Colostrum Therapy Legal Evaluation

Introduction

Mammalian colostrum has historically provided man with both food and medicine. Of course, only the larger mammals -- cows, goats, etc. -- economically provide sufficient colostrum.

For generations either keen observation or superstition has led the dairy farmer to rub infectious fluids on the outside of the milk sac, whence the dairy cow (or goat) absorbed microorganisms and proceeded to prepare antibodies and complement that invaded the milk to some small degree, thence providing an inefficient source of protective fluids.

Modern medicine has fully accepted the paradigm that the insertion of an antigen into the blood stream of any mammal hastens the development of protective antibodies.

What modern medicine has forgotten is that the chief purpose for this vaccination is so that the mammal will produce complement, a very small, specially designed protein molecule that clones itself over and over again, targeting, surrounding and destroying invading microorganisms and other invasive antigens. To make a rather long, complex story short, the many major immune defensive mechanisms we've inherited usually results in producing a complement cascade, which, working together with antibodies, overwhelms an invading organism. (See "How the Immune System Works," http://www.arthritistrust.org.)

Apparently a key survival advantage found in mammals is that, in nursing one's young, antibodies and complement is passed directly from the mother to the offspring, thus protecting the newly born until the newly born's own protective systems are more fully developed. It's clear from direct observations of the application of specially targeted complement, that the demise of microorganisms is fantastically swift.

When *Townsend Letters for Doctors & Patients* reported on former Congressman Berkeley Bedell's speech before Congress relating his apparent miraculous cure from his otherwise instransigent Lyme Arthritis Disease, The Arthritis Trust of America's curiosity was greatly stimulated. The result of that curiosity was reported in part in *Townsend Letters for Doctors & Patients*, but more fully in "Universal Oral Vaccine" Versions 1, 2 and 3 found on our website (http://www.arthritistrust.org.).

(Of great significance is that thru the influence of Congressman Berkely Bedell and Iowa Senator Tom Harkin the U.S. Congress was prompted to establish an Office of Alternative Medicine under the National Institute of Health. This Office has now been upgraded to a Center by Senators Tom Harkin and Arlen Specter, and Representative Peter DeFazio.)

Very briefly, what we uncovered regarding the medical usage of colostrum during the first investigative period, and following that period, is this:

1. People of all races and times have used colostrum for healing.

2. Numerous activities on-going involve the preparation and sale of colostrum to "boost the immune system." These are usually products that result from traditional vaccination of animals -- cows, goats, chickens (for the eggs) -- processed by modern technology to separate out complement/antibodies, and then sold.

Several multi-level marketing firms have successfully marketed their products either worldwide or in the US.

One US scientist from time to time vaccinates a large number of chickens, collects the eggs, and sells them to the army where they are mixed in K-rations, to "boost soldiers' immune systems."

Obviously, therefore, the United States Government is quite cognizant of the importance of supplying complement/antibodies directly for disease protection.

3. Some folks, here and there, have purchased either a goat or a cow, and, with the help of their local veterinarian, have injected specific microorganisms directly into the cistern and thence have collected colostrum for use against a specific disease.

In one recent case a Minnesota retired dairy farmer did just that to cure his daughter of Epstein-Barr Virus disease.

It's clear that most marketing of colostrum, including the army's K-rations, are a wild-eyed guess as to which microorganisms to use for disease protection. One can only include in the animal's vaccination regimen those microorganisms which are most likely to be encountered. The disease producing microorganism affecting a particular individual may or may not be the one found in the colostrum provided and, considering the factors of (a) enormous assortment of microorganisms in our environment, (b) their ability to mutate, and (c) often their pleomorphic nature, only a quick chemical appraisal of the human tissue's infectious contents will suffice for producing the near-miraculous cures desired.

One doesn't need an immense laboratory to determine the many possible infectious organisms that might be contributing to a specific disease as the mammal's cistern provides the quick chemical appraisal. Without further laboratory determinations, human blood will often provide the antigens necessary to produce the specific complements required for that human at that particular time.

This is not to argue that a range of well-known microorganisms should not also be used to prepare special complement/antibodies. Indeed, one company, Impro Products, Inc., of Waukon, Iowa, prepares a whole tray of such complement, using many different antigens, each 3.7 fluid ounce bottle marked accordingly -- gram negative, *Aerobacter aerogenes*, staphyloccous, streptococcus, etc.

It was truly miraculous, to watch the disappearance before our eyes of Psoriasis blotches when using Staphylococcus complement/antibodies on one sufferer. This was demonstrated by Herb Saunders, deceased dairy farmer.

The product he illegally (at that time) used was Impro's specially prepared product that is to be sold only to dairy farmers for use on animals. Impro, of course, did not know of the use of their product on a human or they would have objected violently, such is the nature of the fear inculcated by the FDA and U.S. Department of Agriculture.

To conclude, although there are many ways of preparing and using colostrum, only two methods have rapid, definitive effects:

1. Injection of patient's blood into the mammal's cistern, collection of subsequent colostrum, and applying same to suffering patient topically, sub-lingually and orally, as required.

2. Preparation of specially prepared colostrum by means of known antigens -- *Borrelia burgdorfia*, Staphyloccous, Epstein Barr Virus, etc. -- and applying same topically, sub-lingually, and orally, as required.

As reported in *Townsend Letters for Doctors & Patients*, but more fully in "Universal Oral Vaccine" Versions 1, 2 and 3 found on our website (http://www.arthritistrust.org.), the FDA investigated dairy farmer Herb Saunder's use of colostrum on sick people. They turned their investigation over to local authorities, and Saunders was

twice prosecuted, resulting in a hung jury in each instance.

Attorney Calvin Johnson, Mankato, Minnesota, together with attorney Diane M. Miller of St. Paul, Minnesota, provided a successful defense for Saunders.

Of great importance was their follow-on work, together with alternative/complementary medicine proponents, successfully encouraging the Minnesota government to change laws so that the use of colostrum in the manner performed by dairy farmer Herb Saunders would be legal.

Because of these changed laws, this foundation sought definitive legal evaluation aimed at the possibility of establishing a clinic in Minnesota that would be free to use colostrum on the sick.

The following analysis was performed by Diane M. Miller at the request of The Arthritis Trust of America.

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Colostrum Therapy Project
Research Memorandum

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This memorandum has been completed in response to a request to research the laws regarding the provision of colostrum therapy health care services in the state of Minnesota. The research does not include research on corporate or clinic structure or laws relating to the setting-up of a health care facility in general but rather focuses on the issues surrounding the use of colostrum therapy itself.

