PETITION and NOTES

TO THE US FOOD AND DRUG ADMINISTRATION

From Helane Shields, PO Box 1133, Alton, NH 03809 hshields@tds.net
September 4, 2015

CONTENTS

PETITION TO FDA

FDA Requirements:
For section A. Action Requested, please insert exactly what you would like the Food and Drug Administration to do. What exactly are you requesting of the agency?

Section A - Thank you for the opportunity to petition the FDA. Sewage sludge biosolids is hereinafter referred to as "sludge" in this petition. I am respectfully requesting that the FDA reverse its pro-sludge policies as indicated by its joint statement of policy and guidance issued by EPA, USDA and FDA in 1981 on the production of fruits and vegetables with the application of sludge as a “soil amendment” on human and animal food crops. Since then, FDA has reiterated its support of sludge as a food crop soil amendment (see notes) . I am also requesting that the FDA issue a policy statement terminating the use of sludge as a soil amendment on food crops because sludge contains infectious prions which are taken up by the plants and may already be causing prion diseases and the prion disease epidemics raging in the United States. (See notes)

For section B. Statement of Grounds, please provide your evidence and rationale in this section.

Section B (and see notes attached on evidence and rationale)

(1) The FDA has long supported the use of sludge as an acceptable “soil amendment” for food crops:

http://www.epa.gov/agriculture/tfer.html#Fertilizers%20Made%20from%20Domestic%20Septage%20and%20Sewage%20Sludge%20(Biosolids

. As a result of research and practice showing the safety of biosolids recycling, the U.S. Department of Agriculture, the Food and Drug Administration, and EPA issued a joint policy statement in 1981 that endorsed the use of biosolids on land for producing fruits and vegetables. Then, in 1984, EPA issued a policy statement in the Federal Register that encouraged and endorsed the recycling of biosolids. And again in 1991, EPA was a co-endorser of an Interagency Policy placed in the Federal Register regarding the benefits of using biosolids.
See notes on FDA’s longstanding pro sludge policies.
Sources of human prions in sludge – urine and feces shed to sewers by victims of prion diseases

Alzheimer’s Disease (AD) is prion disease:

“The brain diseases caused by prions include Alzheimer's, Parkinson's and Huntington's, amyotrophic lateral sclerosis, also known as Lou Gehrig's disease, and other varied disorders known collectively as the frontotemporal dementias, Prusiner said.” http://ind.ucsf.edu/news/prions-linked-dementia-ptsd

[Stanley Benjamin Prusiner M.D (born May 28, 1942[2]) is an American neurologist and biochemist. Currently the director of the Institute for Neurodegenerative Diseases at University of California, San Francisco (UCSF). Prusiner discovered prions, a class of infectious self-reproducing pathogens primarily or solely composed of protein. He received the Albert Lasker Award for Basic Medical Research in 1994 and the Nobel Prize in Physiology or Medicine in 1997 for his prion research.]

Alzheimer’s victims shed infectious prions to public sewers in their urine and feces:

Prof. Dr. Adriano Aguzzi - Neuroscience Center Zurich Institute of Neuropathology University Hospital of Zurich

"Further research by the team showed that, if inflammation is induced in any excretory organ of the body, prions are excreted in whatever substance the organ excretes." http://bacteriality.com/2008/05/05/prion

Dr. Adriano Aguzzi, University of Zurich, adriano.aguzzi@usz.ch

http://www.plospathogens.org/article/info:doi/10.1371/journal.ppat.1001257

Several biological fluids and excreta (e.g. saliva, milk, urine, blood, placenta, feces) contain significant levels of prion infectivity [13], [14], [15], [16], [17], and horizontal transmission is believed to be critical for the natural spread of TSEs [18], [19], [20], [21], [22], [23]. Free-ranging animals may absorb infectious prion particles through feeding or drinking [24], [25], and tongue wounds may represent entry sites for prions [26].
See attached notes for more on prions in urine and feces
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There are at least two human prion disease epidemics raging in the United States (US) at the present time. There are millions of Alzheimers/dementia and autism victims excreting prions in their urine and feces into public sewers. (Alzheimers is presently described as having 6 million victims. But The National Institute on Aging says “official mortality figures may have substantially under reported deaths due to Alzheimer’s disease”.http://www.nia.nih.gov/research/announcements/2014/05/number-alzheimersdeaths-found-be-underreported

(3) Children are being infected with Autism, which Dr. David Westaway director of the Alberta Centre for Prions, believes is a prion disease –source - the food they are

eating which was grown in soil/sludge containing prions. Autism numbers are soaring - from one million cases a couple of years ago to now over two million. See attached notes on Autism as a prion disease

Dr. Stanley Prusiner says Parkinson's is also a prion disease -- with another 1 million victims shedding prions to public sewers.

“But Alzheimer's is not just a disease of old age. Up to 5 percent of people with the disease have early onset Alzheimer's (also known as younger-onset), which often appears when someone is in their 40s or 50s.”

http://www.alz.org/alzheimers_disease_what_is_alzheimers.asp

So prion diseases strike children (Autism), middle aged (early onset AD, – sporadic Creutzfeldt Jakob Disease - sCJD) and the elderly AD, sCJD.

