WRITTEN SUBMISSION FOR OPEN PUBLIC COMMEN

Freas, William

From: Terry S. Singeltary Sr. [flounder@wt.net]
Sent: Monday, January 08, 2001 3:03 PM
To: freas@CBS5055530.CBER.FDA.GOV
Subject: CJD/BSE (aka madcow) Human/Animal TSE's--U.S.--Submission To Scientific Advisors and Consultants Staff January 2001 Meeting (short version)

Greetings again Dr. Freas and Committee Members,

I wish to submit the following information to the
Scientific Advisors and Consultants Staff
2001 Advisory Committee (short version).

I understand the reason of having to shorten my submission,
but only hope that you add it to a copy of the long version,
for members to take and read at their pleasure,
(if cost is problem, bill me, address below).
So when they realize some time in the near future
of the 'real' risks i speak of from human/animal TSEs and
blood/surgical products. I cannot explain the 'real' risk
of this in 5 or 10 minutes at some meeting,
or on 2 or 3 pages, but will attempt here;

remember AIDS/HIV, 'no problem to heterosexuals in the U.S.?
no need to go into that, you know of this blunder.

DO NOT make these same stupid mistakes again with
human/animal TSE's aka MADCOW DISEASE. I lost my Mom to hvCJD,
and my neighbor lost his Mother to sCJD as well (both cases
confirmed). I have seen many deaths, from many diseases.
I have never seen anything as CJD, I still see my Mom laying helpless,
jerking tremendously, and screaming "God, what's wrong
with me, why can't I stop this". I still see this, and will
never forget. Approximately 10 weeks from 1st of symptoms to death.
This is what drives me. I have learned more in 3 years about not only
human/animal TSE's but the cattle/rendering/feeding industry/government
than i ever wished to.

I think you are all aware of CJD vs vCJD, but i don't think
you all know the facts of human/animal TSE's as a whole,
they are all very very similar, and are all tied to the
same thing, GREED and MAN.

I am beginning to think that the endless attempt to track
down and ban, potential victims from known BSE Countries
from giving blood will be futile. You would have to ban
everyone on the Globe eventually? AS well, I think we
MUST ACT SWIFTLY to find blood test for TSE's,
whether it be blood test, urine test, eyelid test,
anything at whatever cost, we need a test FAST.

DO NOT let the incubation time period of these TSEs fool you.

To think of Scrapie as the prime agent to compare CJD,
but yet overlook the Louping-ill vaccine event in 1930's
of which 1000's of sheep where infected by scrapie
from a vaccine made of scrapie infected sheep brains,
would be foolish. I acquired this full text version of the
event which was recorded in the Annual Congress of 1946
National Vet. Med. Ass. of Great Britain and Ireland.
from the BVA and the URL is posted in my (long version).

U.S.A. should make _all_ human/animal TSE's notifiable at all ages,
with requirements for a thorough surveillance and post-mortem

examinations free of charge, if you are serious about eradicating this horrible disease in man and animal.

There is histopathology reports describing "_florid_ plaques" in CJD victims in the USA and some of these victims are getting younger. I have copies of such autopsies, there has to be more. PLUS, sub-clinical human TSE's will most definitely be a problem.

THEN think of vaccineCJD in children and the bovine tissues used in the manufacturing process, think of the FACT that this agent surviving 600*C.
PNAS -- Brown et al. 97 (7): 3418 scrapie agent live at 600*C

Then think of the CONFIDENTIAL documents of what was known of human/animal TSE and vaccines in the mid to late 80s, it was all about depletion of stock, to hell with the kids, BUT yet they knew. To think of the recall and worry of TSE's from the polio vaccine, (one taken orally i think?), but yet neglect to act on the other potential TSE vaccines (inoculations, the most effective mode to transmit TSEs) of which thousands of doses were kept and used, to deplete stockpile, again would be foolish.

--Oral polio; up to 1988, foetal calf serum was used from UK and New Zealand (pooled); since 1988 foetal calf serum only from New Zealand. Large stocks are held.

--Rubella; bulk was made before 1979 from foetal calf serum from UK and New Zealand. None has been made as there are some 15 years stock.

--Diphtheria; UK bovine beef muscle and ox heart is used but since the end of 1988 this has been sourced from Eire. There are 1,250 litres of stock.

--Tetanus; this involves bovine material from the UK mainly Scottish. There are 21,000 litres of stock.

--Pertussis; uses bovine material from the UK. There are 63,000 litres of stock.

--They consider that to switch to a non-UK source will take a minimum of 6-18 months and to switch to a non-bovine source will take a minimum of five years.

3. XXXXXXXXXXX have measles, mumps, MMR, rubella vaccines. These are sourced from the USA and the company believes that US material only is used.

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4. XXXXXXXXXXX have a measles vaccine using bovine serum from the UK. there are 440,000 units of stock. They have also got MMR using bovine serum from the UK.

5. XXXXXXXXXXX have influenza, rubella, measles, MMR vaccines likely to be used in children. Of those they think that only MMR contains bovine material which is probably a French origin.

