BEFORE THE UNITED STATES DISTRICT COURT DISTRICT OF COLUMBIA

Farm-to-Consumer Legal : Case No. 1:08-cv-01546-RMC

Defense Fund, et al. :

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Plaintiffs : Judge Rosemary M. Collyer

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v. :

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U.S. Department of Agriculture, et al. :

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Defendants :

PLAINTIFFS' SUR-REPLY TO USDA'S MOTION TO DISMISS FIRST AMENDED COMPLAINT

In accordance with this Court's Minute Order of April 29, 2009, Plaintiffs present their Sur-Reply to address the issue of the origination and authority of a Premises Identification Number ("PIN").

I. Introduction

USDA lacks legislative authority to require a PIN yet it does have legislative authority under the Animal Health Protection Act, 7 U.S.C. 8301 *et seq.*, to enter into "cooperative agreements" with States in order to eradicate tuberculosis ("TB"). *See, e.g.,* 9 CFR 77.4(a)(3). The USDA and Defendant Michigan Department of Agriculture ("MDA") have entered into a series of such agreements ("Memorandum of Understanding" or "MOU") yet nothing in the AHPA that authorizes an MOU authorizes the registration of premises, the collection of private data, or the issuance of a PIN.

USDA and MDA have executed MOUs from 2002 to 2007. Over that time period, those MOUs have incorporated the PIN requirement in the State of Michigan and have followed the Federal-State-Tribal partnership that USDA has proclaimed is critical to the implementation of the National Animal Identification System ("NAIS").

Consequently, the PIN that is at issue in this case, one of the three prongs of NAIS, is the result of a partnership between USDA and MDA. The PIN program was developed and structured by USDA, who retains the data collected and transmitted by MDA.

As a result, Plaintiffs have standing to bring the claims alleged in their First

Amended Complaint because <u>both</u> Defendants in this case are imposing a hardship on Plaintiffs.

II. USDA's 2004 interim and 2007 final rules establish a nationwide, standard and uniform PIN.

In November 2004, USDA proposed a rule that added new definitions to each of several USDA regulatory programs in order to standardize the various databases that were being utilized by the Federal and State governments to track animal disease. Two of the new definitions were "Animal Identification Number" or AIN and "Premises Identification Number" or PIN. *See* Administrative Record filed by USDA, NAIS AR 1740. The 2004 proposed rule was issued final in July 2007 and the following USDA animal disease programs were amended to include these new regulatory definitions: General Provisions (9 C.F.R. Part 71); Tuberculosis (9 C.F.R. Part 77); Brucellosis (9 C.F.R. Part 78); Scrapie in Sheep and Goats (9 C.F.R. Part 79); and Johne's disease in domestic animals (9 C.F.R. Part 80). *See* NAIS AR 1748.

The USDA discussed the significance of these new definitions and the use and policy behind the PIN and AIN in the preamble to the 2007 final rule. Specifically USDA stated the following in the preamble:

Additionally, the rule amends the regulations to authorize the use of a numbering system to identify premises where animals are managed or held.

These new numbering systems [the AIN and PIN] are key elements in the

National Animal Identification System (NAIS).

Since the NAIS is a national system, it is important that each AIN be nationally unique and that duplication be avoided.

Because a uniform animal identification numbering system is needed to make the NAIS successful, we do intend that, in the future, only the "840" AIN will be recognized for official use, to the extent practical.

We view [pre-existing] numbering systems as transitional, however, and anticipate phasing them out as we progress toward full implementation of the NAIS.

As with the AIN, it is important to avoid duplication with the PIN. We are amending the definition of *premises identification number (PIN)* in this final rule to indicate that it is a nationally unique number.

While it is a State or Tribe's responsibility to maintain the system to register premises within its geographic area and to be the direct contact for producers registering their premises, the NAIS, as a State-Tribal-Federal cooperative program, necessitates cooperative efforts for the interpretation of premises definitions to ensure consistent interpretation nationwide. The definition of *premises identification number (PIN)* contained in the interim rule reflected the cooperative nature of this enterprise, a point we are further reinforcing by adding the reference to Tribal authorities to the definition in the final rule.