Thus, millions of prion disease victims are shedding infectious prions into public sewers in their urine and feces.

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What happens to the prions after they enter the sewers ?

NOTHING deactivates prions except, possibly, temperatures exceeding 1000C – 1832 F or an alkaline hydrolysis digester.

3

The US Environmental Protection Agency (EPA) acknowledges wastewater treatment does not inactivate prions. Several years ago, this was posted to EPA's Region 8 web page (When I started citing it in letters to the editor, EPA removed it from the Internet): "We are currently prohibiting the discharge of untreated, potentially prion contaminated wastes to POTWs. Typical treatment and disinfection processes used by non-domestic users and those at Publicly Owned Treatment Works (POTWs) do not deactivate prions.

“Prions will pass through the POTW as a pollutant to be received into receiving waters and concentrated in biosolids. Biosolids are the solids produced by POTWs and typically land applied to food and non-food (grazing) crops."
http://cipca.org/regulatory/factsheetcwdpretreatment.pdf

US EPA National Water Research Compendium 2009-2014 lists PRIONS eight times as an emerging contaminant of concern in sewage sludge "biosolids" , water and manure:
http://www.sludgevictims.com/prions/PRIONSEPAEMERGINGCONTAMINANTSINSLUDGEBIO.pdf

Dr. Joel Pedersen, University of Wisconsin, was the recipient of $5 million grant from Dept. of Defense (and a $100,000 grant from US EPA), to study prions:

July 15, 2008: http://www.ncbi.nlm.nih.gov/pubmed/18754377

Renown prion researcher, Dr. Joel Pedersen, proved sewage treatment does not inactivate prions: ” Our results suggest that if prions were to enter municipal wastewater treatment systems, most of the agent would partition to activated sludge solids, survive mesophilic anaerobic digestion, and be present in treated biosolids. Land application of biosolids containing prions could represent a route for their unintentional introduction into the environment. Our results argue for excluding inputs of prions to municipal wastewater treatment.” “Prions could end up in wastewater treatment plants via slaughterhouse drains, hunted game cleaned in a sink, or humans with vCJD shedding prions in their urine or feces, Pedersen says”

[Note: This study was completed before it was publicly known that Alzheimer’s Disease (AD) is a prion disease and millions of AD victims were shedding infectious prions **into** public sewers. sCJD- sporadic Creutzfeldt Jakob Disease -is the sister prion disease to AD. They are commonly mistaken one for the other. A new strain of AD/CJD is named **"rpAD"** (rapidly progressive Alzheimers Disease – Alzheimers on fast forward]
http://pubs.acs.org/doi/pdfplus/10.1021/es703186e
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PRIONS BECOME MORE INFECTIVE ONCE RELEASED INTO THE SOIL:
"Soil may be doing more than just transporting prions, however. Pedersen and Aiken have recently reported that prion infectivity increased by a factor of 680 when the aberrant proteins were bound to a common type of clay, meaning a prion dose of just 0.2 micrograms (less than one one-hundred millionth of an ounce) could infect a significant number of lab animals. "
http://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.0020032

More from Dr. Pedersen:
Pedersen (continued) "We and others have hypothesized that soil may serve as a reservoir of TSE infectivity [8,9,22,23]. Deliberate and incidental ingestion of soil by ruminants can amount to hundreds of grams daily [24,25]. Prions enter soil environments via decomposition of infected carcasses [8,26], alimentary shedding [11,27,28], deliberate burial of diseased carcasses/material [29], and possibly, urinary excretion [30].

"Our results argue for excluding inputs of prions to municipal wastewater treatment facilities that would result in unacceptable risk of prion disease transmission via contaminated biosolids."

In the July 3, 2010 issue of VETERINARY RECORD, Dr. Pedersen stated: “Finally, the

disposal of sludge was considered to represent the greatest risk of spreading (prion) infectivity to other premises."

Farmers spreading prion contaminated sludge may be permanently contaminating their cropland:

Dr. Joel Pedersen, et al
"Soil represents a plausible environmental reservoir of scrapie and CWD agents, which can persist in the environment for years. Attachment to soil particles likely influences the persistence and infectivity of prions in the environment. Effective methods to inactivate TSE agents in soil are currently lacking, and the effects of natural degradation mechanisms on TSE infectivity are largely unknown. An improved understanding of the processes affecting the mobility, persistence, and bioavailability of prions in soil is needed for the management of TSE-contaminated environments."
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3160281

HUMAN PRIONS ARE 100,000 TIMES MORE INFECTIVE THAN ANIMAL PRIONS:

http://www.ncbi.nlm.nih.gov/pubmed/16352557

"The inactivation of prions in brain homogenates and those bound to stainless steel wires was evaluated by using bioassays in transgenic mice. sCJD prions were more than 100,000 times more resistant to inactivation than Sc237 prions, demonstrating that inactivation procedures validated on rodent prions cannot be extrapolated to inactivation of human prions."

"The human prion is resistant to both heat and chemicals and is reported to be up to a hundred thousand times more difficult to deactivate than the animal form of infective agent which causes well known diseases in cattle, such as mad cow disease, and scrapie in sheep."