The proposed project (hereinafter referred to as The Project) would involve the set-up of a center where persons seeking health would come to the center and the center would guide them through a process as follows: each person would provide a small amount of whole blood which would then be injected into the udder of a pregnant cow exclusively earmarked for that individual, and the process would be repeated at specific intervals during the cows pregnancy, and upon the cow birthing, portions of the colostrum would be given to the person who had provided the whole blood to that particular cow so that the person could ingest the customized colostrum for their own healing. In addition, the project would include using specific antigens such as the spirochete *Borrelia burgdorfia* (Lyme Arthritis disease antigen) to produce colostrum for some patients.

Introduction

This project, although involving a seemingly straightforward plan, encompasses a large number of areas of law, the interplay of which are extremely complex. The memorandum spells out legal concepts that are relevant to the proposed project and their interrelationship with each other. The memorandum concludes with a summary and risk assessment for The Project.

Begin

Laws most directly impacting this project are the following:

1) Laws regarding substances regulated by federal and state governments and

2) State laws regarding health care practitioners and their ability to practice their trades, and public health laws.

Substances:

We begin with substance law because it helps clarify what the treatment actually will be and what laws will apply. Substances are generally regulated by federal and state laws and a discussion of when federal jurisdiction is limited to interstate commerce as opposed to federal jurisdiction over intrastate commerce will be important. In contrast, health care practitioner law is generally reserved to the states however there are certain circumstances where federal law impacts practitioner practices as well.

Firstly we review federal substance law to discern whether the Project's substances would be under the jurisdiction of the federal government. The project proposes to involve at least three substances, and all of which might potentially be regulated by federal laws and rules. The substances are:

1) Human blood;

2) *Borrelia burgdorfia* antigen; and

3) Immune colostrum.

The FDA is involved in the regulation of substances and its mission states in part that it

> "… is responsible for insuring that:
>
> Foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe.
>
> Regulated products are honestly, accurately and informatively represented.
>
> These products are in compliance with the law and the FDA regulations; noncompliance is identified and corrected; and any unsafe or unlawful products are removed from the market place in order to advance health and safety of the public by keeping interstate channels free from deleterious adulterated and misbranded articles of specified types." [1]

Identifying which category a substance is in is the first step towards guiding the path a substance will take within the law. According to federal law, relevant classifications for this project would be whether the substance is; a "drug", a "food", a "food additive", a "dietary supplement", a "human biologic", or an "animal biologic". Food and dietary supplements are generally regarded as presenting less potential for harm to the consumer and receive less regulation than new drugs or biologics. Substances added to food (food additive) are generally regarded as potentially more harmful than foods but less harmful than drugs. For purposes of this project it will be extremely important to determine whether a substance is considered a drug or biologic, or whether it is consider a food or dietary supplement.

The following definitions differentiate these categories.

The FDCA is the federal law for the Federal Drug Administration. The FDCA broadly defines "drug" as follows:

> "…(g)(1) The term "Drug" means
>
> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
>
> (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
>
> (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
>
> (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and

403(r)(3) of this title or sections 403(r)(1)(B) and 403(r)(5)(D) of this title, is made in accordance with the requirements of section 403(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement. [2]

NOTE: A key element in the definition of drug, and often times litigated, is whether a substance has an intended use and the statutory definition indicates that

> "whether a product is a drug depends on its intended application." [3]

The FDCA defines "food" as follows:

> "…(f) The term "food" means
> (1) articles used for food or drink for man or other animals,
> (2) chewing gum, and
> (3) articles used for components of any such article." [4]

NOTE: It is important to note that a food does not lose its status of food just because it puts a health claim label on it. Pre-approval of health claims is possible through special regulations of the FDA.[5]

The FDCA defines "dietary supplement" as follows:

> "…(ff) The term ''dietary supplement'' –
>
> (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
> (A) a vitamin;
> (B) a mineral;
> (C) an herb or other botanical;
> (D) an amino acid;
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
> (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
> (2) means a product that -
> (A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i) of this title; or
> (ii) complies with section 411(c)(1)(B)(ii) of this title;
> (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
> (C) is labeled as a dietary supplement; and
> (3) does -
> (A) include an article that is approved as a new drug under section 505 or licensed as a biologic under section 351 of the Public Health Service Act (42 USC 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f) of this title;and
> (B) not include -
> (i) an article that is approved as a new drug under section 505 of this title, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 USC 262), or
> (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter. [6]

The definitions of "drug", "animal drug", "food" and "dietary supplement" are all included in the FDCA law. However "human biologics" and "animal biologics" are referenced in other statutes. The history of FDCA is lengthy and complex, having been amended over 57 times since 1938[7]. Other federal laws with even earlier origins, include the Public Health Service Act (PHS) regulating human biologics[8], and the Virus, Serum and Toxin Act (VSTA[9]) under the U.S. Department of Agriculture and Animal and Plant Health Inspection Service regulating non-human animal biologics. These statutes interface with FDCA in direct and complex ways.

The PHS defines biological product as follows:

> "…(i) ''Biological product'' defined
> In this section, the term ''biological product'' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.
> (j) Application of Federal Food, Drug, and Cosmetic Act The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act (21 U.S.C. 355). [10]

NOTE: These biologics are applicable to treating humans.

The definition of animal biologics is found in VSTA under the Department of Agriculture laws as follows:

"It shall be unlawful for any person, firm or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories or in any place under the jurisdiction of the United States, or to ship or deliver for shipment in or from the United States, the District of Columbia, any territory of the United States, or any place under the jurisdiction of the united States, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as herein after authorized" [11]

Animal biologics are further clarified in terms of definition by the Code of Federal Rules as follows:

"….Biological products. The term biological products, also referred to in this subchapter as biologics, biologicals, or products, shall mean all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. The term ``biological products'' includes but is not limited to vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components, that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies.

(1) A product's intended use shall be determined through an objective standard and not a subjective one, and would be dependent on factors such as representations, claims (either oral or written), packaging, labeling, or appearance.

(2) The term analogous products shall include:

(i) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which are similar in function to biological products in that they act, or are intended to act, through the stimulation, supplementation, enhancement, or modulation of the immune system or immune response; or

(ii) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity; or

(iii) Substances, at any stage of production, shipment, distribution, or sale, which resemble or are represented as biological products intended for use in the treatment of animals through appearance, packaging, labeling, claims (either oral or written), representations, or through any other means.