The PIN is intended to identify a geographical location where livestock or poultry are managed or held rather than the species present at the premises.

Thus, the purpose of the 2007 final rule was to establish uniformity in the Federal-State-Tribal administration of animal disease programs nationwide and the AIN and PIN requirements were an integral part of that strategy.

The new definitions created by the 2007 final rule officially amended the following regulations: 9 C.F.R. 71.1, 77.2, 78.1, 79.1 and 80.1. Except for the definition of PIN in 77.1 (which also refers to a Group Identification Number or GIN as an acceptable form of PIN), each definition is exactly the same in each section. For instance, AIN is defined under each program as follows:

A numbering system for the official identification of individual animals in the United States providing a nationally unique identification number for each animal. The AIN contains 15 digits, with the first 3 being the country code (840 for the United States), the alpha characters USA, or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording. The AIN beginning with the 840 prefix may be used only on animals born in the United States.

PIN is defined under each program (except the Brucellosis program in 78.1 which incorporates the definition of PIN in 77.1) as follows:

A nationally unique number assigned by a State, Tribal, and/or Federal animal health authority to a premises that is, in the judgment of the State, Tribal, and/or Federal animal health authority, a geographically distinct location from other premises. The premises identification number is associated with an address, geospatial coordinates, and/or location descriptors which provide a verifiably unique location. The premises identification number may be used in conjunction with a producer's own livestock production numbering system to provide a unique identification number for an animal. The premises identification number may consist of:

- (1) The State's two-letter postal abbreviation followed by the premises' assigned number; or
- (2) A seven-character alphanumeric code, with the right-most character being a check digit. The check digit number is based upon the ISO 7064 Mod 36/37 check digit algorithm.

The second half of this definition refers to the NAIS numbering system.

As described in the next section, USDA generates a "PIN allocator;" the PIN is actually assigned by either the States or the Tribes; and the data generated by the PIN is stored by USDA in a national database. Thus, NAIS' use of a PIN is achieved only by Federal-State-Tribal cooperation.

Moreover, the NAIS AIN and PIN are inextricably tied together. As USDA itself has stated in its User's Guide, Version 2, December 2007 ("User's Guide"), "in order for

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¹ 9 C.F.R. 77.1 includes this single additional sentence "It may also be used as a component of a group/lot identification number (GIN)" right before the last sentence that begins with "The premises identification number may consist of:"

producers to obtain official identification devices [i.e., an AIN], they first need to register for a premises identification number." *See* Administrative Record filed by USDA, NAIS AR 1394. Although USDA did not include this requirement in the formal regulations, Plaintiffs contend that this requirement has been enforced across the country. In other words, a producer *must* get a PIN generated by USDA and held in USDA's database in order to get an AIN. This requirement was developed and enforced by USDA. As a result, when Plaintiffs were mandated by MDA to obtain AINs for their cattle USDA's requirement for a PIN was also imposed on them.

III. USDA's own documents describe how PINs are to be generated and assigned.

USDA's User's Guide (NAIS AR 1381-1443) was developed to "provide the public with basic information about" NAIS and describes NAIS as a "State-Federal-industry partnership." NAIS AR 1384, 1390. The User's Guide describes premises registration as "the foundation of NAIS" and admits that a PIN's information is "held in databases maintained by the States and by USDA." NAIS AR 1391.

The User's Guide describes the various roles of the States, Tribes and Federal governments and Industry. NAIS AR 1399. For instance, States/Tribes, in part: "maintain premises registration systems; identify and register premises within their geographic areas; submit premises data to USDA's National Premises Information Repository." NAIS AR 1399, 1405. Industry, in part, has been chosen to "develop and maintain animal tracking databases." NAIS AR 1399. Finally, USDA has been chosen to "develop and maintain the National Premises Information Repository and premises number allocator and provide the Standard Premises Registration System for States and Tribes." NAIS AR 1399, 1405. If ever there was a partnership, it is NAIS.

