Centers for Disease Control and Prevention
National Center on Birth Defects and Developmental Disabilities

National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect

Conference Call Summary Report
January 23, 2003

Present on the call were the following:

Members	Other Participants	CDC
Edward P. Riley, Ph.D. Chair, National Taskforce on FAS	Barbara Anderson Wine Group	Martha Alexander, M.P.H.
José F. Cordero, M.D., M.P.H. Acting Executive Secretary	Diouna Baker, M.P.H. SAMHSA	Jacquelyn Bertrand, Ph.D.
Louise Floyd, D.S.N., R.N. Designated Federal Official	Christina Chambers, Ph.D., M.P.H. UCSD Medical Center	Connie Granoff
Michael E. Charness, M.D. Harvard Medical School	Daniel Dubovsky, M.S.W. FAS Center for Excellence	Elizabeth Parra, M.P.H.
Claire D. Coles, Ph.D. FAS Center, Marcus Institute	Jean Mahoney ACOG	Jorge Rosenthal, Ph.D.
Nancy L. Day, Ph.D. University of Pittsburg	Kathleen Masis, Ph.D. Indian Health Service	Jasjeet Sidhu, M.D., M.P.H.
Fred W. Garcia WA State Division of Alcohol/Substance Abuse	Pam Gillen Colorado	Tanya T. Sharpe, Ph.D., M.S.
Teresa M. Maresca, M.D.	Jessie O'Cain University of Maryland	Mary Kate Weber, M.P.H.
Kathleen T. Mitchell National Organization on FAS	Robert M. Schacht, Ph.D. Northern Arizona University	Jacqueline Vowell, Committee Management Specialist
Deidre Roach (representing Faye Calhoun) NIAAA, NIH	Debra Stone FAS Center for Excellence	
Luther Robinson, M.D. State University of NY – Buffalo	Barbara Wybrecht Michigan	
Charles Schad, Ed.D. Educator	Richard Evancheck, Bureau of Alcohol, Tobacco, & Firearms (ATF)	
Liaison Representatives	Sarah Horton Bobo Michigan	
Deborah Cohen, Ph.D. NJ Dept of Human Services		
Karla Damus, R.N., Ph.D. March of Dimes		
George A. Hacker, J.D. Center for Science in the Public Interest		
Robert J. Sokol, M.D. Wayne State University		

Welcome/Introductions

José Cordero, M.D., M.P.H., Acting Executive Secretary
Director, National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control and Prevention

Dr. Cordero welcomed those on the call, thanking them for their participation. He indicated that Dr. Dixie Snider would not longer be able to serve on this Committee due to his new responsibilities. Dr. Cordero explained that the new CDC Director, Dr. Julie Gerberding, had reorganized the Office of the Director (OD) to include two Deputies, Dr. David Fleming and Dr. Ed Thompson. In addition, there is a new designation of Chief Operating Officer and there is a new Chief of Staff. With regard to the National Center on Birth Defects and Developmental Disabilities (NCBDDD), Dr. Cordero stressed that the reorganization of the Office of the Director would have little if any impact other than to improve and simplify ways to communicate to the Office of the Director.

Background/Discussion on Final Version of the FAS Statement by the Public Affairs Committee of the Teratology Society

Dr. Christina Chambers
Public Affairs Committee
Teratology Society

Regarding the FAS Statement by the Public Affairs Committee of the Teratology Society, Christina Chambers indicated that the Public Affairs Committee of the Teratology Society periodically prepares and publishes statements on topics of interest they think are of wide public health interest in the area of teratology. The FAS Statement was put together over a year-long period, and was completed in 2002. As a strategic planning goal, the Teratology Society plans to make a more concerted effort to take on issues that are important to the Society and to expand their interests to create liaisons with other groups that have similar interests. The Society would like to have wide public readership of the FAS statement and to help draw attention to this issue on a broader basis than might normally be achieved by publication in the *Journal of Teratology.* The Society decided to seek endorsement from or collaboration with the Task Force in supporting their statement on Fetal Alcohol Syndrome.