(3) The term treatment shall mean the prevention, diagnosis, management, or cure of diseases of animals…." [12]

NOTE: These biologics are applicable for treatment of animals.

In the case of a "drug" the FDCA mandates that before a drug is marketed to the consuming public it's safety and efficacy must be established.

" Sec. 355 (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."[13]

The term "new drug" is defined as follows:

"(p) The term ''new drug'' means -

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a ''new drug'' if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." [14]

The application of each of these categories has it's own intricacies. For example, proponents of several natural unorthodox cancer

treatments (most notably laetrile) have argued that their drug was not a "new drug" within the meaning of the federal Act and that "experts" recognized its safety.[15] However they did not prevail in the courts[16]. In response to this dilemma, a number of states have passed laws allowing for the use of laetrile in their state, however there are concerns that if these state laws were challenged they might be preempted by the federal Act[17].

In the case of a "food" or "dietary supplement", the FDA may deem them misbranded if they make health claims outside of the federal regulatory allowances. Regarding food in particular:

> "Sec. 343. A food shall be deemed to be misbranded (r)(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication –
>
> (A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or
>
> (B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D). [18]

Dietary supplements hold a special place in the federal law. Referencing and regarding the paragraph (B) above, dietary supplements have a special ability to make labeling statements regarding health as follows:

> (6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if -
>
> (A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient, (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and
>
> (C) the statement contains, prominently displayed and in boldface type, the following: ''This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.
>
> A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made." [19]

The FDA has authority to make proposed regulations regarding labeling in order to promote, ban, or modify a proposed claim.[20] But only if it finds "significant scientific agreement" among experts that the claim is supported by available evidence. "Courts have indicated that the FDA must explain what it means by significant scientific agreement or at minimum what it does not mean."[21]

In the case of a "new drug", obtaining approval involves controlled clinical trials and large financial investments and an application for an IND (Investigational New Drug.) This can be very intimidating to a small producer with limited funds. However, even if a product has an intended drug purpose, a product is not a "new drug" within the meaning of the FDCA if its composition is such that it is "…generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof,…[22]

> *"A finding that a product is "generally recognized" by experts as safe and effective for its intended use must be supported by substantial evidence as defined in 21 U.S.C.A. Sec 355(d) (for new drugs)…"* [23]

An example of the importance of how a product is categorized is exemplified in U.S. v. Veterinary Products for Use[24]. This case dealt with colostrum for animal use. The United States attempted to condemn six products manufactured by Iowa company Immuno-Dynamics as unsafe and adulterated new animal drugs.

> *"Immuno-Dynamics protested the need for such approval, contending that these products are mere nutritional supplements or food and not drugs subject to FDCA regulation."* [25]

Since the statutory definition of a new drug indicates that

> "Whether a product is a drug depends on its intended application",

the courts accepted evidence of intent including product labels and promotional materials accompanying the product and any materials being distributed with the product that customers relied on.[26] The court then explored evidence regarding the concept that even if the product labeling or written materials evidence some intended drug purpose, a product is not a new animal drug if its composition is such that it is generally recognized among experts as safe and effective for use as suggested in the product's label or if, as a result of investigations to determine its safety and effectiveness, it has become recognized as safe and effective for the recommended use.[27] The Court of Appeals in this case agreed that it was proper to submit these questions to a jury and upheld the jury verdict in favor of Immuno-Dynamics that the products were not new drugs.[28]

However in an earlier case, U.S. v. Pro-Ag Inc.[29], the courts found that Impro Products Inc. of Waukon, Iowa, manufacturers of colostrum based products, could be enjoined from marketing these products in interstate commerce because the definition of drug applied to them

> "because they are designed and intended to

be applied directly to dairy cows and change the function of the cows." (affecting the milk production and the amount of feed required). [30]

In addition the courts found that the products were not shown to be generally recognized by qualified experts as safe and effective for their labeled indications thus they fell under the new drug regulatory requirements.[31]

In the case of a new drug requiring a new drug application, or of a food or dietary supplement wishing to make a health claim, research is an important component of the process. Companies that propose to develop drugs or health claims on products perform and collect this research to support their products and product applications for approval. In the case of food and dietary supplements that do not pose a risk of safety to the public, clinical trials are often set up, under a proper Independent Research Board (IRB,) within a state and according to all state laws regarding the subject matter, and following federal protocols for research and the use of human subjects. For "new drugs," intended for use in the treatment of disease, an IND may be necessary to proceed.

In addition to federal substance laws many states have their own mini-FDA laws, which regulate the manufacture and marketing of products intrastate (within the state). For example in many areas Minnesota law conforms closely with the federal Food, Drug, and Cosmetic Act requirements. But an example of non-conformity is Minnesota's rule 1720.0640 stating that the

> "rules shall not apply to biological products and antigens manufactured and sold exclusively for use in poultry;…"[32]

Jurisdiction:

The FDCA indicates that the FDA's jurisdiction over unapproved new drugs is limited to introduction into interstate commerce.[33] In addition, jurisdiction over interstate commerce can, in some circumstances, be extended to state activity where the state activity works to undermine the broad mission of the FDCA. Given these parameters, if a new drug is manufactured within a state and there is no intention of introducing a product into interstate commerce, it may be that the FDA will not be able to regulate. Two examples of this dynamic are as follows:

The Burzynski cases had to do with Dr. Burzynski MD, and a substance used to treat human disease. In 1985, Dr. Burzynski MD of Texas, was enjoined by FDA from distributing an unapproved and controversial cancer treatment that he had himself manufactured in the state of Texas. In this case, the agency obtained injunctive relief under the new drug provisions of the FDCA, which prohibit introduction of unapproved new drugs into interstate commerce. The agency's relief did not extend to intrastate sales.[34] However soon thereafter the state of Texas Board of Medical Examiners attempted to stop his activities under Texas law. In 1996, after a long legal path, a Texas Court of Appeals upheld the Texas Board of Medical Examiners order that suspended Dr. Burzynski's license to practice medicine based on an interpretation of Texas law that

> "….does not allow physicians to prescribe non-FDA approved drugs."[35]

Another example where the FDA declined to establish jurisdiction is the Saunders case[36]. Saunders recommended, developed and provided individually customized colostrum to consumers who were requesting the colostrum product for health care purposes. The FDA completed a two-year undercover investigation of Saunders and declined jurisdiction. The state then underwent an undercover investigation and filed charges under state law of fraud, swindle, cruelty to animals and practicing medicine without a license. All of the charges except practice of medicine without a license were dropped before the first trial.[37] The final charges of practicing medicine were dropped by state prosecutors after two hung juries.