Plants uptake and internalize the prions from sludge and soil: "Our results suggest that prions can be taken up by plants and that contaminated plants may represent a previously unrecognized risk of human, domestic species and wildlife exposure to prions."

Christopher Johnson, et al, University of Wisconsin:
http://transmissiblespongiformencephalopathy.blogspot.com.br/2015/05/prion-2015-oraland-poster.html

http://www.sciencedirect.com/science/article/pii/S2211124715004374
Friday, May 15, 2015 Grass Plants Bind, Retain, Uptake, and Transport Infectious Prions

Highlights
• Grass plants bind prions from contaminated brain and excreta
• Prions from different strains and species remain bound to living plants
6
• Hamsters fed with prion-contaminated plant samples develop prion disease
• Stems and leaves from grass plants grown in infected soil contain prions
Summary
Prions are the protein-based infectious agents responsible for prion diseases. Environmental prion contamination has been implicated in disease transmission. Here, we analyzed the binding and retention of infectious prion protein (PrP^{Sc}) to plants. Small quantities of PrP^{Sc} contained in diluted brain homogenate or in excretory materials (urine and feces) can bind to wheat grass roots and leaves. Wild-type hamsters were efficiently infected by ingestion of prion-contaminated plants. The prionplant
interaction occurs with prions from diverse origins, including chronic wasting disease. Furthermore, leaves contaminated by spraying with a prion-containing preparation retained PrP^{Sc} for several weeks in the living plant. Finally, plants can uptake prions from contaminated soil and transport them to aerial parts of the plant (stem and leaves). These findings demonstrate that plants can efficiently bind infectious prions and act as carriers of infectivity, suggesting a possible role of environmental prion contamination in the horizontal transmission of the disease.
See study attached: http://www.cell.com/cell-reports/pdfExtended/S2211-1247(15)00437-4

http://www.genengnews.com/gen-news-highlights/feeding-on prioncontaminatedplantssickens-animals/81251282/
May 18, 2015
Feeding on Prion-Contaminated Plants Sickens Animals
““A new study, however, is less encouraging. It indicates that grass plants bind prions. Also, stems and leaves from grass plants grown in infected soil contain prions. Finally, when prion-contaminated plant samples are fed to hamsters, the animals develop prion disease.”

[Humans are developing prion diseases – AD, Autism, ADHD, etc. at an alarming rate from food infected with prions via uptake from prion contaminated sludge.]

Per EPA and sewage industry, 6 to 7 metric tons of sludge are land applied as “fertilizer” on food crops each year. Of particular concern are those grains heavily fertilized with sludge which constitute the backbone of human and animal food supplies: corn, sorghum, soybeans and *wheat*. These crops (and all others) uptake prions from the sludge.

“ Plants subject to uptake and contamination by infectious prions in soil:

Maize (corn), barley, alfalfa, tomatoes “

http://chronic-wasting-disease.blogspot.com/2013/09/uptake-of-prions-into-plants.html

“. . . PrP_{Sc} contained in diluted brain homogenate or in excretory materials (urine and feces) can bind to wheat grass roots and leaves . . . “

□ Wheat is a major ingredient in such foods as bread, porridge, crackers, biscuits, Muesli, pancakes, pies, pastries, cakes, cookies, muffins, rolls, doughnuts, *gravy*, boza (a fermented beverage), and breakfast cereals (e.g., Wheatena, Cream of Wheat, Shredded Wheat, and Wheaties). . .

“Apr 11, 2010 - Gluten is *made* up of the sticky proteins that act as a binder in foods. It is difficult to find foods that do not contain some form of *wheat*,”

“Americans also eat an extraordinary amount of soybean oil, another key ingredient in most processed foods. Checking labels during a recent trip to the grocery store I found soybean oil in everything from tortilla chips to fruit syrup.”
http://articles.cnn.com/2007-09-22/health/kd.gupta.column_1_high-fructose-cornsyrup-corn-refiners-association-soybean-oil?_s=PM:HEALTH

Around 75% of the food on your supermarket shelves contains corn. From salad dressing to yogurt, corn has infiltrated our diets in ways that don’t look or taste anything like the “on-the-cob” variety.
http://www.forbes.com/fdc/welcome_mjx.shtml

“Animal feeding is one of the most important markets for sorghum production in the United States. Sorghum is utilized in the nutrition of dairy and beef cattle as well as swine and poultry. The grain, stalks and leaves are all animal feeding products.

The consequences of feeding Americans prion infected foods are the prion disease epidemics presently spreading uncontrollably across the country.

Other countries in Europe and around the world are also spreading prion infected sludge on food crops. The consequences:
https://www.newscientist.com/article/dn24709-soaring-dementia-rates-prompt-call-forglobal-action/
Soaring dementia rates prompt call for global action:

“The number of people around the world living with dementia is predicted to rise from 44 million today to 135 million by 2050. The increase is 17 per cent higher than a forecast made four years ago due, in part, to the inclusion of new data from African

countries and China."