With that in mind, the FAS Statement was circulated to the members of the Task Force for review and comments. The Society agreed to make a number of revisions offered by Task Force members which have now been incorporated into the FAS Statement. The Public Affairs Committee of the Teratology Society then decided that they would like the Task Force to consider endorsing the FAS Statement as a joint publication, submitting it to more widely-read sources, perhaps as some type of commentary. The original FAS Statement was published in the December 2002 issue of the *Journal of Teratology* as it was approved by the Society at that time.

The version distributed to Task Force members for the purposes of this conference call varied slightly from the original document in the following ways:

Section 1: Improved Recognition of the Fetal Alcohol Syndrome (FAS):

- One recommendation was that research be encouraged to develop more successful methods of eliciting disclosure of alcohol consumption information in pregnant women, and the Public Affairs committee added "as well as women of child bearing age."

Section 4: Risk Factors for and Prevention of the Fetal Alcohol Syndrome:

- The first sentence, "Despite the fact that FAS is the most recognizable cause of mental retardation" originally read "no prevention program…" but was changed to read "no widely-used prevention program has successfully dealt with this problem."

- There were changes in the wording for the recommendations under Section 4, the first two in particular:

  - The change was to include "high-risk women including those who have previously given birth to an affected child" as a focus for prevention programs.
  - To the second one recommending that "outreach programs be established to identify pregnant women who drink and extend to them interventions directed at correcting nutritional deficiency" they added "and eliminating drinking."
  - To the third recommendation, the phrase "risk factors for FAS including" was added to "…the extent to which genetic factors play a role in the incidence of this disorder and that poor nutrition confers susceptibility."

Section 5: Social and Economic Factors Associated With the Prevalence and Prevention of FAS:

The quote regarding the prevalence of FAS in first grade classes in South Africa was corrected to read, "In a recent study, 46 of 1000 (4.6%) children in the normal first grade classes in a rural town in South Africa were documented to have FAS (May et at., '00), a rate which is 30 times higher . . ."

Discussion Points:

- Dr. Cordero inquired as to whether the Society was seeking endorsement from other groups such as ACOG, alcohol research groups, etc. to request that they, too, embrace this statement. Dr. Chambers responded that the Society would like very much to be able to do that. They approached the Task Force first because they thought that the mutual interest of the two groups was the most logical. Following that, if the Society were to approach the Task Force and be able to receive endorsement or co-authorship on the FAS Statement, they would then be highly interested in having other groups sign on as well.

- Concern was expressed that there may be difficulty in distinguishing between the two versions of the FAS Statement, particularly with regard to how readers would decide which was the version endorsed by the Task Force given that the original statement, without the Task Force changes, had already been published in the *Journal of Teratology*. Dr. Chambers responded that the changes were minor, that the version being reviewed by the Task Force could still be considered a work in progress to which they could suggest further change, and that the Society planned to seek publication elsewhere.

- Some Task Force members continued to express concern regarding the endorsement of a statement that differed from that which had already been published. In addition, concern was expressed regarding whether the Task Force was in the business of endorsement as part of their mandate or role. Dr. Cordero pointed out that perhaps they were troubled by the term "endorsement." He stressed that as an Advisory Committee, a basic mission of the Task Force was to provide direction for the work being carried out in the prevention of FAS, as well as the direction in which FAS research should go. He asked the Task Force to consider instead whether the FAS Statement represented recommendations that the Task Force, as a group, could "embrace." He stressed that there was a great deal of precedence for Advisory Committees and Task Forces to harmonize recommendations on important issues, using immunization as an example. Moreover, there have been a number of incidences wherein slightly differing versions of recommendations have been published.

- Dr. Floyd pointed out that the FAS Statement very much mirrored the recommendations made in the *MMWR* in the Fall of 2002. In addition, she noted that the Teratology Society is a science-based group which is highly regarded worldwide for their contributions in the fields of birth defects and developmental disabilities.

