>1</sup> All of those cases involved a declaratory judgment action that addressed the issue of whether there was anything in the Food, Drug and Cosmetic Act ("FDCA") that precluded a court from a pre-enforcement review of the legality of an administrative regulation issued by the FDA. In none of those cases did any court rely on an "administrative record" in reaching its decision. To the contrary, the U. S. Supreme Court stated that "the Administrative Procedure Act's 'generous review provisions' must be given a 'hospitable' interpretation." *Abbott Laboratories*, 387 U.S. at 140-141. Moreover, the District Court in *Abbott Laboratories* concluded that because FDA's rules were "properly here for a declaratory judgment it is not necessary to discuss the procedure for review of administrative rule making." *Abbott Laboratories v. Celebrezze*, 228 F.Supp. at 861 fn. 4.

Essentially, a court resorts to an administrative record when it is asked to review an agency's *factual* determination but not when purely legal issues are involved. Consequently, because Plaintiffs' challenge presents a legal issue about the validity of applying 1240.61 and 131.110 to Plaintiffs' conduct, Defendants' "administrative record" arguments on pages 1-8 of its Resistance are irrelevant to the issues presented by Plaintiffs in their motion for summary judgment.

**II. FDA's characterization of all raw milk as a communicable disease *per se* exceeds its statutory authority.**

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<sup>1</sup> See also *Abbott Laboratories v. Celebrezze*, 352 F.2d 286 (3<sup>rd</sup> Cir. 1965) and *Abbott Laboratories v. Celebrezze*, 228 F.Supp. 855 (D. Del. 1964).

FDA argues on pages 8 and 9 of their Resistance that the Public Health Services Act (“PHSA”) authorizes FDA to “prevent the introduction, transmission, or spread of communicable diseases.”<sup>2</sup> Although “communicable disease” is not defined by the PHSA, 21 C.F.R. 1240.3 defines “communicable diseases” as, in part, “illnesses due to infectious agents or their toxic products.” A communicable disease is something like tuberculosis, typhoid, malaria, HIV/AIDS, measles, mumps, rubella, etc., it is not a “thing” or an “object” like a bottle of raw milk. Thus, FDA makes a quantum illogical leap when it equates raw milk to a communicable disease.

FDA’s statement on page 8 of its Resistance that its ability to control communicable diseases “depends in large part [on] the ability to regulate the carriers of such diseases” constitutes an admission that FDA considers all raw milk as *per se* a communicable disease. In other words, even in the *absence* of the testing of any of the milk or in the absence of *any evidence* that the raw milk has been found to contain any “infectious agents or their toxic products,” FDA considers *all* such milk to be a “carrier” of a disease. Thus, FDA’s interpretation and application of 1240.61 and 131.110 to Plaintiffs’ conduct falls outside the authority granted to it under the PHSA.

FDA also cites to the infamous turtle case of *Louisiana v. Matthews*, 427 F.Supp. 176 (E.D. La. 1977) to support its illogical argument that all raw milk is *per se* a communicable disease. Counsel for Plaintiffs has read the *Matthews* case countless times and still cannot fashion a means of distinguishing it except to say

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<sup>2</sup> Thus, FDA’s authority under the PHSA is to regulate “communicable diseases,” not to regulate “interstate commerce.”

that: the *Matthews* case is simply wrong and had it been appealed to a higher court would probably have been reversed; this case is about milk (not cows) and not about turtles; this Court is not bound by a decision from a District Court in Louisiana; and that the prohibition on the sale of turtles or turtle eggs was not limited to interstate commerce but extended to “any other type of commercial or public distribution.” *See* 21 C.F.R. 1240.61. In other words, the prohibition on the sale of turtles and turtle eggs is much broader than the prohibitions of 1240.61 and 131.110 and FDA exceeded its statutory authority when it deemed raw milk a communicable disease *per se*.

