implemented innovative practices in their delivery of services. Respondent: State or Local Governments.

BURDEN ESTIMATES

Instrument	Number of respondents	Responses	Hours per response	Total hours
State CPS Directors	63	1	2	126
Local Survey—Administration	158	1	.5	79
Local Survey—Intake	158	1	1	158
Local Survey—Investigation	233	1	1	233
Local Survey—Other CPS Resp	100	1	1	100
Local Survey—New Directions	188	1	1	188
Site Visit—Director Interview	12	1	1	12
Site Visit—Managers	16	1	2	32
Site Visit—Worker Focus Group	80	1	2	160
Site Visit—External Managers	48	1	2	96
Site Visit—Policy Review Group	48	1	2	96
Estimated Burden Total				1,288

OMB Desk Officer: Allison Herron Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690–6207. Written comments and recommendations for the proosed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th street NW., Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington DC, 20201. Written comments should be received within 30 days of this notice.

Dated: August 14, 2001.

Kerry Weems,

Acting Deputy Assistant Secretary, Budget.

[FR Doc. 01–21143 Filed 8–21–01; 8:45 am]

BILLING CODE 4154–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Meeting

AGENCY: Office of the Secretary, HHS.

ACTION: Notice of meeting.

At the request of the Secretary, a meeting will be held to determine if and how the Public Health Service Bovine Spongiform Encephalopathy/ Transmissible Spongiform Encephalopathy (BSE/TSE) Action Plan can be expanded to capitalize on the human and physical resources of the pharmaceutical and biotechnology industries. A copy of this plan is appended to this Notice. The meeting will be held in the Office of the Secretary, Hubert H. Humphrey Building, 200 Independence Ave. SW., Washington, DC 20201 on Monday, September 24, 2001, from 9 a.m. to 3 p.m. Because of space limitations, attendance at the meeting will be limited to approximately 100 persons, and will therefore be limited to those who have preregistered.

Up to 30 of the approximately 100 spaces available will be reserved for those who submit a written proposal of no more than two single-spaced pages in length, and preferably no more than one page, that describes in general terms (1) needs in areas of basic research on any aspect of BSE or any TSE that are currently unmet and (2) human and physical resources under their control that could be recruited to support this research. This solicitation of ''industries'' is directed at industries of all sizes, and to non-profit as well as for-profit entities.

Preference for the 30 reserved spaces will be given to those whose proposals are received by the undersigned no later than close of business Friday, August 31, 2001. A paper copy and an electronic copy in either Microsoft Word (R) or WordPerfect (R) format are requested, but fax and e-mail submissions will be accepted. Proposals must include a return mailing address, individual to contact, and telephone number of that individual. If available, a fax number and an e-mail address should also be provided.

A period of up to one hour will be reserved for public comment. Persons who wish to comment on their own proposal or any other matter will be asked to do so for no more than 5 minutes.

The sole purpose of this meeting is to gather information. No decisions will be made at this meeting. A transcript and a summary of the meeting will be available from the undersigned on or before October 8, 2001.

Those considering submission of a proposal or speaking at the meeting are advised that all information received in response to this Notice will be considered to be in the public domain.

For Registration or Further Information Contact

Stephen D. Nightingale, M.D., Office of Public Health and Science, Department of Health and Human Services, 200 Independence Ave., SW., Washington, DC 20201, phone (202) 690–5558, fax (202) 260–9372, e-mail *StephenDNightingale@osophs.dhhs.gov*.

Dated: August 17, 2001.

Stephen D. Nightingale,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

Bovine Spongiform Encephalopathy/ Transmissible Spongiform Encephalopathy (BSE/TSE) Action Plan

Background

Bovine spongiform encephalopathy (BSE), or ''mad cow disease,'' was first recognized in the United Kingdom in 1986. Major efforts were undertaken to control the BSE epidemic that followed. These included the precautionary slaughter of about 4.5 million asymptomatic cattle, and increasingly broader prohibitions against recycling animal tissues and byproducts into the food chain through livestock feed supplements. There is compelling epidemiological evidence that these actions reversed the course of the BSE epidemic within the United Kingdom.