- Dr. Day expressed concern with Section 4 about the statement regarding impoverished women in that the statement appears to imply that only poor women drink. Not only did she think that there is not good data for this, but also she was concerned that this kind of proclamation may give the impression that this is just something that poor women do. This may cause other women who are not poor, but who drink just as much, to be overlooked. Other Task Force members expressed concern as well, indicating that they wanted to reflect the concept that women who are marginalized face many other issues as well. Dr. Riley noted that Section 5 read more like a social commentary than an evidence- based recommendation. There was some sentiment that this section be left out entirely. Also of concern was that some children are not being identified, for example those born to mothers who drank heavily before they knew they were pregnant. Dr. Chambers acknowledged that the statement regarding poor women was the most contentious piece of the FAS Statement from the outset. However, the intent was never to imply that poor women were supposedly at greater risk. She stressed that the statement could be reworded more clearly to reflect these concerns.

- Dr. Cohen stressed that the FAS Statement was created by the Teratology Society, and that while it was important for the Task Force to give some motion of support, this was not the Task Force's statement to rewrite entirely. Dr. Riley suggested that this depended upon how

the Public Affairs Committee of the Teratology Society viewed the role of the Task Force. It was not clear whether the Task Force was going to co-author or simply endorse the FAS Statement. A Task Force member expressed the sentiment to Dr. Riley that it should be the Task Force making recommendations about FAS priorities, which would, in turn, be endorsed by other organizations—not other organizations making the recommendations and then asking the Task Force to endorse them. Dr. Cordero stressed that if that approach had been taken in the immunization world, nothing would have been accomplished, and that they needed to begin harmonizing with other partners in the FAS world. He applauded the Teratology Society for taking the initiative to put together the document and suggested that the Task Force consider whether they could embrace the FAS Statement. Others agreed that the messages about FAS must be disseminated widely, and that one way to move that along would be for the Task Force to endorse the FAS Statement. It was noted that none of the recommendations made by the Society contradicted any of the recommendations made by the National Task Force.

- Daniel Dubovsky referred the group to Sections 1 and 2 of the FAS Statement, noting that something should be included about adolescents and adults as well, given that children with FAS become adolescents and adults with FAS. While early intervention is important, he thought that there should be more emphasis on the ability to identify adults. Perhaps they could make a recommendation regarding more research in this area. Others agreed that this might call for a separate recommendation.

- Ultimately, the following points were agreed to:

  - A letter, signed by Dr. Riley, will be sent immediately to the President of the Teratology Society saying that the Task Force is supportive of the FAS Statement crafted by the Society.

  - Separately, Task Force recommendations for fine-tuning the FAS Statement will be forwarded to Dr. Chambers, who will subsequently produce another draft of the FAS Statement. Action on finalizing the FAS Statement can be taken during the March 2003 Task Force meeting.

  - There is a line somewhere between endorsing the FAS Statement and co-authorship that requires significant further discussion.

  - Further discussion should take place among Task Force and Teratology Society members regarding other organizations that should be at the table (e.g., representation from pediatrics, addictive medicine, nursing, Hispanics, African Americans, et cetera).

  - The American Academy of Pediatrics published an article in 2000 that made some recommendations regarding FAS which were probably consistent with the FAS Statement. This should be reviewed during the March 2003 Task Force meeting.

Update on Activities by the Center for Science in the Public Interest on Labeling of Alcohol Beverages and Response from the Bureau of Alcohol, Tobacco, and Firearms

George A. Hacker, J.D.
Director, Alcohol Policies Project
Center for Science in the Public Interest

Dr. Hacker reminded the group that his intention at the last meeting was to ask the Task Force to go on record or to recommend that the Centers for Disease Control and Prevention (CDC) go on record with the Bureau of Alcohol, Tobacco, and Firearms (ATF) regarding the issue of proposed rule making related to improving the current requirements for health warning labels on alcohol beverage containers. On November 14, the Center for Science in the Public Interest (CSPI) received a letter from ATF which rejected the petition that CSPI filed regarding the proposed rule making, and which essentially diverted any attention that ATF might use in this area, at least for now.