**III. 1240.61 and 131.110 have nothing to do with “honesty and fair dealing.”**

FDA admits on page 10 of its Resistance that the purpose of 21 C.F.R. 131.110’s standard of identity is to “inform consumers about the content of the milk they purchase and to protect against fraud and misrepresentation.” Consequently, if raw milk is labeled as raw milk, query the “fraud and misrepresentation?” Therefore, 131.110 is not a “standard of identity;” it is instead nothing more than a ban on the interstate distribution and sale of a legitimate product that is legal to consume in all 50 states and legal to sell and distribute in 28 states. In other words, 131.110 is FDA’s backhanded way to force the consumption of pasteurized dairy products.

FDA also makes the irrelevant argument on page 10 of its Resistance that it has “never initiated a single enforcement action” based on a violation of 131.110. Again, FDA has admitted in its answers to the Court’s questions *ante* that Plaintiffs are violating 131.110 so the question of whether FDA has or has not ever brought an

enforcement action for violating 131.110 has nothing to do with whether or not Plaintiffs' claims in this case are valid. In addition, FDA has issued at least one warning letter<sup>3</sup> to a farmer that refers to 131.110, thus, its allegation that Plaintiffs' claim is "not ripe" or is "not justiciable" rings hollow.

**IV. 1240.61 and 131.110 are *Ultra vires*.**

The PHSA authorizes FDA to prevent and control the spread of *communicable diseases* but it does not authorize FDA to regulate the commercial distribution of dairy products in interstate commerce. However, FDA argues on page 12 of its Resistance that the PHSA authorizes it to "prevent the transmission of disease, etc. 'from one State or possession into any other State or possession.'" In making this argument, it appears FDA is claiming the "spread" of disease from "one State to another" is a commercial activity that can be regulated under the PHSA. In other words, FDA suggests that there is a commercial market for commodities that cause communicable diseases. That argument makes no sense and reinforces the notion that 1240.61 and 131.110 are *ultra vires*.

**V. Plaintiffs are not engaged in interstate commerce.**

FDA argues on pages 13-14 that "this Court has held already" that Plaintiffs are engaged in interstate commerce. Plaintiffs cannot find any such holding in this Court's order that denied FDA's motion to dismiss. *See* Doc. #27. The Court's use of the word "plausibly" is interpreted by Plaintiffs to mean just that, "plausibly," or in other words "it could be" or "perhaps." Had this Court meant to "hold" that Plaintiffs were engaged in interstate commerce it surely would have clearly stated so instead

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<sup>3</sup> See Doc. No. 15-3, pg. 6.

of citing to *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 92 (1964) and *United States v. Sullivan*, 332 U.S. 689, 696 (1948).

FDA argues on pages 14 and 15 that Congress' authority under the commerce clause is so broad and "plenary" that it includes "any personal article being carried across state lines" and cites to *United States v. Hill*, 248 U.S. 424 (1919) and *United States v. Simpson*, 252 U.S. 465 (1920) in support. If that is the case then everything anybody does, whether of a commercial nature or not, that involves crossing state lines is "commerce." The U. S. Supreme Court would not agree with FDA's argument and once again, as it did with the *Ewing* case in its motion to dismiss, FDA is mischaracterizing case law to this Court.

Both *Hill* and *Simpson* involved a federal statute adopted during the Prohibition Era that made it a crime to take liquor across State lines into a State *if the State itself prohibited the manufacture of liquor within its borders*. However, the statute in both *Hill* and *Simpson* was subsequently repealed and thus neither *Hill* nor *Simpson* remain good law. In addition, the analysis in *Hill* and *Simpson* has been rejected by the U. S. Supreme Court in *U.S. v. Lopez*, 514 U.S. 549 (1995), which held that some form of "commercial activity" must be involved before Congress can regulate it under the commerce clause. Thus, the mere act of taking one's personal property across State lines cannot be described as "interstate commerce."