And millions more are now at risk thanks to the FDA policy of encouraging prion infected sewage sludge to be applied to food crops:

"Cases of fatal brain disease showing up decades after infection"
http://www.foxnews.com/health/2015/08/21/cases-fatal-brain-disease-showing-updecades-after-infection/

Thanks to FDA policies, we are all being exposed to infectious prions in our food. Apparently one of the reasons we are not all suffering prion disease infections right now lies with our genes (see attached notes)
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In the "Bad Bug Bok" the FDA states:
"Under the laws administered by FDA, a food is adulterated if it contains (1) a poisonous or otherwise harmful substance that reasonable possibility of injury to health, is not an inherent natural constituent of the food itself, in an amount that poses a *reasonable possibility* of injury to health,"
http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf

The prions in our food which are taken up from sludge fertilizer promoted by the FDA are not only harmful, but also constitute adulteration and "a *reasonable possibility* of injury". Prions in our food are very likely to be responsible for the prion disease epidemics sickening and killing millions of Americans right now.

Section C. Environmental Impact, please state that you are claiming a categorical exclusion from the requirement to provide said statement
9
I am claiming a categorical exclusion from the requirement to provide said statement

Section D. Economic Impact, please state that you will provide an economic impact statement at the request of the Commissioner.

I don't have the ability or resources to provide this information.

Section D-1 - "…representative data and information known to the petitioner which are unfavorable to the petition:
"http://www.nebiosolids.org/prions-tses-alzheimers-and-biosolids
NEBRA: Prions, TSEs, Alzheimer's, & Biosolids 7/10/15

Water Environment Federation
http://wef.org/AWK/pages_cs.aspx?id=2154
Prion Fact Sheet

http://www.ncbi.nlm.nih.gov/pubmed/21391030
Survival of infectious prions in Class B biosolids.
Miles SL[1], Takizawa K, Gerba CP, Pepper IL.

Section E. Certification, please use the sample certification in 21 C.F.R. 10.30 section E, Certification.

Citizen Petition
Date: September 4, 2015
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it **includes representative data and information known to the petitioner which are unfavorable to the petition (see Section D-1 above)**

Helane Shields
PO Box 1133
Alton, NH 03809
603-875-3842
(Signature)_____

FDA NOTES

Section B - evidence and rationale for petition requesting FDA to terminate its policy supporting the application of sludge containing infectious prions to food crops:

The FDA has long supported the use of sludge as an acceptable “soil amendment” for food crops:

http://www.epa.gov/agriculture/tfer.html#Fertilizers%20Made%20from%20Domestic%20Septage%20and%20Sewage%20Sludge%20(Biosolids)

As a result of research and practice showing the safety of biosolids recycling, the U.S. Department of Agriculture, Food and Drug Administration, and EPA issued a joint policy statement in 1981 that endorsed the use of biosolids on land for producing fruits and vegetables. Then, in 1984, EPA issued a policy statement in the Federal Register that encouraged and endorsed the recycling of biosolids. And again in 1991, EPA was a co-endorser of an Interagency Policy placed in the Federal Register regarding the benefits of using biosolids.

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm187676.htm

Manure and Municipal Biosolids

“Properly treated manure or biosolids can be an effective and safe fertilizer.”
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Sewage industry praises FDA for their pro-sludge policies:

http://www.nebiosolids.org/nebra-comments-to-fda-epa/ (NEBRA is sewage industry lobbying and PR agency)

NEBRA stated:
"The proposed FDA rule includes biosolids as one of many “biological soil amendments” that is available to farmers, just like animal manures. …. It is clear from this and past FDA actions that the agency properly recognizes that biosolids are, in reality, just one of several biological soil amendments commonly in use, that biosolids are currently adequately regulated for safety, and that all such amendments should be managed in similar ways to reduce the risk of human or environmental impacts.”
[1]
http://wrrfdata.org/NBP/Newsletter/2013/12/19/wef-submits-comments-on-fdaproposed-rule-for-standards-for-the-growing-harvesting-packing-and-holding-ofproduce-for-human-consumption/

(NBP – National Biosolids Partnership: Water Environment Federation (WEF), in collaboration with the National Association of Clean Water Agencies (NACWA) and local and regional biosolids management organizations across the U.S. and Canada with support from the U.S. Environmental Protection Agency (EPA).

… Supporting local Water Resource Recovery Facilities (WRRFs) with education, training and technical support on biosolids management is a core mission for WEF. WEF supports beneficial recycling of biosolids through land application that is best suited to meet the needs of local communities, and we are pleased that FDA’s proposed a framework that will allow for continued use of biosolids in growing produce for human consumption.

http://www.foodsafetynews.com/2013/09/send-lawyers-guns-and-moneybiological-chemical-and-radiological-inputs-to-produce/#.VdJ6RnlzP3g

Violating the explicit language of the Food Safety Modernization Act (FMSA), the Food and Drug Administration’s (FDA) Proposed Produce Rule gives a complete pass to imported vegetables grown with sewage sludge, contaminated to various degrees with heavy metals, polycyclic aromatic hydrocarbons, volatiles, flame retardants, pharmaceuticals, steroids, hormones (1,2) radiologicals (3) and undescribed contaminants. “

“And, in Section IV of their introductory discussion of the Proposed Rule, FDA states that it tentatively concludes that the Proposed Rule should be limited to biological hazards. FDA eliminated any consideration of chemical, pesticide, heavy-metal and radiological hazards for the Proposed Rule.” [PRIONS are a biological hazard which was not considered.]