Essentially, the Alcohol Beverage Labeling Act of 1988 required a 41-word health warning to be placed on all alcoholic beverage containers. It was the result of a compromise in Congress that addressed the issue of drinking during pregnancy, drinking and driving, and other health problems. In November 1999, the Center for Science in the Public Interest, the National Council on Alcoholism and Drug Dependence, four members of Congress, and 120 other groups petitioned the ATF to ask for improvements in that label, noting in the petition that many labels were obscure, were placed vertically on the containers, were on neck rings, were on non-contrasting backgrounds, were not separate from other text, were almost universally printed in all upper-case letters, were many times compressed making them difficult to read, and were presented in ways that did not meet even the basic elements of label design, such as those that had been developed for the nutrition label required by the Food and Drug Administration (FDA).

CSPI, et.al filed a petition requesting greater legibility, clarity, readability, and contrast. The petition indicated that the best science showed that labels that (1) were horizontal on the front label, (2) that were in contrasting colors (i.e., black on red, red on white), (3) were placed in a box, and (4) included a pictorial element were the most noticeable and would probably be helpful in conveying the messages of the label. They specifically *did not* ask for changes in the label language because that was a Congressional prerogative, and would have required going directly to Congress, which probably was not a good idea politically.

As a result of the petition, the Surgeon General, on behalf of the FDA, CDC, National Institutes of Health, and SAMHSA, seconded the motion that ATF revisit this issue, and the Federal Trade Commission in March of 2000 had recommended that any changes be consumer tested. In May 2001, ATF issued an advance notice of proposed rule making, essentially opening a comment period that lasted until September 2001. ATF received 958 comments, almost all of which were from members of the alcoholic beverage industry. For example, a lot of wineries suggested that having to change their labels would run them out of business and destroy the aesthetics of their label. At the time of the comment period, CSPI submitted a national survey that basically showed that few people usually noticed the warning label. People said they could read it, but

few really noticed it—it did not jump out at them on a regular basis. There were a lot of other findings in that survey as well. In addition, CSPI encouraged and got about 50 state medical and public health officials to publicly support the petition. CSPI also solicited comments from other researchers who also supported the petition, saying the label could be improved.

Nevertheless, in November 2002, ATF rejected the petition (basically citing a number of comments, all of which came from the alcoholic beverage industry) and essentially said that even if they had the best possible label on containers, they could not prove that this would have a demonstrable effect in preventing alcohol abuse or fetal alcohol syndrome regardless of the prominence. ATF argued that because the health risks are common knowledge, there was no need to improve the label—that it was an insult to consumers' intelligence. These were industry arguments that were detailed by ATF in a letter to CSPI. Industry attacked the label suggestion on the basis that it would destroy the aesthetics of wine labels, for example. They said that consumers notice the label regardless of where it is on the container, that it would impose significant costs on small producers in particular, which would require a detailed cost-benefit analysis under Executive Order 12866, that it would adversely affect trade, and that rather than require a decent label, the solution for ATF was to enforce its standards more strictly.

There was no data to change the 1990 analysis by ATF allowing quite a bit of flexibility in terms of labeling requirements. In addition, the Industry raised First Amendment concerns with respect to the fact that the labeling bill sought maximum flexibility for the Industry to label as they saw fit. ATF agreed that front label, horizontal and pictorial warnings would be noticed more quickly by consumers, but they suggested in their letter that a difference of a few seconds did not indicate that consumers were failing to notice the warning. ATF pointed out that at least initially, when the warnings went into effect, there was some limited success in increasing consumer awareness of those risks related to alcohol consumption.