FDA argues on pages 15 and 16 of its Resistance that interstate commerce includes "the whole transaction" and cites to the *Bruhn's Freezer Meats of Chicago* and *Barnes* cases in support. As Plaintiffs previously stated, *Bruhn's Freezer Meats* involved the Packer's and Stockyard Act that specifically defined interstate

commerce to include any article “with the expectation that they will end their transit, after purchase, in another [state].” Neither the FDCA nor the PHSA have such statutory language. Moreover, if Plaintiffs purchase their products in a State, when does the “transaction” end? Under FDA’s argument, there would never be an end to “commercial” transactions.

As for the *Barnes* case, that court expressly followed *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 92 (1964) and *United States v. Sullivan*, 332 U.S. 689, 696 (1948) in pronouncing that the purpose of the FDCA “is the protection of the consuming public.” The *Barnes* court also stated that “transactions” that involve transportation across State lines must involve transportation across State lines “of which such transporting is a part.” *Barnes v. U.S.*, 142 F.2d at 651. In other words, intra-state transactions initiated and completed by the consumer come to an immediate end and the subsequent transportation of the article across State lines does not encompass “interstate commerce.”

FDA then suggests on page 17 that the case relied on by Plaintiffs, *U.S. v. Ruffin*, 490 F.2d 557 (8<sup>th</sup> Cir. 1974), has been “overruled” by the United States Supreme Court in *Barrett v. United States*, 423 U.S. 212 (1976) but yet again FDA is mischaracterizing a case to this Court. In *Ruffin*, the issue before the 8<sup>th</sup> Circuit was whether 18 U.S.C. 922 prevented a convicted felon from receiving a firearm in interstate commerce. The *Ruffin* court held that interstate commerce was not involved and thus 18 U.S.C. 922 did *not* prohibit a convicted felon from receiving a firearm in *intrastate* commerce.

The issue before the U. S. Supreme Court in *Barrett*, on the other hand, was

whether 18 U.S.C. 922 prohibited a convicted felon from receiving a firearm via both interstate *and* intrastate commerce. The *Barrett* court stated that Section “922(d) prohibits a licensee from knowingly selling or otherwise disposing of any firearm (whether in an interstate or intrastate transaction, *see Huddleston v. United States*, 415 U.S., at 833, 94 S.Ct., at 1273) to the same categories of potentially irresponsible persons.” *Id.* at 218. Consequently, the *Barrett* court did not “overrule” the *Ruffin* court on its analysis of the distinction between intra- and interstate commerce. Rather, the *Barrett* court overruled the *Ruffin* court on whether convicted felons are prohibited from receiving firearms via both inter- and intra-state commerce.

**VI. 1240.61 and 131.110 violated Plaintiffs’ right to travel and their right to privacy.**

FDA insinuates on page 18 that if Plaintiffs win this case, there would be dangerous “consequences” in the government’s ability to “protect the public health.” That is not true. The government could still protect the public’s health, safety and welfare. It would just not be able to prohibit the citizens of this country from exercising their constitutional and inalienable rights.

FDA also suggests on page 19 that Plaintiffs’ case is merely an “attempt to circumvent state public health laws.” That also is not true. This case is about the government’s attempt under the guise of “the public’s health, safety and welfare” to circumvent the citizenry’s liberty to exercise their rights.

**VII. Conclusion.**

The Defendants in this case are wrong. They do not have the statutory authority to interfere with Plaintiffs’ right to travel; to interfere with their right to privacy; to interfere with their right to a healthy body; to decree that all raw milk in

any form whatsoever constitutes a communicable disease *per se*; to mandate under the guise of a “standard of identity” that only pasteurized dairy products can be taken across State lines; or that an agent is prohibited from doing what an individual is allowed to do.

For these reasons and for the reasons stated in their motion for summary judgment, Plaintiffs are entitled to a summary judgment in this matter.

Dated: July 8, 2011

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on July 8, 2011, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system that will send notification of such filings(s) to the following:

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