Unfortunately, these measures were insufficient, or not instituted in time, to prevent the occurrence of BSE in other European countries. These initially included France, Ireland, Portugal, and

Switzerland, and have more recently included Belgium, Denmark, Germany, Italy, Netherlands, and Spain. However, BSE has not yet been found in the United States.

BSE is one of several transmissible spongiform encephalopathies (TSEs). Other animal TSEs include scrapie in sheep and goats, and chronic wasting disease (CWD) of deer and elk. Scrapie and CWD are found in the United States. Human TSEs include kuru, a disease of the South Pacific Fore people; Creutzfeldt-Jakob disease (CJD), which occurs throughout the world, including the United States (where it occurs at a stable rate of about 1 per million population per year); and new variant CJD (vCJD), which was first reported in the United Kingdom in 1996. There is no evidence to date of vCJD in the United States. There is no known treatment for any TSE, and they are all invariably fatal.

The TSEs are named for the characteristic spongelike appearance associated with deposits of proteins, called prions, that are found in patients' brains. In some but not all TSEs, there are characteristic deposits of prions, sometimes detectable preclinically, in other tissues as well. Prions are proteins that have been highly conserved in mammalian evolution, but whose function is not well understood. They do not cause disease in their native state, but only when they become abnormally folded.

What causes the abnormal folding to occur, why affected individuals cannot dispose of or develop immunity to these proteins, and what factors other than the prions themselves affect the transmission or the pathogenesis of the TSEs are poorly understood. In particular, the lack of a sensitive and specific noninvasive test for either animal or human TSEs, or methods for identifying those at increased risk of a TSE, are major obstacles to progress. However, recent investigations in this field appear to hold substantial promise.

Issue

The report of vCJD (a disease of humans) in the United Kingdom only ten years after the recognition of BSE (a disease of animals) was by itself an event of great concern. This concern has been reinforced by the findings that the transmissible agent of BSE and the transmissible agent of vCJD are indistinguishable by current bioassays from each other; that BSE has spread from the United Kingdom to other countries, and that vCJD has begun to appear in some countries to which BSE has spread. These events call for a vigorous DHHS effort—coordinated with those of other government agencies, the private sector, and the international community—to contain this epidemic and assist those affected by it.

Response

The BSE/TSE Action Plan of the Department of Health and Human Services (DHHS) has four major components: *Surveillance, Protection, Research,* and *Oversight. Surveillance* for human disease is primarily the responsibility of the Centers for Disease Control and Prevention (CDC). *Protection* is primarily the responsibility of the Food and Drug Administration (FDA). Surveillance of animals, feeds, and foods is also a responsibility of FDA, which it shares with the United States Department of Agriculture (USDA). *Research* is primarily the responsibility of the National Institutes of Health (NIH). *Oversight* is primarily the responsibility of the Office of the Secretary (OS). Core actions in each area are as follows:

1. Surveillance—CDC

A foundation of CDC disease surveillance and outbreak investigation activities is its relationship with—and support of—state and local health agencies and officials, who are often the first to encounter newly emerging human diseases or changes in the epidemiology of recognized human diseases. These relationships complement those that CDC maintains with health care providers and institutions such as healthcare facilities. These relationships are designed to maximize the likelihood that a sentinel event will be detected as soon as it occurs, whether in an expected or an unexpected location.

CDC collects, reviews, and when indicated actively investigates reports by health care personnel or institutions of possible CJD or vCJD cases. CDC also monitors overall mortality data and carefully scrutinizes mortality data in certain populations (for example, persons with hemophilia). In addition, after the report of vCJD in the United Kingdom in 1996, CDC augmented its domestic CJD surveillance. Because of the striking age differences between vCJD and CJD patients, CDC, in partnership with state and local health departments, initiated post-mortem followup investigations of patients diagnosed with CJD who were less than 55 years of age at death. In 1996–1997, CDC established, in collaboration with the American Association of Neuropathologists, the National Prion Disease Pathology Surveillance Center at Case Western Reserve University, which performs special post-mortem tests for vCJD.

Under this Action Plan, CDC will provide additional financial and technical support for state and local health department surveillance for CJD and vCJD cases. The Action Plan anticipates the need for more case investigations and risk assessments, particularly if the epidemiology of vCJD changes. The action plan will increase the range, accuracy and timeliness of current efforts.