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm187676.htm
****
Beneficial Co-Utilization of Agricultural, Municipal and Industrial by-Products
Edited by Sally L. Brown, J. Scott Angle, Lee W. Jacobs

Page 47 - "When EPA first issued formal regulations addressing land application to cropland in 1979, some food processors questioned the safety of food crops grown on biosolids-amended soils and were concerned about potential liability problems. A joint statement of policy and guidance issued by EPA, USDA and FDA in 1981 on the production of fruits and vegetables with biosolids (EPA/USDA/FDA, 1981) did not adequately relieve their concerns."
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NBP February 2013:
FDA Proposed New Food Safety Rules, Biosolids Included
The U. S. Food & Drug Administration proposed a new set of standards for “the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.” Biosolids are specifically mentioned in the proposed regulations, along with “humus, manure, non-fecal animal byproducts, peat moss, preconsumer vegetative waste…, table waste, agricultural tea, or yard trimmings.” How these soil amendments, any of which may contain pathogens, are managed in food crop production, is important to food safety. For example, the proposed language specifically prohibits the use of human waste for growing all produce covered by the proposed regulations, “except sewage sludge biosolids used in accordance with the requirements of 40 CFR Part 503, subpart D, or equivalent regulatory requirements.”

Prions in urine and feces

Prof. Dr. Adriano Aguzzi - Neuroscience Center Zurich Institute of Neuropathology University Hospital of Zurich:

"Further research by the team showed that, if inflammation is induced in any excretory organ of the body, prions are excreted in whatever substance the organ excretes."
http://bacteriality.com/2008/05/05/prion (this link is no longer good)
Dr. Adriano Aguzzi, University of Zurich, adriano.aguzzi@usz.ch

The detailed characterization of uPrP reported here definitely proves the presence of PrP in human urine and will help determine the origin of prion infectivity in urine.
http://www.ncbi.nlm.nih.gov/pubmed/20670940
http://sludgevictims.com/prions-intestines-feces.html

Prions have been found in the blood and urine of CJD victims. (Gabizon, et al, 2001; Reichl, et al 2002) Undertakers. Undertakers and medical facilities routinely discharge CJD infected blood and body fluids into public sewers. (Yale; UC Davis, CDC)
Since the publication in 2006 of Annex 1 (Major Categories of Infectivity) in the‘‘WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies’’, some tissues (ovary, uterus, mammary glands/udder, skin, adipose tissue, and heart/pericardium) and body fluids (saliva, milk, urine, and feces) in which infectivity had not been detected, have since been found to contain infectivity or PrPTSE “

http://www.who.int/bloodproducts/TSEPUBLISHEDREPORT.pdf
Iron content of ferritin modulates its uptake by intestinal epithelium: implications for co-transport of prions. http://www.molecularbrain.com/content/3/1/14
Bhupanapadu Sunkesula SR, Luo X, Das D, Singh A, Singh N.
“High titers of infectious prions (6.6 $\log_{10}$ ID_{50}/g) were detected in the feces of orally challenged hamsters in the first week”
http://jid.oxfordjournals.org/content/198/1/8.full
http://www.jneurosci.org/cgi/content/abstract/24/50/11280
Ravi Shankar Mishra, * Subhabrata Basu, * Yaping Gu, Xiu Luo, Wen-Quan Zou, Richa Mishra, Ruliang Li, Shu G. Chen, Pierluigi Gambetti, Hisashi Fujioka, and Neena Singh
Because ferritin shares considerable homology across species, these data suggest that PrP^{Sc}-associated proteins, in particular ferritin, may facilitate PrP^{Sc} uptake in the intestine from distant species, leading to a carrier state in humans.

Dr. Stanley Prusiner, et al http://www.ncbi.nlm.nih.gov/pubmed/18505383
Transmission and detection of prions in feces.
“Our findings suggest that horizontal transmission of disease among herbivores may occur through the consumption of feces or foodstuff tainted with prions from feces of CWD-infected cervids and scrapie-infected sheep.”
http://jid.oxfordjournals.org/content/201/11/1615.full
4
A Kiss of a Prion: New Implications for Oral Transmissibility
The last mode of transmission is of particular interest because it indicates that the consumption of meat and other products derived from animals experiencing prion disorders may pose a real risk to humans.
Recent reports suggest that, in addition to meat, bodily fluids such as

blood, saliva, feces, and milk may well be risk factors for possible transmission of TSEs to humans.
http://edwardmd.wordpress.com/2013/06/21/alzheimers-disease-deadly-infectiouscause-known-and-hidden-prions-2/ June 21, 2013
Alzheimer's Disease: Deadly Infectious Cause Known and Hidden – Prions

The CNS, Central Nervous System – Brain, Spine, Motor and Sensory Nerves and all their Fluids contain the highest concentrations of the protein. Although recent studies have shown that the intestine is also a 'reservoir' of prions and would account for the high concentration of prions in feces. The 'meat' concentrations should have the least amount of contamination, minus any nerves in the meat as those are high concentrations of prions.
http://www.who.int/bloodproducts/tablestissueinfectivity.pdf