VSTA which oversees animal biologics under the Department of Health is different than the FDA jurisdiction for new drugs in that VSTA regulates both interstate and intrastate vaccines.[38] Regarding VSTA, Congress found that federal regulation over all animal vaccines was

> "necessary to prevent and eliminate burdens on commerce and to effectively regulate such commerce." [39]. .

Given the above laws and discussion the following is a review of each substance in The Project separately.

Antigen *Borrelia burgdorfia* :

The fact that *Borrelia burgdorfia* antigen is proposed in The Project to be used to "vaccinate animals" indicates that it might fit within the definition of an animal biologic. VSTA has jurisdiction over animal biologics. Any new animal biologic antigen manufactured or used would need to comply with VSTA regulations. However if an already licensed *Borrelia burgdorfia* vaccination is being used to directly vaccinate animals, then the federal laws for manufacturing and selling a new product would not apply.

In the case of the use of an unlicensed and unapproved *Borrelia burgdorfia* antigen, where the antigen is either made available in some form in the state or is being isolated from a patient's blood, and intended to be used to develop a specific colostrum, the antigen in this case would not be actually being used for purposes of treating an animal's health but rather for developing a human product and outcome. This would indicate that as a biologic it would not be able to be approved for the benefit of the animal. If it cannot be approved then we need to ask the question, what are the circumstances that an unapproved animal biologic can be used. We find that according to VSTA, unapproved animal biologics are exempted from need for licensure if: prepared by veterinary practitioners solely for administration to animals in the course of a state licensed professional practice,[40] products prepared by a person solely for administration to animals owned by that person,[41] or products prepared solely for distribution within the State of production pursuant to a license granted by such State.[42] In the case of the use of an already licensed antigen, these exemptions would not be necessary.

An interesting note of United States and Minnesota history regarding the use of antigens and cows: On September 25, 1963, Honorable Albert H. Quie, Congressman from Minnesota in the House of Representative, read into the record a statement summary of his comments regarding a study being conducted by W.E. Petersen Research Institute of St. Paul, Minnesota, on the physical and financial values of immune milk. His comments described antibody being synthesized locally in the mammary gland stimulated by direct immunization through the teat canal. He also pointed out beneficial experiments with people suffering from arthritis and meningitis with sufficient remissions of infection.[43]

Whether or not the Project involves an approved or unapproved antigen, the laws regarding practitioner and consumer use of vaccines is relevant and must be considered.

It is common knowledge that animals are often vaccinated by Veterinarians, farmers, animal owners, and Veterinarian assistants with purchased vaccines, some over-the-counter products, and some prescription drug products only. A look at Minnesota Veterinarian

law and Animal law shows the parameters a person must follow in such practices.

Health Care Practitioner Laws:

Minnesota Board of Veterinary Medicine law states that:

> "Subd. 3. Requirements to be engaged in practice. Any person who sells or offers to apply, any prescription drug, biologic preparation, including sera, vaccines, bacterins, tuberculin, mullein, johnin, or any other agent for the treatment, vaccination, or testing of any animal belonging to another, shall be engaged in the practice of veterinary medicine." [44]

And

> "156.12 Practice of veterinary medicine.
>
> Subdivision 1. Practice. The practice of veterinary medicine, as used in this chapter, shall mean the diagnosis, treatment, correction, relief, or prevention of animal disease, deformity, defect, injury, or other physical or mental conditions; the performance of obstetrical procedures for animals, including determination of pregnancy and correction of sterility or infertility; and the rendering of advice or recommendations with regard to any of the above. The practice of veterinary medicine shall include but not be limited to the prescription or administration of any drug, medicine, biologic, apparatus, application, anesthetic, or other therapeutic or diagnostic substance or technique. The practice shall not be construed to include the dehorning of cattle and goats or the castration of cattle, swine, goats, and sheep, or the docking of sheep." [45]

There are limitation on this broad scope of practice most notably (d) and (g) as follows:

> " Subd. 2. Authorized activities. No provision of this chapter shall be construed to prohibit:
>
> (a) a person from rendering necessary gratuitous assistance in the treatment of any animal when the assistance does not amount to prescribing, testing for, or diagnosing, operating, or vaccinating and when the attendance of a licensed veterinarian cannot be procured;
>
> (b) a person who is a regular student in an accredited or approved college of veterinary medicine from performing duties or actions assigned by instructors or preceptors or working under the direct supervision of a licensed veterinarian;
>
> (c) a veterinarian regularly licensed in another jurisdiction from consulting with a licensed veterinarian in this state;
>
> (d) the owner of an animal and the owner's regular employee from caring for and administering to the animal belonging to the owner, except where the ownership of the animal was transferred for purposes of circumventing this chapter;
>
> (e) veterinarians employed by the University of Minnesota from performing their duties with the college of veterinary medicine, college of agriculture, agricultural experiment station, agricultural extension service, medical school, school of public health, or other unit within the university; or a person from lecturing or giving instructions or demonstrations at the university or in connection with a continuing education course or seminar to veterinarians;
>
> (f) any person from selling or applying any pesticide, insecticide or herbicide;
>
> (g) any person from engaging in bona fide scientific research or investigations which reasonably requires experimentation involving animals;
>
> (h) any employee of a licensed veterinarian from performing duties other than diagnosis, prescription or surgical correction under the direction and supervision of the veterinarian, who shall be responsible for the performance of the employee;
>
> (i) a graduate of a foreign college of veterinary medicine from working under the direct personal instruction, control, or supervision of a veterinarian faculty member of the College of Veterinary Medicine, University of Minnesota in order to complete the requirements necessary to obtain an ECFVG certificate. [46]

The broad scope of practice laws described above give Veterinarians exclusive jurisdiction over the medical care of animals. In some circumstances, these statutes may make a lay person vulnerable to charges of practicing Veterinary Medicine if a person vaccinates an animal. In addition to these exclusive rights, Veterinarians themselves must follow the laws of their own practice acts in order to remain in good standing with their practice Boards. The most notable part of practice acts regarding standard of care is the fact that licensed health care practitioners in general can lose their licenses for practicing outside of the minimum standards of acceptable and prevailing practice. The acceptable and prevailing practice may not be the practice of choice for a Veterinarian who practices in innovative projects. The Minnesota Veterinarian Act includes the following in their grounds for disciplinary actions:

> "…(11) fraud, deception, or incompetence in the practice of veterinary medicine, including any departure from or failure to conform to the minimum standards of acceptable and prevailing practice without actual injury having to be established; [47]

The requirement to abide by conventional medically prevailing scientific parameters, even without actual injury having to be established has motivated almost 20 states to pass laws that allow Medical Physicians to expand their ability to practice to include complementary and alternative care services. Each state has approached this problem with different legal language, some more successfully than others. Florida recently passed such a law that not only includes Medical Doctors but applies to all licensed health care providers.[48] Most recently, National Health Freedom Action has drafted proposed legislative language for states to consider when drafting these

types of practitioner statutes[49] . The new state language will allow licensed practitioners of all kinds to expand their options for providing treatments at the same time provide proper informed consent and disclosures to consumers.[50] Whether this type of statute is adequate for animal practitioners is a question.

In Minnesota an important component of the Veterinary law is that the Veterinarian must have a veterinarian-client-relationship.

> "No prescription drug may be prescribed, dispensed, or administered without the establishment of a veterinarian-client-patient relationship.[51]

And

> "General standard. The delivery of veterinary care must be provided in a competent and humane manner consistent with prevailing standards of practice for the species of animal and the professed area of expertise of the veterinarian. For a veterinarian to exercise properly the rights granted by the veterinary license, a veterinarian-client-patient relationship must exist.[52]

And

> "A licensed veterinarian shall treat animals entrusted to the veterinarian by a client consistent with prevailing professional standards of humane treatment and care.[53]

In light of the above laws of Veterinary medicine it will be important in The Project to discern whether the vaccines being given to the cow or other animal are within the prevailing and accepted standard of care of the licensed provider or its delegated assistant, whether there are circumstances where a Veterinarian might do certain things during research, or whether the state law has adopted an expanded practice act which would include Veterinarians such that they could go beyond the accepted and prevailing standard of care in some circumstances and parameters according to the new law.

Disease Reporting Laws:

In addition to practice acts, licensed health care practitioners are often mandated to report various types of diseases. Physicians must report diseases included in a specific list

> "when attending a case, suspected case, carrier, or death…"[54]

The reportable list included *Borellia burgdorferi.*

> "…GG. Lymes Disease (*Borellia burgdorferi*)"[55]

Health care facilities and medical laboratories must also report disease. In Minnesota care the Veterinarian rules are as follows:

.

> "Subp. 5. Veterinarians and veterinary medical laboratories. The commissioner of health shall, under the following circumstances, request certain reports of clinical diagnosis of disease in animals and reports of laboratory tests on animals:
>
> A. The disease is common to both animals and humans.
>
> B. The disease may be transmitted directly or indirectly to and between humans and animals.
>
> C. The persons who are afflicted with the disease are likely to suffer complications, disability, or death as a result.
>
> D. Investigation based upon veterinarian and veterinary medical laboratory reports will assist in the prevention and control of disease among humans. [56]

And

> "Subp. 6. Others. Unless previously reported, it shall be the duty of every other licensed health care provider who provides care to any patient who has or is suspected of having any of the diseases listed in part 4605.7040 to report within one working day to the commissioner as much of the information outlined in part 4605.7090 as is known." [57]

Cruelty to Animals:

Another area of law relevant to The Project is law regarding cruelty to animals. Although the vaccination of animals is a common practice, whether or not a vaccination would be considered cruelty to an animal is a factor to be considered. Veterinarians as well as laypersons are prohibited from mistreating animals. The following are excerpts from the Minnesota statutes regarding this issue:

> "343.21 Overworking or mistreating animals; penalty.
>
> Subdivision 1. Torture. No person shall overdrive, overload, torture, cruelly beat, neglect, or unjustifiably injure, maim, mutilate, or kill any animal, or cruelly work any animal when it is unfit for labor, whether it belongs to that person or to another person.[58]

And

> "…Subd. 3. Torture; cruelty. "Torture" or "cruelty" means every act, omission, or neglect, which causes or permits unnecessary or unjustifiable pain, suffering, or death.
>
> Subd. 4. Impure milk. "Impure and unwholesome milk" means all milk obtained from diseased or unhealthy animals, or from animals fed on any substance which is putrefied or fermented….
>
> Subd. 8. Substantial bodily harm. "Substantial bodily harm" means bodily injury which involves a temporary but substantial disfigurement, or which causes a temporary but substantial loss or impairment of the function of any bodily member or organ, or which causes a fracture of any bodily member to a service animal or a pet or companion animal.
>
> Subd. 9. Great bodily harm. "Great bodily harm" means bodily injury which creates a high probability of death, or which causes serious permanent disfigurement, or which causes a permanent or protracted loss or impairment of the function of any bodily member or organ, or other serious bodily harm to a service

animal or a pet or companion animal…..[59]

There is much evidence that many vaccines enhance the health and performance of cows and animals. However, given the nature of The Project, and the unusual use of whole blood and *Borellia burgdorferi*, cruelty to animal issues should be at least considered. Information from researchers should be gathered with experience in the injection of cows to assure the safety of this type of vaccinations. To contribute in that regard, in the Minnesota case of State v. Saunders, a case of a farmer using cows to develop immune colostrum to provide to consumers, and charged with "practicing medicine without a license," the original complaint included charges of "cruelty to animals." However the charges were dropped before criminal trial.[60] The reason for dropping the charges is unknown however it is believed that there was a lack of evidence for the charge.

Whole Blood:

Injecting substance into the teat canal of a cow is a common practice in veterinary medicine, especially for the use of antibiotics for mastitis. However the injection of whole human blood into the teat canal is not common but has been done in research settings. In fact some of the original research on this process was done by a doctor in Germany, almost 50 years ago. In Saunders, there was expert witness testimony that indicated that historical Native American customs included rubbing the whole blood of a sick person onto the outside of the mammary gland of a pregnant horse during the horse's pregnancy in order to affect the healing qualities of the future colostrum.[61] This is similar in concept to The Project's proposal except that The Project proposes to use an applicator or infuser instead of an external application.