Basically, it appears that ATF decided that the benefits did not outweigh the costs, and that this change would not have made a substantial difference in alcohol problems. There may be other reasons why ATF came to this conclusion. Dr. Hacker thought that, at least for now, the political environment was not very open to these kinds of interventions. Therefore, it would likely not be worth anyone's time to pursue this issue. He pointed out that ATF, in its newsletter which came out in November 2002, just when they rejected the CSPI petition, noted that there had been an increase in the number of applications for label approval that failed to comply with the mandatory health warning statement requirement. They pointed out, almost precisely, the same kind of problems that CSPI, et.al defined in their petition. It seems that ATF recognizes that there is a problem in the industry, and CSPI hopes that ATF will look more closely at individual labels as they are presented and will require them to be more prominent. CSPI will be presenting individual examples of products with warning labels which clearly do not meet even minimal ATF requirements to ATF.

In terms of future activities, Mr. Hacker's sense was that CSPI is going to enhance its efforts to get states and localities to require, either voluntarily or otherwise, point-of-purchase warning signs about drinking during pregnancy, which is probably as good an opportunity as any to reach consumers when they are most likely to notice that kind of information. Their local Atlanta Task

Force has been very interested in this issue. He wondered what kind of data ATF may have about where people put the signs, how accessible they are, the quality of the signs, etc. A number of years ago, CSPI started a campaign nationally to encourage both state and locally required signage, and they gathered some fairly rigorous data that was put together by an activist, some of which was published in the *Journal of the American Medical Association (JAMA)* or the *Journal of the American Public Health Association (JAPHA)*. That data indicated that point-of-purchase signage was a very good way to increase consumer awareness of the health message. Whether that translates into attitudinal or behavioral change is another question. In terms of creating awareness, it is a good way to reach as many consumers as possible. However, CSPI has conducted informal surveys in restaurants, and have been unsuccessful in locating such signs. In Atlanta, they did find a copy of a black and white sign that was printed in 1971.

Discussion Points:

- Dr. Coles noted that studies on the effects of labeling laws, signage, and public awareness campaigns have recently been published. She conducted the original review of those studies.

- Noted was that signage for restaurants et cetera is governed at the city, county, and/or state levels. The labeling with which ATF works has to do with interstate commerce. Hence, these are two different labeling issues.

- The Task Force has a leadership role in the broader issue of public awareness/education, so it was proposed that this broader issue be placed on a future agenda. Others agreed. The following suggestions were made:

    - Pursue labeling other types of products which do not have a vested economic interest, such as pregnancy tests (noted was that this was previously pursued, but met with little interested by the pharmaceutical companies, however, times may have changed enough to peak their interest now)

    - Take out advertisements, in "plain English" in the *New York Times*, *Washington Post*, and various other newspapers.

    - Even if the political climate is not currently receptive to the labeling issue, perhaps the Task Force should maintain a track record of pursuing the issue, just not on the level of a full-scale petition.

    - A suggestion was made to identify someone with experience in point-of-sale signs, to what degree they are currently used in states, and the extent of their effectiveness who can present a review during the next Task Force meeting.

Discussion of the Request to the Surgeon General's Office to Reissue the Federal Advisory Against Drinking During Pregnancy

Dr. Ed Riley, Chair
Director, Center for Behavioral Teratology
San Diego State University

Dr. Riley noted that during the previous Task Force meeting, Dr. Ken Warren was asked to take charge of drafting a letter to the Surgeon General about re-releasing the federal advisory against drinking during pregnancy. At this point, the draft had not been completed but is expected to be presented during the March Task Force meeting.

Discussion Points:

- Dr. Cordero indicated his expectation that the Surgeon General would have a positive response to the letter, and asked the group to be thinking about some roll-out activities that would coincide with the release of the advisory. Suggestions included the following:
  - April is Alcohol Awareness Month, so perhaps they could schedule the release during this time when there is already additional focus on alcohol in general. However, this may prove to be a tight deadline.
  - September 9th is Fetal Alcohol Syndrome Day.
  - The week of Mother's Day is Prevention of Alcohol and Other Drug Related Birth Defects week.
  - CDC typically authors an *MMWR* article and NIAAA has activities around alcohol and other drug-related birth defects around Mother's Day.
  - NIAAA and SAMHSA cosponsor National Alcohol Screening Day in April.
  - Regardless of what they choose, it would be helpful to coordinate the release of the advisory with something else that is newsworthy in order to garner media support.
  - Also noted was that given the impending possibility of global war, it may be better served to wait until 2004 for a more favorable and receptive news cycle.
  - It was suggested that the Task Force have some activities ready to go in the event that an appropriate time arose.