World Health Organization
Since the publication in 2006 of Annex 1 (Major Categories of Infectivity) in the ''WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies'', some tissues (ovary, uterus, mammary glands/udder, skin, adipose tissue, and heart/pericardium) and body fluids (saliva, milk, urine, and feces) in which infectivity had not been detected, have since been found to contain infectivity or PrPTSE and therefore have there been moved from the category of ''tissues with no detectable infectivity'' '' to the category of ''lower-infectivity tissues.''
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2013
Colorado State University:
CSU scientists discovered that body fluids such as saliva, blood, urine and feces harbor infectious prions
http://csu-cvmbs.colostate.edu/Pages/hoover-ed.aspx

Dr. Stanley Prusiner – brain diseases caused by prions
"The brain diseases caused by prions include Alzheimer's, Parkinson's and Huntington's, amyotrophic lateral sclerosis, also known as Lou Gehrig's disease, and other varied disorders known collectively as the frontotemporal dementias, Prusiner said." http://ind.ucsf.edu/news/prions-linked-dementia-ptsd

Types of FTD:
The term "frontotemporal dementia" (FTD) includes three different clinical subtypes: behavior variant FTD (also historically called "frontal variant FTD" or "Pick's Disease"), semantic dementia and progressive non-fluent aphasia. The specific areas of the brain affected by each subtype cause different symptoms for each type.
http://memory.ucsf.edu/ftd/

“Functional neural network analysis in frontotemporal dementia and Alzheimer's disease using EEG and graph theory “
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2736175/

Attention-deficit and hyperactivity disorder (ADHD) = Another prion disease with mostly children as victims – are they being infected by prions in the food they are eating?

ADHD (Attention-Deficit/Hyperactivity Disorder) = frontotemporal dementia?
“Interestingly, in an fMRI study of ADHD patients a similar shift towards a more ordered network type was reported [31], and the same seems to be happening in patients with Parkinson's disease dementia (Olde Dubbelink KTE, unpublished results).”
http://www.biomedcentral.com/1471-2202/10/101

It is conceivable that FTLD leads to a pathologically ordered and rigid network by altering long-distance network traffic to and from the coordinating frontal areas, but this hypothesis has to be explored in future studies. Interestingly, in an fMRI study of ADHD patients a similar shift towards a more ordered network type was reported [31],
6
and the same seems to be happening in patients with Parkinson's disease dementia (Olde Dubbelink KTE, unpublished results).
http://www.biomedcentral.com/1471-2202/10/101

http://newsguide.us/education/science/Adult-ADHD-significantly-increases-risk-ofcommon-form-of-dementia/?date=2011-01-18
Adult ADHD significantly increases risk of common form of dementia
Adults who suffer from attention-deficit and hyperactivity disorder (ADHD) are more than three times as likely to develop a common form of degenerative dementia than those without, according to research in the January issue of the *European Journal of Neurology*.

Researchers from Argentina confirmed the link during a study of 360 patients with degenerative dementia and 149 healthy controls, matched by age, sex and education. The dementia patients comprised 109 people with dementia with Lewy bodies (DLB) and 251 with Alzheimer's.

"Our study showed that 48 per cent of patients with DLB (dementia with Lewy bodies) – the second most common cause of degenerative dementia in the elderly after Alzheimer's – had previously suffered from adult ADHD" says lead author Dr Angel Golimstok. "This was more than three times the 15 per cent rate found in both the control group and the group with Alzheimer's.

ADHD sufferers are at a higher risk of DLB than AD

These Argentinean researchers compared clinical records for 109 patients with DLB and 251 patients with "Alzheimer disease type," and evaluated whether or not these patients had attention-deficit and hyperactivity disorder (ADHD) prior to the onset of DLB or ADT. They found that there was a "higher risk of DLB in patients with preceding adult ADHD symptoms." There is "no clear explanation for the association found."
http://www.lbda.org/community/forum/viewtopic.php?f=14&t=2291

Alzheimer's - a vastly underreported cause of death around the world. Untold profits could be made if a cure is found:
After spending millions of dollars on research, the drug companies apparently now realize Alzheimer's is an incurable prion disease and they have abandoned their AD/dementia research:
7
Drug Companies are giving up
Drug companies abandon Alzheimer's research
http://www.abc.net.au/pm/content/2012/s3611062.htm
'BRENDAN TREMBATH: Some of Australia's leading experts on Alzheimer's disease say an alarming number of drug companies are abandoning research into drug treatments for dementia. Despite huge advances in neuro-imaging and diagnostic techniques, there's been little progress when it comes to drugs to fight the disease. Pharmaceutical companies now in retreat cite the huge cost of research and the failure of drug trials to date.'

Will Pharma Companies Get Out of Alzheimer's Disease R&D?
http://www.forbes.com/sites/johnlamattina/2012/08/29/will-pharma-companies-get-outof-alzheimers-disease-rd/
"Clinical trial results in Alzheimer's Disease (AD) reported over the past few weeks have been disappointing to both patients and the academic community. The failure of both bapineuzumab (Pfizer/Johnson & Johnson) and solanezumab (Eli Lilly) to improve cognitive function has shown the difficulties inherent in trying to develop drugs to treat AD. "

Sanofi Abandons Alzheimer's Research
http://social.eyeforpharma.com/clinical/sanofi-abandons-alzheimers-research
Apr 17, 2013
"Science isn't advanced enough to justify the costs to develop a [Alzheimer's] drug," says Sanofi CEO, Chris Viehbacher."