The proposals are as follows:

A. By the end of 2001, CDC will support cooperative agreements with state and local health departments to:

i. Enhance pre-mortem surveillance to increase the number of post-mortem studies on individuals, who by virtue of their symptoms (*e.g.*, ataxia or dementia) and situations (*e.g.*, long exposure to food products from the United Kingdom) might be at increased risk for TSEs, and

ii. Expedite national surveillance of CJD through accelerated review of CJD mortality data and clinical investigation of all such cases under 55 years of age to identify possible cases of vCJD.

B. CDC will enhance its current collaborative agreement with the National Prion Disease Pathology Surveillance Center at Case Western Reserve University by the end of FY 2001.

C. CDC will enhance and expand infection control recommendations to protect patients and health care workers from the potential transmission of TSE in healthcare facilities by the end of FY 2002.

D. CDC will maintain and, as appropriate, expand its contact with national and local health officials in countries that have found, or may find, new or increasing numbers of animal or human TSEs within their borders (FDA and NIH, in the course of actions described below, will do the same with their regulatory and scientific counterparts).

The following additional activities and expansion of A above will require additional or reallocated resources.

A. CDC will enhance and expand its technical assistance to the increasing number of state and local health personnel whom these cooperative agreements will make available to identify and investigate possible cases of TSEs.

B. CDC will develop laboratory capacity at its main campus to provide analytic support for health investigations, and to conduct research on methods to improve these investigations by the end of FY 2003. This activity will depend on the

completion of new laboratory space, anticipated to become available in FY 2004.

2. Protection—FDA

The foundations of FDA consumer protection and health promotion activities are rigorous application of scientific knowledge to regulatory policies and actions, appropriate caution when scientific knowledge is insufficient to determine the optimal policy or action, a strong regulatory infrastructure to assure compliance with established regulations, and aggressive pursuit of the scientific knowledge necessary to anticipate as well as resolve regulatory issues. Maintenance of an environment in which these practices can flourish requires timely and open dialogue about the agency's actions, and the reasons for its actions, with both stakeholders on specific issues and with the public at large.

Consistent with this overall strategy, FDA has undertaken five major initiatives to enhance, sustain, and communicate safeguards. These are:

A. FDA, in partnership with USDA, seeks to prevent exposure of the public to TSE agent(s) through food products. FDA will continue and as necessary expand its import and animal feed surveillance/inspection programs and enforcement actions to control the use of mammalian protein in ruminant feed, to keep potentially infected products out of the United States, and to address further the issue of CWD in domestic deer and elk.

B. FDA will continue and as necessary expand its policies designed to prevent potential exposure to TSE agent(s) through blood transfusion and tissue transplantation. Reevaluations occur both on a routine, at least semi-annual basis in conjunction with meetings of the FDA TSE Advisory Committee, and whenever new information becomes available.

C. FDA will continue and as necessary expand its policies to prevent potential exposure of the public to TSE agent(s) through drugs, devices, vaccines, other biologics, cosmetics, food, food additives, or dietary supplements that use in their manufacture at-risk bovine materials. These efforts are routinely incorporated into the pre-approval review of new entities that are required to undergo such review, and by targeted post-marketing review of specific entities that may either contain at-risk bovine materials, or entities that may be exposed to at-risk bovine materials during their manufacture. Ongoing enhancements to guidances and regulations regarding acceptability of source materials for these products are an integral component of this effort.

D. FDA will continue and as necessary expand its coordinated education and outreach program to inform consumers, patients, practitioners, and industry of the risks of TSEs and of their potential transmission through the products that FDA regulates.

E. FDA will continue and as necessary expand its regulatory research agenda regarding TSEs. As noted above, the lack of a sensitive, specific, and non-invasive test to detect either humans or animals with an increased risk of developing or incubating a TSE is a major obstacle to progress against TSEs, and to FDA's efforts to meet its consumer protection and health promotion mandates. While FDA is encouraged by recent progress in this field, FDA nevertheless feels obligated to continue both intramural and extramural research to support the development and evaluation of tests for premortem detection of TSE agents(s) that will have sufficient sensitivity and specificity for diagnostic, screening, and quality control purposes. FDA will also pursue studies to evaluate the safety and effectiveness of sterilization/decontamination/inactivation procedures for BSE/TSE agent(s) so that these procedures can become part of Good Manufacturing Practices.