Injecting whole blood into cows will involve the same legal issues as do apply to the injecting of antigens into a cow regarding federal and state laws for biologics except for the following dilemma:

Since the whole blood is being put into an animal in order to stimulate the animal to have an increase immune production, it might be considered an animal biologic, because it is

> "intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response.**"**[62]

If this is the case, then it will be similar to an antigen regulated by VSTA interstate and intrastate and practicing under an exemption will be necessary. However if a person takes the view that human blood fits within the definition of a human biologics,

> "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."[63]

then the blood would be under the FDA and its jurisdiction. However if this is the case the following discussion will be relevant.

One element of the use of whole blood is different than the use of an antigen vaccine; namely, with whole blood there is no duplication of product; a person takes their own blood and develops a customized product for themselves. As compared to the use of an antigen where the product would not be customized to the exact person but rather would be antigen specific and given to a number of persons suspected of lyme disease. Comments regarding the whole blood type of situation are described in a legal memorandum prepared in 1982 under contract for the Office of Technology Assessment by Schwartz and Burke entitled "Legal Constraints on the Availabilty of Unorthodox Cancer Treatments: Consumer Protection View".[64] In part it reads as follows:

> "…State jurisdiction may also be lacking if (in addition to the above conditions which prevent FDA from regulating) state law does not cover drugs (or biologicals such as autogenous vaccines) which are in effect produced from, or using an individual's own body fluids and customized for use only by that individual.[65]
>
> That may explain why some cancer treatments such as the Livingston-Wheeler vaccine have not been subjected to state regulation. *Footnote 80*.
>
> *Footnote 80* reads as follows:
>
> 'Another possible explanation for the lack of State regulation of the Livingston-Wheeler vaccine may be that it appears to be produced under sterile conditions and there have been no published reports of adverse effects. Thus while technically its production may have violated the law, the state, exercising its enforcement discretion, may have decided to pursue more dangerous products'".[66]

There is a difference between the Livingston-Wheeler method and the whole blood colostrum project in that the colostrum project requires the use of an intermediary step; namely the cow. It may be that the government would not have jurisdiction over the colostrum itself since it was made from a person's own body fluid and not sold in the market-place. However the injection of blood into an animal may trigger VSTA and necessitate the use of the exemptions.

Regarding other areas of law, the same legal issues will apply to whole blood as do apply to the injecting of antigens into the cow; i.e.; Minnesota Veterinary use and standards, reporting statutes, and cruelty to animals. Regarding veterinary care with whole blood, if a veterinarian performs the procedure, then they will have to be within the parameters of the practice act for standard of care. If a person owns the cow and chooses to inject the natural substance of blood without a veterinarian's help, then that person may be vulnerable to charges of "practicing veterinary medicine without a license", or "cruelty to animals" if the process negatively affects an animal's well-being.

Colostrum

The Project's use of colostrum is much different legally than that of the blood and antigens because it is the product of the cow rather than the substance used to inject into the cow. Also the intended use appears to be for treatment of human illness as opposed to affecting the biology of the cow.

Substance law indicates that colostrum might be considered a "new drug" under federal law because of its intended use. It will also fall under the state definition of "drug" because of its intended use.[67] If not adulterated or misbranded, the federal government would not have jurisdiction over it as a "new drug" unless it was going to be placed in interstate commerce.

However, the state may have jurisdiction over the produced colostrum as a "drug", and the state may demand that one abides by FDA guidelines and regulation according to state law.

Minnesota Drug Law requires compliance with federal regulations and reads as follows:

> "Subd. 5. Drug. The term "drug" means all medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals, and all substances and preparations, other than food, intended to affect the structure or any function of the bodies of humans or other animals. [68]
>
> Subd. 6. Medicine. The term "medicine" means any remedial agent that has the property of curing, preventing, treating, or mitigating diseases, or that is used for that purpose."[69]

If the colostrom substance in The Project is going to have a clearly intended use for *external and internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease* then the Minnesota state "drug" category may apply. In Minnesota the law states:

> "A drug shall be deemed to be adulterated:
>
> (1) if it consists in whole or in part of any filthy, putrid or decomposed substance; or if it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been rendered injurious to health, or whereby it may have been contaminated with filth; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice as required under the federal act to assure that such drug is safe and has the identity, strength, quality, and purity characteristics, which it purports or is represented to possess; or, its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the federal act, or it is a color additive, the intended use of which in or on drugs is for the purposes of coloring only, and is unsafe within the meaning of the federal act." [70]

and Minnesota Drug law also gives exceptions to the law but refers to federal law when it says:

> "Nothing in this chapter shall apply to or interfere with the vending or retailing of any nonprescription medicine or drug not otherwise prohibited by statute which is prepackaged, fully prepared by the manufacturer or producer for use by the consumer, and labeled in accordance with the requirements of the state or federal Food and Drug Act; nor to the manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature, for use for nonmedicinal purposes. Nothing in this chapter shall prevent the sale of drugs or medicines by licensed pharmacists at a discount to persons over 65 years of age."[71]

Given the intended use of the colostrum in The Project, the colsotrum would be potential candidate for needing to abide by "new drug" regulations. To avoid such regulation consideration the following is relevant:

It may be that colostrum could qualify for the status of a "generally recognized as safe and effective" substance by federal and state governments. Under federal law a product is not a "new drug" within the meaning of the FDCA if its composition is such that it is

> "…generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling…"[72] .

Or it may be considered to be outside of federal jurisdiction because it is analogous to the Livingston-Wheeler discussion in that it's development is customized and produces a colostrum that is customized only for that person, in a sense, a safe oral customized vaccine. This argument of defense would not apply to colostrum produced after the injection of the antigen *Borrelia burgdorfia* and used for more than one patient.

Another approach is that dietary supplement jurisdiction might be sought. An introductory and preliminary stage of The Project might portray the customized colostrum without making health claims regarding specific disease but rather portray the colostrum as a customized dietary supplement, no claim of cure or treatment of disease, but rather as a healthful supplement, similar to other colostrum dietary supplement products on the market. This would require abiding by the dietary supplement health claim regulations.