""I think we have to do a lot more basic science work to understand what's going on," Viehbacher said in the interview at an industry event in San Diego. "We really, at best, partially understand the cause of the disease. It's hard to come up with meaningful targets."

Drug companies 'giving up' on Alzheimer's treatment after series of expensive failed trials Read more:
http://www.dailymail.co.uk/news/article2205339/Leadingpharmaceutical-firms-giving-Alzheimers-treatment-series-expensive-failedtrials.html#ixzz3aM3p7iGi 19 September 2012

‘ Leading pharmaceutical companies are 'giving up' on a cure for Alzheimer's after the failure of several high-profile trials.

“Drug firms are scaling down the search for new Alzheimer's treatments after spending millions on late-stage trials which have collapsed in the past five years.
“Last month Pfizer and Johnson & Johnson pulled the plug on the experimental drug bapineuzumab after the failure of two high-profile clinical trials.’
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AUTISM – ANOTHER PRION DISEASE ?
Autism Cases on the Rise; Reason for Increase a Mystery
Scientists are scouring genetic and environmental data to find a cause for the rise in autism
http://www.webmd.com/brain/autism/searching-for-answers/autism-rise

The Autism epidemic in US has claimed over one million victims. (2015 – there are now 2 million cases – and there is a rapid increase in new cases
https://www.autismspeaks.org/what-autism/faq)

The Prion Institute in Alberta, Canada, is investigating Autism spectrum disorder as a prion disease
PAGE 41: http://www.prioninstitute.ca/forms/WEBSITE%20AR.pdf
and
http://www.prioninstitute.ca/index.php?page=webpages&menucat=42&id=26&action=displaypage&side=1
"Research Lead: Dr. David Westaway, University of Alberta Project: "Extending the spectrum of Prionopathies to Amyotrophic Lateral Sclerosis and Autism" "
Prions ("proteinaceous infectious particles) are transmissible seeding proteins which misfold and infect adjacent cells. The infectious proteins cause neurodegenerative diseases by cascading through the brain.

Recent evidence indicates that diverse neurodegenerative diseases might have a common cause and pathological mechanism — the misfolding, aggregation and accumulation of proteins in the brain, resulting in neuronal apoptosis.
http://www.als-tdf.org/forum/Default.aspx?g=posts&t=48785

Each prion disease has a specific misfolding prion/protein – Alzheimer's= Tau and Amyloid-B; (The amyloid beta protein has been identified as an important component of both cerebrovascular amyloid and amyloid plaques of Alzheimer's disease and Down syndrome) Parkinsons = alpha-synuclein; Huntingtons = huntingtin protein ; ALS = Misfolded mutant SOD1 protein. Neuroligins have been identified as the misfolding prion/protein which causes Autism:

http://www.medicalnewstoday.com/releases/200742.php

"Misfolded Neural Proteins Linked To Autism Disorders"
"Both neuroligins and the autism mutations are relatively new to science. The former were characterized 15 years ago, the latter discovered just seven years ago. Taylor said identifying and describing the misfolded protein link advances understanding of the complex causes of certain autisms, including the influences of genes versus environment, and perhaps offers a new target for potential drug therapies."
http://www.google.com/patents?printsec=description&dq=AUTISM,+PRIONS&id=A4fOAAAAEBAJ&output=text

METHODS AND COMPOSITIONS FOR THE TREATMENT OF SYMPTOMS OF PRION DISEASES CROSS REFERENCE TO RELATED APPLICATIONS

"SUMMARY
"[0021] it has been determined by the present inventor that the gastrointestinal tract of dysautonomic individuals is impaired, and that the proper levels of pancreatic enzymes and/or their precursors including the zymogens and bicarbonate ions are not present in sufficient quantities to allow proper digestion. While that impairment is relevant to the digestion of carbohydrates, fats and proteins, it is most specific and most severe with respect to protein digestion. Accordingly, while not being bound by theory, the present inventor believes that many, if not all, dysautonomias have a GI component, and thus that dysautonomias may actually have their etiology in gastrointestinal dysfunction. For example, with Guillain-Barre syndrome, it is postulated that a GI pathogen is a causative factor in the formation of the Guillaine Barre dysautonomia. Similarly, it has been found by the present inventor that populations of autistic children suffer from GI disturbances and other conditions which are dysautonomic in nature. In general, these findings represent a possible link between the etiology of autism and autonomic dysfunction. Thus, the inventor believes that other dysautonomic conditions also have GI primary etiologies. [0022] The symptoms of dysautonomic conditions, however, may have various manifestations due to the genetic makeup of the individuals suffering from the conditions. Various gene sequences in the genetic code of the individual will result in manifestation of certain diseases or symptoms that are expressed uniquely in each individual."