3. Research—NIH

A foundation of NIH research portfolio management is to maintain a balance between its support of research focused on health matters of immediate concern, and research that aspires to address concerns that may arise in the future. The NIH supports both intramural and extramural research, some of which is guided by agency directives, and some by proposals of individual investigators. In addition to fostering individual proposals, the NIH fosters the training and professional development of the young investigators necessary to sustain the country's research efforts in the future.

The first scientific work on human TSE to be undertaken anywhere in the world was initiated on the NIH campus in the early 1960's. Currently NIH funding for TSE research, which is provided for investigators throughout the United States, is focused on four areas:

i. Understanding the prions that cause TSEs;

ii. Defining how TSEs are transmitted among animal species and, most importantly, across apparent species barriers;

iii. Developing diagnostic tests for animals and humans using tissues and blood;

iv. Designing drug therapy.

Pursuant to these goals, major TSE research programs are currently being supported by the following institutes:

i. The National Institute of Neurological Disorders and Stroke (NINDS) supports basic and applied research on TSEs in both its intramural and extramural programs. Prior accomplishments of the intramural program have been recognized by the award of the Nobel Prize to Dr. Carleton Gadjusek for demonstrating that both kuru and CJD were transmissible, and prior accomplishments of the extramural program have been recognized by the award of the Nobel Prize to Dr. Stanley Prusiner for his work on prions. NINDS funding for TSE research was $8.87 million in FY 1999 and $12.75 million in FY 2000.

ii. The National Institute of Allergy and Infectious Diseases (NIAID) also supports both intramural and extramural research on TSEs, with a particular focus on chronic wasting disease (CWD) of deer and elk. The intramural NIAID program, which is conducted at the NIAID Rocky Mountain Laboratories in Hamilton, Montana, has developed genetically engineered mouse models of scrapie and CWD and used these to study the effects of particular genes and of species barriers on the natural history of these diseases. The laboratory has also initiated a drug discovery program. Renovation of the Rocky Mountain facilities devoted to TSE research is currently under way, at a cost of $1.62 million dollars. In FY 2002, NIAID expects that roughly $1 million will be allocated to the Rocky Mountain Laboratories for support of TSE-related research.

iii. The National Heart, Lung, and Blood Institute (NHLBI) is the lead institute within NIH for the development of tests for TSEs that would be suitable for screening the blood supply. The research currently funded is targeted at developing and validating test strategies for various human and animal TSEs in samples of known infectivity. This program includes two contracts jointly sponsored by NHLBI and NINDS that run from fall 2000 to fall 2005 and three NHLBI-initiated research grants that run from fall 2000 to fall 2003. NHLBI funding for TSE research was $0.9 million in FY 1999 and $2.2 million in FY 2000.

Efforts in all of the above areas are being expanded. However, there is a critical shortage of investigators and specialized laboratory facilities that can

handle the hazardous material used in studies of TSEs. A goal of the NIH is to address these needs by mounting a coordinated effort among the Institutes at NIH as well as with other Federal agencies to achieve these objectives:

A. Establish a repository for research reagents by the next fiscal year;

B. Double the laboratory facilities available over the next two years;

C. Triple the number of investigators involved in TSE research over the next five years;

D. Double or if possible triple current spending for TSE research by the end of FY 2002. To do this, the NIH will convene a special meeting to identify the major needs and opportunities for research in this field. The product of this workshop will form the basis of a Request for Applications. The scientific quality of the applications received will determine the total funding committed to this initiative. The Acting Director, NIH, has agreed to provide funding as needed for this purpose from the Director's Discretionary Fund.

E. Consider, in consultation with OS, the establishment of a ''prize'' of about $1 million for the first person(s) or organization(s) to provide proof of principle for the development of a minimally invasive test that would be sufficiently sensitive and specific for screening random populations for presymptomatic infection with CJD or vCJD, and a ''prize'' of about $5 million to the first person(s) or institution(s) to obtain FDA approval and to place into commercial distribution a minimally invasive screening test that would be sufficiently sensitive and specific for screening random populations for presymptomatic infection with CJD or vCJD.