6. XXXXXXXXXXX have diphtheria/tetanus and potasses on clinical trial. These use veal material, some of which has come from the UK and has been made by XXXXXXXXXXX (see above).

I have documents of imports from known BSE Countries, of ferments, whole blood, antiallergenic preparations,

human blood plasma, normal human blood sera, human immune blood sera, fetal bovine serum, and other blood fractions not elsewhere specified or included, imported glands, catgut, vaccines for both human/animal, as late as 1998. Let us not forget about PITUITARY EXTRACT. This was used to help cows super ovulate. This tissue was considered to be of greatest risk of containing BSE and consequently transmitting the disease.

ANNEX 6

MEETING HELD ON 8 JUNE 1988 TO DISCUSS THE IMPLICATIONS OF BSE TO BIOLOGICAL PRODUCTS CONTAINING BOVINE - EXTRACTED MATERIAL

How much of this was used in the U.S.?

Please do not keep making the same mistakes;
'Absence of evidence is not evidence of absence'.

What are the U.S. rules for importing and manufacturing vaccines, medicines and medical devices?

Does the U.S.A. allow sourcing of raw material of ruminants from the U.S.A.?

U.S. cattle, what kind of guarantee can you give for serum or tissue donor herds?

The U.S. rendering system would easily amplify T.S.E.'s:

Have we increased the stability of the system (improved heat treatments) since the EU SSC report on the U.S.A. was published in july 2000?

What is done to avoid cross-contaminations in the U.S.A.?

How can the U.S. control absence of cross-contaminations of animal TSE's when pig and horse MBM and even deer and elk are allowed in ruminant feed, as well as bovine blood? I sadly think of the rendering and feeding policy before the Aug. 4, 1997 'partial' feed ban, where anything went, from the city police horse, to the circus elephant, i will not mention all the scrapie infected sheep. I am surprised that we have not included man 'aka soyent green'. It is a disgusting industry and nothing more than greed fuels it.

When will the U.S. start real surveillance of the U.S. bovine population (not passive, this will not work)?

When will U.S. start removing SRMs?

Have they stopped the use of pneumatic stunners in the U.S.?
If so, will we stop it in all U.S. abattoirs or only in those abattoirs exporting to Europe?
If not, WHY NOT?

same questions for removal of SRM in the U.S.A.,
or just for export?
If not, WHY NOT?

How do we now sterilize surgical/dental instruments in the U.S.A.?

Where have we been sourcing surgical catgut?
(i have copies of imports to U.S., and it would floor you)

When will re-usable surgical instruments be banned?

Unregulated "foods" such as 'nutritional supplements' containing various extracts from ruminants, whether imported or derived from

US cattle/sheep/cervids ("antler velvet" extracts!) should be forbidden or at least very seriously regulated.
(neighbors Mom, whom _also_ died from CJD, had been taking bovine based supplement, which contained brain, eye, and many other bovine/ovine tissues for years, 'IPLEX').

What is the use of banning blood or tissue donors from Germany, France, etc... when the U.S.A. continues exposing cattle, sheep and people to SRM, refuses to have a serious feed ban, refuses to do systematic BSE-surveillance?

The FDA should feel responsible for the safety of what people eat, prohibit the most dangerous foods, not only prohibit a few more donors - the FDA should be responsible for the safe sourcing of medical devices, not only rely on banning donors "from Europe",
The 'real' risks are here in the U.S. as well, and have been for some time.

We must not forget the studies that have proven infectivity in blood from TSE's.

The Lancet, November 9, 1985

Sir,--Professor Manuelidis and his colleagues (Oct 19, p896) report transmission to animals of Creutzfeldt-Jakob disease (CJD) from the buffy coat from two patients. We also transmitted the disease from whole blood samples of a patient (and of mice) infected with CJD.1 Brain, Cornea, and urine from this patient were also infectious, and the clinicopathological findings2 are summarised as follows.

snip...

Samples were taken aseptically at necropsy. 10% crude homogenates of brain and cornea in saline, whole blood (after crushing a clot), and untreated CSF and urine were innoculated intracerebrally into CF1 strain mice (20 ul per animal). Some mice showed emaciation, bradykinesia, rigidity of the body and tail, and sometimes tremor after long incubation periods. Tissues obtained after the animal died (or was killed) were studied histologically (table). Animals infected by various inocula showed common pathological changes, consisting of severe spongiform changes, glial proliferation, and a moderate loss of nerve cells. A few mice inoculated with brain tissue or urine had the same amyloid plaques found in patients and animals with CJD.3

snip...

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JUN TATEISHI

(full text-long version)

and

CWD and transmission to man will be no different than other TSE's.

"Clearly, it is premature to draw firm conclusions about CWD passing naturally into humans, cattle and sheep, but the present results suggest that CWD transmissions to humans would be as limited by PrP incompatibility as transmissions of BSE or sheep scrapie to humans. Although there is no evidence that sheep scrapie has affected humans, it is likely that BSE has

caused variant CJD in 74 people (definite and probable variant CJD cases to date according to the UK CJD Surveillance Unit). Given the presumably large number of people exposed to BSE infectivity, the susceptibility of humans may still be very low compared with cattle, which would be consistent with the relatively inefficient conversion of human PrP-sen by PrPBSE. Nonetheless, since humans have apparently been infected by BSE, it would seem prudent to take reasonable measures to limit exposure of humans (as well as sheep and cattle) to CWD infectivity as has been recommended for other animal TSEs."