Prion diseases and the gastrointestinal tract
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2538961/
The gastrointestinal (GI) tract plays a central role in the pathogenesis of transmissible spongiform encephalopathies.
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PRIONOPATHIES – ALS and AUTISM?
Research Lead: Dr. David Westaway, University of Alberta
Project: "Extending the spectrum of Prionopathies to Amyotrophic Lateral Sclerosis and Autism"

This project proposes to link the chemistry of the prion protein to the new territory of other nervous system diseases, such as ALS (Lou Gehrig's disease) and the socialization disorder autism-diseases which are at least one thousand times more common than prion protein may operate in other types of brain diseases, which could lead to new ways of thinking about incurable disorders. The project will create changes in the amounts of the various forms of the new membrane protein, and then perform an array of analyses on the behavior and nervous system transmission of laboratory mice. Nervous transmission by electrical impulse can be measured in isolated brain cells, a system that is also convenient to study the effect of stress by adding small amounts of toxins to the fluids bathing the cultures. By these means, the project aims to extend the boundaries of what is considered "prion disease."
http://ranchers.net/forum/viewtopic.php?t=46314

Genes may determine who does and does not contract prion diseases – [thanks to the FDA, EPA and sewage industry, we are all eating prion contaminated food – why don't we all have prion diseases ?
Alzheimer's study reveals new genes implicated in disease

"Findings from the international team suggest at least 20 genes play a role in the common late-onset form of Alzheimer's, more than double the number scientists had previously identified.

The work gives researchers an unprecedented view of the biological pathways that drive the neurodegenerative disorder, and raises the prospect of a test that could determine a person's susceptibility to the disease. Such a test could be helpful in the future if preventative drugs become available.
http://www.theguardian.com/science/2013/oct/27/alzheimers-study-new-genesimplicated
http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf
page 191 of 292

6. Target Populations
All cases of vCJD, to date, have occurred in individuals of a single human genotype

that is homozygous for the amino acid methionine at codon 129 of the prion protein. About 40% of the total human population belongs to this methionine-methionine homozygous state. The susceptibility of other genotypes is not yet known.
http://ghr.nlm.nih.gov/gene/PRNP
prion disease - caused by mutations in the *PRNP* gene
More than 30 mutations in the *PRNP* gene have been identified in people with familial forms of prion disease, including Creutzfeldt-Jakob disease (CJD), Gerstmann-Sträussler-Scheinker syndrome (GSS), and fatal familial insomnia (FFI).
http://www.foxnews.com/health/2015/08/21/cases-fatal-brain-disease-showing-updecades-after-infection/
Cases of fatal brain disease showing up decades after infection
(Present victims of prion diseases – AD, sCJD, Autism, ADHD, etc. were probably infected years ago by eating food grown in prion infected sludge)

Researchers think that certain people who are exposed to the abnormal proteins become sick more quickly: those whose natural prion gene matches that of the infecting prion at a specific point in the gene.
In the United Kingdom, most of the people who became ill (from mad cow disease – variantCJD) early on had a genotype known as VV, and the researchers think the reason for this is that the tissue donor also had this genotype. "We know from human
12
and animal work that compatibility between donor and recipient shortens incubation period," Rudge said.
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Scientists Discover New Disease Caused By Prion Protein August 31, 2015
[Multiple-system atrophy or MSA]
http://www.npr.org/2015/08/31/436377464/scientists-discover-new-disease-caused-byprion-
proteinNews
Researchers: Dr. Stanley Prusiner, Kurt Giles, and UCSF neurology team

STEIN: Corine Lasmezas is a neuroscientist at the Scripps Research Institute in Florida. If a prion can cause MSA, Lasmezas says that's a big boost for the idea that prions could cause other much more common diseases like Alzheimer's, Parkinson's and Lou Gehrig's disease.
KURT GILES: There's been, the past 10 years now, but really, more so maybe the past five years, the understanding that many neurodegenerative diseases may be prion diseases.
"Now we've conclusively shown that a new type of prion causes MSA," said Kurt Giles, a neurology expert at UCSF who worked on the study.
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"http://www.nbcnews.com/health/health-news/rare-brain-disease-caused-cousin-madcow-
agent-study-finds-n419096 September 1, 2015
A rare, incurable brain disorder that resembles Parkinson's disease is caused by a misfolded brain protein called a prion, similar to the prions that cause mad cow disease, researchers reported on Monday.
"Multiple system atrophy or MSA" was discovered by Dr. Stanley Prusiner and his team at UCSF . Dr. Prusiner won the Nobel Prize in 1997 for his prion discoveries. Since 1981, the US FDA has been feeding us prions in the sewage sludge they promote for use on food crops. Prion diseases can incubate for years before striking. "

End of NOTES attached to Petition to FDA to discontinue its policy supporting the application of sewage sludge biosolids as a soil amendment to food crops.

ATTACHMENT: CELL REPORTS

Grass Plants Bind, Retain, Uptake, and Transport
Infectious Prions – Dr. Claudio Soto, et al
http://www.cell.com/cell-reports/pdfExtended/S2211-1247(15)00437-4
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The Petition to FDA, these notes and FDA response will be posted on my web page:
http://www.alzheimers-prions.com/
And new Facebook web page to be set up on this subject.
……
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