4. Oversight—OS

The foundations of OS oversight activities are the statutory obligations of the Secretary, and the lessons that have been learned from experience with the HIV and hepatitis C epidemics.

In 1995, at the request of the Department, the Institute of Medicine (IOM) issued a report titled ''HIV and the Blood Supply: An Analysis of Crisis Decisionmaking.'' The IOM recommended that the Secretary establish a Public Health Service (PHS) Blood Safety Committee (BSC). The Secretary designated the Assistant Secretary for Health to be the chair of this committee and to be the Blood Safety Director for the Department. Other BSC members are the directors of CDC, FDA, and NIH; the Assistant Secretary for Planning and Evaluation; and the Associate General Counsel for Public Health. This committee exists so that threats to the safety or availability of the blood supply can be brought immediately to the highest levels of the Department. The BSC has met on the issue of deferring blood donors at risk of transmitting BSE by virtue of prior residence in the United Kingdom. The BSC also met on issues relating to the development of CJD at an unusually young age in a hunter who had been a long time plasma donor, and on issues related to the discovery of a poorly characterized TSE that recently appeared in two flocks of East Freisian sheep which had been imported to Vermont from Belgium. The group stands ready to be convened for similar matters in the future.

The Department has also established an Interdepartmental Steering Committee for BSE/TSE Affairs. This committee is chaired by the Commissioner of FDA and includes representatives of CDC, FDA, NIH, USDA, the United States Trade Representative, the Office of Management and Budget, the Customs Service, the Department of State, the Department of Defense, the State Association of Feed Control Officials, the National Association of State Departments of Agriculture, and the White House Office of Science and Technology Policy. This committee assures ongoing coordination between agencies; integrated contingency planning in case BSE or of vCJD is found in the United States; identification of and response to potential vulnerabilities in the United States to BSE and vCJD; and coordination of risk communication plans by the various agencies. A summary of each meeting of this group will be forwarded through the Assistant Secretary of Health to the Secretary within thirty days of each meeting, and on a more expedited basis as necessary.

The Department must assure timely, accurate, thorough, and clear communication to the public about the nature and extent of the threats posed by BSE/TSE and about the actions that each agency of government is taking to protect the public from these threats. In addition, each agency must anticipate the worst case scenarios of a case of BSE or of vCJD being recognized in the United States, and each agency must have a plan not only for dealing with this contingency but also for communicating the event itself, and the agency response to the event, to the public. Furthermore, the communications of the various agencies must be consistent with each other. For this reason, the BSE/TSE Steering Committee will establish a communications workgroup to develop an interdepartmental communications strategy and plan for dealing with a potential occurrence of BSE and/or vCJD and serve as a public affairs/communications resource in dealing with BSE/TSE issues.

Also, the FDA TSE Advisory Committee meets publicly on at least a semi-annual basis. One standing agenda item of this committee is review of current regulations and guidance to prevent exposure of the United States population to the agent(s) of BSE/TSE through blood, tissues, and other regulated products. A summary of this meeting, with particular attention to this agenda item and to public comment about it, will be forwarded through the Assistant Secretary for Health to the Secretary within thirty days of each meeting, and on a more expedited basis as necessary.

Issues that warrant OS oversight at this time include the following:

A. Assurance of adequate program support to enhance TSE surveillance by CDC as planned.

B. Assurance of adequate program support for FDA regulatory and research activities related to TSEs.

C. Assurance of adequate program support for the TSE research initiatives proposed by NIH.

D. Assurance and coordination of integrated risk communication messages to the public and to industry regarding the true nature of threats posed by BSE/TSEs, particularly in the event of a confirmed case within the United States.

E. Assurance of a seamless collaboration with USDA and other federal and state agencies on BSE/TSE issues.

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BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Statement of Organization, Functions, and Delegations of Authority

Part E, Chapter E (Agency for Healthcare Research and Quality), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (61 FR 15955–58, April 10, 1996, most recently amended at 65 FR 16395 on March 28, 2000) is further amended to reflect organizational changes necessitated by section 902 of the Public Health Service (PHS) Act as amended by the Healthcare Research