State Health Care Practitioner Law

In addition to substance law, colostrum may be impacted by state health care practitioner laws. However unlike whole blood and antigens used by veterinarians or animal owners, the practitioner laws would be those relating to human health care practitioners. For example, in State (Minnesota) vs. Saunders, the farmer was prosecuted for practicing medicine without a license.[73] . At that time the Minnesota law read as follows:

> "Subd. 3. Practice of medicine defined. For purposes of this chapter, a person not exempted under section 147.09 is "practicing medicine" or engaged in the "practice of medicine if the person does any of the following:
>
> …(3) offers or undertakes to prevent or to diagnose, correct, or treat in any manner or by any means, methods, devices, or instrumentalities, any disease, illness, pain, wound, fracture, infirmity, deformity or defect of any person;…" [74]

Exemption to Medical Practice Act:

Since State vs. Saunders, and in the year 2000, the law of Minnesota changed and it now provides an exemption to the practice

of medicine criminal charges as follows:

> "147.09 Exemptions.
>
> Section 147.081 does not apply to, control, prevent or restrict the practice, service, or activities of:
>
> … (15) An unlicensed complementary and alternative health care practitioner practicing according to chapter 146A."[75]

Minnesota Statute 146A is enforced by the Minnesota Department of Health out of the Office of Unlicensed Complementary and Alternative Health Care Practices and allows for unlicensed complementary and alterative health care practitioners to practice under certain conditions and with certain disclosures. Grounds for disciplinary actions are spelled out in the statute. The definition of complementary and alternative health care practices under the jurisdiction of the Department is as follows:

> "Subd. 4. Complementary and alternative health care practices. (a) "Complementary and alternative health care practices" means the broad domain of complementary and alternative healing methods and treatments, including but not limited to: (1) acupressure; (2) anthroposophy; (3) aroma therapy; (4) ayurveda; (5) cranial sacral therapy; (6) culturally traditional healing practices; (7) detoxification practices and therapies; (8) energetic healing; (9) polarity therapy; (10) folk practices; (11) healing practices utilizing food, food supplements, nutrients, and the physical forces of heat, cold, water, touch, and light; (12) Gerson therapy and **colostrum therapy** (bold added); (13) healing touch; (14) herbology or herbalism; (15) homeopathy; (16) nondiagnostic iridology; (17) body work, massage, and massage therapy; (18) meditation; (19) mind-body healing practices; (20) naturopathy; (21) noninvasive instrumentalities; and (22) traditional Oriental practices, such as Qi Gong energy healing.
>
> (b) Complementary and alternative health care practices do not include surgery, x-ray radiation, administering or dispensing legend drugs and controlled substances, practices that invade the human body by puncture of the skin, setting fractures, the use of medical devices as defined in section 147A.01, any practice included in the practice of dentistry as defined in section 150A.05, subdivision 1, or the manipulation or adjustment of articulations of joints or the spine as described in section 146.23 or 148.01.
>
> (c) Complementary and alternative health care practices do not include practices that are permitted under section 147.09, clause (11), or 148.271, clause (5).
>
> (d) This chapter does not apply to, control, prevent, or restrict the practice, service, or activity of lawfully marketing or distributing food products, including dietary supplements as defined in the federal Dietary Supplement Health and Education Act, educating customers about such products, or explaining the uses of such products. Under Minnesota law, an unlicensed complementary and alternative health care practitioner may not provide a medical diagnosis or recommend discontinuance of medically prescribed treatments." [76]

It appears that an unlicensed person abiding by Minnesota Statute 146A would have an opportunity to perform colostrum therapy and not be subject to charges of practicing medicine without a license. However that would depend on whether the Minnesota Department of Health had a complaint, which indicated fraud or an imminent risk of harm to the public or other grounds for disciplinary action.

Summary

This research was completed in order to inform proponents of the proposed Colostrum Therapy Project, of laws that may impact the feasibility of the Project. The Project notably involves three important substances: whole blood; *Borrelia burgdorfia* antigen; and colostrum. It also involves both animals and humans. Regarding humans, it involves both consumers and health care practitioners. The Project also involves federal and state law. The interface between all of these areas of law is very complex.

Review of substance law has assisted in identifying categories or classifications for the substances The Project might potentially fall under. The jurisdictional review has helped clarify jurisdiction over potential categories.

Animal and veterinary laws indicate a need to abide by all state and federal laws regarding animal care and safety.

State health care practitioner laws indicated a need to work with Veterinarians, Medical Doctors, Unlicensed complementary and Alternative Health Care practitioners, and other licensed providers within the scope of their licenses and within the proper standards of care or practice parameters.

Given this research a preliminary risk assessment can be entertained for future discussion of feasibility.

Risk Assessment

Principles to follow in order to manage risk for this project.

1. Dietary Supplement status. Consider attaining your goal of helping persons with major illnesses without producing a new drug product that makes treatment or cure of a disease, or other health claims. If health claims are made, choose the category of dietary supplement, but follow all guidelines for dietary supplement regulation of health claims.

4. New Drug. If the Project has decided to make disease cures and treatment claims, then pursue a request from the FDA as to whether the category of colostrum would be exempt from new drug status because it is generally recognized as safe and effective. If so you will be able to proceed and still make claims.

2. Unapproved Antigen. Consider either using already licensed antigens or in the alternative, consider isolating an antigen within the state and using it under the exemption of Veterinarian or owner or obtain a license to use it directly from the state.

3. Research. Consider searching for research facilities in the state that contains access to a local IRB that would be interested in this type of a research project. Research under an IRB might be conducted as a dietary supplement project in general. Entry requirements into the clinical trials might be a positive diagnosis of Lyme disease or other illnesses and assessments might be general structure/ function or quality of life assessments.

5. State before federal. Before making any federal contact, consult with the State about the Project, describing it and obtaining advice of how to proceed within the law. I.e., Consult with the Min-

nesota Department of Agriculture and Board of Animal Health to get the go ahead and abide by their requirements for the use of an unapproved antigen. If this is accomplished it will be an important beginning.

6. Medical and Animal Health Team. Coordination of professionals familiar with the Department of Agriculture and professionals involved in Human Health will be key to this project. Developing a willing and working team of professionals to pursue further feasibility will be important.

7. Whole blood. Obtain approval from the state of the safe use of whole blood as an antigen in a cow at the same time you obtain permission to use *Borrelia burgdorfia* antigen. Consider ahead of time potential safety issues to the cow for example the danger imposed on a cow if it is injected with alcohol or chemotherapy drugs within a human blood sample. Regarding practice laws, obtain feedback from the Board of Chiropractic or the Board of Medical practice to access the standard of care issues regarding the taking of human blood and how to obtain a doctor's order for phlebotomy. Unlicensed practitioners may not draw blood and this will be an important aspect to clarify.