Request for Clarification and Definitions of FASD by Federal Agencies Currently Using the Term

Dr. Jacquelyn Bertrand
Behavioral Scientist
Fetal Alcohol Syndrome Prevention Team
NCBDDD, CDC

Dr. Bertrand addressed the issue of the definition and clarification of the term "fetal alcohol spectrum disorder (FASD)." There was a recent RFA by NIAAA where this term was specifically used. SAMHSA is now using the term as well. The major concern is that, based on calls received at CDC through public inquiry, and in talking with clinicians and others involved in FAS, there are about three different ways the term "FASD" is being defined currently. First is the idea of using FASD as an umbrella term that includes all diagnostic terms like FAS, ARND, ARBD, and partial FAS in a similar way that Autism Spectrum Disorder is used. Second, the term is being proposed as a new diagnostic term in and of itself that replaces all other terms that are currently in existence that relate to FAS. Third is as a new diagnostic term that replaces only ARND and does not include anything else.

In order to prevent confusion in the public eye, CDC would like to propose that the Task Force develop a definition for FASD that embraces the current science as well as the need for an overarching term designating prenatal alcohol effects. CDC also recognizes the complication of using the term in that it does not have an ICD-9 or 10 code. Those who are using these diagnostic criteria know that there is no code for FASD (e.g., both legal and practical issues). Nevertheless, CDC thought that perhaps the Task Force and other ancillary working groups could come to some common agreement regarding the definition of the term.

Discussion Points:

- Dr. Coles agreed that while the federal agencies need to come to some common definition, if it could not be put on an insurance slip, it would really have no meaning to the clinician or service provider. Dr. Bertrand concurred, but pointed out that she has encountered various uses and understanding of FASD. There is no agreed upon working definition.

- Also noted was that conference brochures were using different definitions, and if there was not action soon, the term would take on a life of its own. If people hear the term used in a certain way at a Town Hall Meeting, for example, and a patient presents at a clinician's office using the term, the clinician will be faced with the problem of diagnoses coding etc. and the confusion over terms will continue.

- Dr. Cordero noted that terms evolved over time. The ICD-9 codes include the term FAS and FAS is the only medical diagnosis officially recognized at present.

- Dr. Riley suggested that this issue be brought before the Interagency Coordinating

Committee on FAS (ICCFAS). Others agreed, and it was also agreed that whenever they were discussing new terminology, the issue of ICD code implications should also be addressed.

- Deidra Roach agreed to present the Task Force's request to Faye Calhoun and the ICCFAS. It was agreed that the issue requires immediate attention, particularly given that the term has already been used in RFAs.

Public Comment

At the outset of the call, Dr. Riley requested that anyone wishing to offer public comment indicate their plans to do so. At this time, no one indicated a desire to make public comment, nor were any public comments offered during the two officially allotted time periods.

Closing Remarks

The following closing items of business were discussed:

- Dr. Riley requested that suggestions on items for the next meeting's agenda be e-mailed to him.

- The next meeting will be held March 13-14, 2003 in Atlanta, GA. Although a number of participants indicated conflicts, it was noted that these dates were chosen by participants during the previous Task Force meeting. It was ultimately agreed that March 13-14, 2003 would stand.

- The Town Hall meetings in Mississippi and California will be taking place February 11-12, 2003 and March 26, 2003 respectively, and a brochure is being created for each meeting.

With no further business posed, the meeting was officially adjourned.

Minutes approved on 03/10/03
by Edward P. Riley, Ph.D.
Chair, National Task Force on FAS/FAE