Finally, the User's Guide describes the "process for collecting" PIN information. For example, each State and Tribe "adheres to the national data standards and guidelines for premises registration established by USDA." NAIS AR 1405. Specific types of information is required to be collected, e.g., PIN, name, address, phone number, latitude/longitude coordinates, etc., yet States or Tribes "may choose to collect additional information." NAIS AR 1405. States/Tribes are required to "forward a subset of information to USDA's National Premises Information Repository." NAIS AR 1405.

In addition to the User's Guide, the 2007 Draft Business Plan also makes several statements on how the PIN is generated and how responsibilities are allocated. For example, the Business Plan states that USDA "will take steps to standardize data elements in existing disease programs" by using "a consistent data format that identifies premises importing and exporting livestock." NAIS AR 1454. States "play a critical role in advancing national animal disease traceability" and USDA will work "in close partnership with State, Tribal, and Territorial officials." NAIS AR 1455. Moreover, USDA will "continue to facilitate the development of each State's disease traceability infrastructure." NAIS AR 1455.

The Draft Business Plan also clearly provides that the entire point of NAIS is to create a uniform *national* system, something that only USDA can do. Indeed, the Business Plan states: "Since 2004, USDA has been working to establish the NAIS PIN as the standard format for location identifiers." NAIS AR 1482. USDA claims that it is the "lack of standardization of data elements and integration within U.S. animal health data systems" that poses the greatest challenge to tracking animal disease. NAIS AR 1458. To accomplish this alleged goal, States and Tribes will "use established standards to

register premises within respective geographic regions and maintain Premises

Registration Systems." NAIS AR 1461. This is especially true for the cattle, swine,
horse and sheep industries, where USDA recommends required use of standardized PINs.

See NAIS AR 1471, 1473, 1477, 1479. Finally, USDA states that either guidelines or
"regulations for the use of the PIN in health certificates and permits will be a top APHIS
priority." NAIS AR 1483. Thus, the 2007 Business Plan reinforces this partnership.

In addition to the User's Guide and the 2007 Business Plan, USDA has issued two Veterinary Services ("VS") Memos, No. 579.19, which further describe this partnership, which now includes partnering with private veterinarians. The first memo, effective September 2008, announced how USDA was going to implement its VS "cooperative animal disease program activities," stating that its purpose is to provide guidance to "VS personnel, state cooperators, and accredited veterinarians" on how to implement the premises registration component of NAIS. *See* Plaintiffs' Opposition to USDA's Motion to Dismiss First Amended Complaint, Exhibit V, pg. 1. MDA is designated as a "cooperating state" and all private veterinarians that do TB testing are designated as "accredited veterinarians." *See, e.g.,* 9 CFR 77.2.

The September 2008 VS memo identified several actions, for example, a vaccination, a diagnostic test, an epidemiologic investigation, a routine inspection or an appraisal, that would trigger the registration of a premises and the requirement to obtain and record an individual's personal, private data. If the person responsible for the premises "chooses not to complete the form to register his/her premises" then either a State or Federal animal health official, or even a private veterinarian, will "collect the defined data fields" which will then "be provided to the State so the records may be

added electronically to the State's premises registration system." See Exhibit V, pg. 2.

The September VS Memo also provided that private veterinarians who collect the data will do so "for submission to the State or Federal office in that State for interfacing with the Allocator to obtain a PIN for the premises" and that the PIN will be "provided to the appropriate databases." Exhibit V, pgs. 2, 3. The September 2008 VS memo concludes by stating that from "the date of issuance of this VS Memorandum, all PINs issued in accordance with this policy will be included in all NAIS premises registration statistical summary reports." Exhibit V, pg. 3.