G.J. Raymond1, A. Bossers2, L.D. Raymond1, K.I. O'Rourke3, L.E. McHolland4, P.K. Bryant III4, M.W. Miller5, E.S. Williams6, M. Smits2 and B. Caughey1,7

or more recently transmission of BSE to sheep via whole blood
Research letters Volume 356, Number 9234 16 September 2000

Transmission of BSE by blood transfusion in sheep

Lancet 2000; 356: 999 - 1000

F Houston, J D Foster, Angela Chong, N Hunter, C J Bostock

See Commentary

"We have shown that it is possible to transmit bovine spongiform encephalopathy (BSE) to a sheep by transfusion with whole blood taken from another sheep during the symptom-free phase of an experimental BSE infection. BSE and variant Creutzfeldt-Jakob disease (vCJD) in human beings are caused by the same infectious agent, and the sheep-BSE experimental model has a similar pathogenesis to that of human vCJD. Although UK blood transfusions are leucodepleted--a possible protective measure against any risk from blood transmission--this report suggests that blood donated by symptom-free vCJD-infected human beings may represent a risk of spread of vCJD infection among the human population of the UK."

"The demonstration that the new variant of Creutzfeldt-Jakob disease (vCJD) is caused by the same agent that causes bovine spongiform encephalopathy (BSE) in cattle1 has raised concerns that blood from human beings in the symptom-free stages of vCJD could transmit infection to recipients of blood transfusions (full text long version)"

and...

"The large number of cases (1040), temporal clustering of the outbreaks (15 in the first 6 months of 1997), the high in-flock incidence, and the exceptional involvement of goats (390 cases), suggested an accidental infection. The source of the epidemic might have been TSE-contaminated meat and bonemeal, but eight flocks had never been fed any commercial feedstuff. Infection might have risen from the use of a formol-inactivated vaccine against contagious agalactia prepared by a single laboratory with brain and mammary gland homogenates of sheep infected with Mycoplasma agalactiae. Although clinical signs of TSE in the donor sheep have not been found, it is possible that one or more of them were harbouring the

infectious agent. Between 1995 and 1996, this vaccine was given subcutaneously to 15 of the affected flocks (to one flock in 1994); in these animals the disease appeared between 23 and 35 months after vaccination. No information is available for herd 13 because it was made up of stolen animals. Sheep from the remaining three flocks (1-3, figure) did not receive the vaccine, thus suggesting a naturally occurring disease." (again, full text long version).

IN SHORT, please do under estimate this data and or human/animal TSE's including CWD in the U.S.A.

A few last words, please.

The cattle industry would love to have us turn our focus to CWD and forget about our own home grown TSE in Bovines. This would be easy to do. Marsh's work was from downer cattle feed, NOT downer deer/elk feed. This has been proven.

DO NOT MAKE THAT MISTAKE.

There should be NO LESS THAN 1,000,000 tests for BSE/TSE in 2001 for U.S.A. French are testing 20,000 a week. The tests are available. Why wait until we stumble across a case from passive surveillance, by then it is to late. IF we want the truth, this is a must???

United States Total Bovine Brain Submissions by State,

May 10,1990 thru October 31, 2000

Total 11,700

FROM 1.5 BILLION HEAD OF CATTLE since 1990 ???

with same feeding and rendering practices as that of U.K. for years and years, same scrapie infected sheep used in feed, for years and years, 950 scrapie infect FLOCKS in the U.S. and over 20 different strains of scrapie known to date. (hmmm, i am thinking why there is not a variant scrapie, that is totally different than all the rest)? just being sarcastic.

with only PARTIAL FEED BAN implemented on Aug. 4, 1997??? (you really need to reconsider that blood meal etc. 'TOTAL BAN')

http://www.aphis.usda.gov/oa/bse/bsesurvey.html#charts

AND PLEASE FOR GODS SAKE, STOP saying vCJD victims are the only ones tied to this environmental death sentence. "PROVE IT". It's just not true. The 'CHOSEN ONES' are not the only ones dying because of this man-made death sentence. When making regulations for human health from human/animal TSEs, you had better include ALL human TSE's, not just vCJD. Do NOT underestimate sporadic CJD with the 'prehistoric' testing available to date. This could be a deadly mistake. Remember, sCJD kills much faster from 1st onset of symptoms to death, and hvCJD is the fastest. Could it just be a higher titre of infectivity, or route or source, or all three?

Last, but not least. The illegal/legal harvesting of body parts and tissues will come back to haunt you. Maybe not morally, but due to NO background checks and human TSEs, again it will continue to spread.

Stupidity, Ignorance and Greed is what fuels this disease. You must stop all of this, and ACT AT ONCE...