8. Be upfront with legal authorities regarding the project and work with highly qualified individuals so that it does not run into legal vulnerability in the future. It is a complex project and will require an open-minded and assertive team that can convince authorities of its merit.

I. Sample Scenario:

1. The colostrum product will be produced as a dietary supplement and no claims of treating or curing a disease will be made and no unusual health claims will be made.

2. *Borrelia burgdorfia* antigen already licensed will be purchased and used for vaccination of cows or the state will provide approval to use an unapproved antigen isolated in Minnesota.

3. If exemption is necessary then use the federal exemptions of Veterinarian or owner.

4. State research facilities will participate in research, and human clinical trials will be set up under a state IRB for persons with entry requirement of positive diagnosis of Lyme disease to measure structure/function changes.

5. Licensed Veterinarians or owner shall be used for all cow management.

6. Colostrum will be handled by Grade A and organic dairy operations.

7. Professional researchers and medical assessment teams will be used for follow up on symptoms, chart reading, and data collection of human subjects.

8. Human center will meet with requirements for medical care.

9. Persons properly licensed and authorized to draw blood will participate with humans.

References:

[1] Fundamentals of Law and Regulation, Volume I, page 10, The FDA's Mission. 1997.

[2] 21 U.S.C. Sec. 321 (g) 2002

[3] U.S. v. Drugs for Veterinary Use, 50 F. 3d 497 (8th Circuit) 1995.

[4] 21 U.S.C. Sec. 321 (f) 2002

[5] Fundamentals of Law and Regulations Id.

[6] 21 U.S.C. Sec. 321 (e) 2002

[7] Fundamentals of Law and Regulation Supplement, An in-depth look at the 1997 Food and Drug Administration Modernization Act, 1999.

[8] PHS Public Health Service Title 42, Chapter 6A, 2001

[9] VSTAVirus Serum and Toxin Act 21 U.S.C. Sec. 151, 2001

[10] 42 U.S.C. Sec. 262 (i). 2001

[11] 21 U.S.C Sec. 151 2001

[12] Code of Federal Regulation 9 C.F.R. Section 101.2.

[13] 21 U.S.C. Sec. 355 (a), 2002

[14] 21 U.S.C. Sec. 321 (P) (1) and (2), 2002.

[15] Rutherford v. U.S., 582 F2d 1234, 1978

[16] U.S. v. Rutherford et al., 442 U.S. 544, 1979

[17] Office of Technological Assessment Project: Unorthodox Cancer Treatment: Information, Evaluation, and Policy, Contract Report*: Legal Constraints on the Availability of Unorthodox Cancer Treatments: Consumer Protection View*, by Ronald D. Schwartz and Rebecca l. Burke, White, Fine and Verville, 1156 15th Street, N.W. Suite 1100 Washington D.C 4/8/88

[18] 21 U.S.C. Sec. 343(r)(1), 2002.

[19] Id at Sec. 343 (r) (6).

[20] Id. at Sec. 343 (r) (7).

[21] Pearson V. Shalala, 334 U.S. App.D.C. 71 at [59], 164 F.3d 650 (D.C.Cir. 01/15/19999)

[22] 21 U.S.C. Sec. 321 (p)(1) 2002.

[23] U.S. v. Articles of Drug for Veterinary Use, 50 F.3d 497 at [25], 8th Circuit (1995).

[24] U.S. v. Articles of Drugs for Veterinary Use, 50 F.3d 497, 8th Circuit (1995)

[25] Id. at [12].

[26] Id.

[27] Id.

[28] Id.

[29] U.S. v. Pro-Ag Inc. 968 F.2d 681 (8th Circuit 1992).

[30] Id. at [21].

[31] Id. at [22].

[32] Minnesota Rules 1720.0640 2003

[33] 21 U.S.C. Sec 331 (d) 2002.

[34] U. S. v. Burzynski Cancer research Institute, 819 F.2d 1301 (5th Cir. 1987)

[35] Texas State Board of Med v. Stanislaw R. Burzynski 1996. TX. 568 No. 03-95-00222-CV.

[36] State v. Saunders 542 N.W.2d 67 1996

[37] Id.

[38] 21 U.S.C Section 151, (see also Silvey v. Mallinckrodt, Inc., 976 S.W. 2d 497 (Mo. App. E.D. 1998.)

[39] Id.

[40] Code of Federal Regulation 9 CFR 107.1(a)

[41] 9 CFR 107.1(b)

[42] 9 CFR 107.2

[43] Congressional Record, 88th Congress, First Session, September 25, 1963, A6058.

[44] MN Stat 156.12 Subd. 3. 2002.

[45] MN Stat 156.12 Subd. 1. 2002

[46] MN Stat 156.12 Subd. 2. 2002

[47] MN Stat. 156.081 Subd. 2. (11). 2002

[48] Florida Statute Title XXXII, Chapter 456, 456.41. 2002

[49] National Health Freedom Action (NHFA) National Proposed Language Model

[50] NHFA Id.

[51] MN Rules Chaper 9100.0800 Subpart 2. A. 2000.

[52] MN Rules Chapter 9100.0800 Subpart 1. General Standard. 2000

[53] MN Rules Chapter 9100..0800 Subpart 8. Humane Care. 2000

[54] MN Rules Chapter 4605.7030 Persons required to report disease 2000

[55] MN Rules Chapter 4605.7040 Disease and Reports; isolate submissions. 2000

[56] MN Rules Chapter 4605.7030 Persons required to report disease. 2000

[57] Id.

[58] MN Stat. 343.21 Subd. 1. 2002.

[59] MN Stat 343.20 Sud. 3., 4., 8, and 9. 2002

[60] State v. Saunders Id.

[61] Expert Witness testimony of Dr. Walter Clifford of Colorado via video March 4, 1995.

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[65] Id.

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[67] MN Stat 151.01 Subd 5. 2002.

[68] MN Stat 151.01 Subd. 5. and 6. 2002

[69] Id at 6

[70] MN Stat 151.35 (1), 2002

[71] MN Stat 151.26 Subd. 1, 2002

[72] 21 U.S.C. Sec. 321 (P) (1), 2002.

[73] State v. Saunders Id.

[74] MN Stat. 147.081 Sud.3 (3) 2002

[75] MN Stat 147.09 (15), 2002

[76] MN Stat. 146 A 2002.