The September 2008 VS Memo raised such a public outcry that it was rescinded by a December 2008 VS Memo 579.19. *See* Exhibit W, attached to Plaintiffs' Opposition to USDA's Motion to Dismiss First Amended Complaint. The December 2008 VS Memo reiterated USDA's policy for using PINs in administering animal disease programs under the AHPA and specifically stated that PINs will refer to "all location identifiers issued for VS disease program activities;" that all locations where VS personnel conduct disease program activities "will be identified with a standardized PIN;" and that private veterinarians "while not directly involved in the issuance of the PIN, will collect the defined data fields on official disease program forms ... for submission to the State or Federal office in that State." *See* Exhibit W, pgs. 1, 4. Consequently, private veterinarians are now encompassed in this Federal-State-Tribal partnership to implement NAIS and its PINs on a national basis.

Perhaps the clearest evidence of this partnership consists of the PIN wallet cards that were issued to Plaintiffs Dan Nolt and Robert Keyworth. Nolt is a resident of Pennsylvania and his wallet card clearly says "United States Department of Agriculture,

National Animal Identification System, Premises Identification Number" and that it was issued by the Pennsylvania Department of Agriculture. *See* Exhibit G attached to Plaintiffs' Opposition to USDA's Motion to Dismiss First Amended Complaint. Keyworth is a resident of Michigan and his card says "Michigan Livestock Premises Registration Card." *See* Exhibit M to Plaintiffs' Opposition to USDA's Motion to Dismiss First Amended Complaint. Neither Nolt nor Keyworth asked to have their premises registered nor to have their personal, private data transferred to a national database.

Thus, PINs reflect the partnership between Federal-State-Tribal authorities in implementing a national system, NAIS. Consequently, PINs are not only an MDA requirement, they are also a USDA requirement.

IV. The Zanoni case does not prove that the NAIS PIN is a State requirement.

In support of its argument that the PIN is a State and not a Federal requirement, USDA cites *Zanoni v. USDA*, C.A. No. 8-939, Mem. Op. (D.D.C. March 31, 2009). That case addressed Ms. Zanoni's Freedom of Information Act (FOIA) request for the identities and contact information of all the people in the NAIS premises registration database and requested information on those who had been removed from that database. The case did not directly address the question of whether the NAIS PIN is a Federal or State requirement but the court's opinion is replete with statements that are consistent with Plaintiffs' argument that the NAIS PIN is both a State and a Federal requirement. For example, the *Zanoni* court stated that "[t]he gathering of information for the [NAIS and NPIR] databases is conducted by the federal government with cooperation from the states." *See Zanoni* at p.2. The *Zanoni* court also noted that USDA's "APHIS processes

opt-out requests for the NPIR, and states are responsible for deleting the requesting

producer's information from the state database." *Id.* at p.3. Ms. Zanoni's request was

processed by the USDA's Office of Veterinary Services, "which, among other things,

maintains NAIS." *Id.* at p.4.

USDA also incorrectly claims that Mary Zanoni is a director of the Plaintiff

Farm-to-Consumer Legal Defense Fund ("Fund") and that Plaintiffs "cannot revisit" the

issues raised by the Zanoni case. See USDA Reply at note 1. However, Ms. Zanoni is

not and has not ever been a director of the Fund. The Directors of the Fund are listed on

the Fund's website and can be viewed at <u>www.ftcldf.org</u>. Moreover, the FOIA requests

referenced in Plaintiffs' opposition brief, which were submitted by one of the Fund's

directors, sought the scientific studies that were used to develop NAIS in general and the

NAIS Business Plan in particular. See Exhibit C attached to Plaintiffs' Opposition to

USDA's Motion to Dismiss First Amended Complaint. Thus, the Zanoni case has

nothing to do with Plaintiff Fund or the FOIA requests referenced in Plaintiffs'

Opposition.

V. Conclusion

PINs are integral to the NAIS, which is a partnership between Federal-State-

Tribal governments. Consequently, PINs are required by both Defendants in this case.

Dated: May 6, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 6, 2009, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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