

MEETING REPORT

for

Contract Number 200-98-0102

DES NATIONAL EDUCATION CAMPAIGN MEETING OF WORKING GROUP MEMBERS AND CAMPAIGN PARTNERS

April 26, 2000

Ramada Plaza Hotel, Atlanta, GA

to

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EXECUTIVE SUMMARY

On April 26, 2000, members of the DES National Education Campaign Working Group and campaign partners met for the third time since August, 1999. Earlier meetings had focused on the development of campaign goals, audiences, and partners (August 24, 1999), and gaining consensus concerning lessons learned from the DES pilot studies that formed recommendations for the national campaign (January 27, 2000). Participants at the April 26th meeting convened to consider a *Campaign Development Proposal* and a *Proposal for Formative Research* developed by creative contractor, Porter Novelli, for the DES National Education Campaign. Both plans had been distributed to participants before the meeting with a set of discussion questions.

The participants endorsed the *Campaign Development Proposal* and *Proposal for Formative Research* in general. During the discussions, a number of modifications to the proposals emerged.

Changes to the Campaign Development Proposal included the following:

Modifications for Stage I of Campaign Development

- , Staging of the provider campaign will be determined on the bases of the findings of the formative research. Decisions about which provider types will be targeted as primary, secondary, and/or complementary audiences will be determined by the results of focus groups with health care providers.
- , Participants in the formative research will be expanded by including persons born or pregnant during the entire distribution period for DES (1938-1971).
- , Officers and/or counselors from patient advocacy groups will serve as key informants on emotional reactions from patients who discover their exposure to DES.

Partnering with the National Centers of Excellence in Women's Health

- , Participants agreed that materials for the DES National Education Campaign should be consistent in content, tone, and style. However, the materials should be adaptable to include organizational logos (and other identifying marks) of the institutions/agencies that will distribute materials to their members/constituents.

Ethical Concerns

- , Participants concurred that the campaign should encourage DES daughters to talk with health care providers about the possible impact of DES exposure on menopause and hormone replacement therapy. Even though studies in these areas have not yet been completed, women should be encouraged to consider the possible implications and discuss their individual risks with providers.

Educational Materials from Pilot Studies

Participants noted the following corrections and additions to the proposals:

- , One of the brochures referenced in *Proposal for Campaign Development*, "Were you born between 1938-1971," was identified as targeting DES mothers. However, the brochure was developed to reach all consumer audiences.
- , Participants want an educational brochure using a three-fold format that is easily reproducible to be developed as part of the campaign materials.
- , Participants noted that many persons do not have access to the Internet. They advocated the use of public libraries as valuable resources for disseminating print materials to the public.
- , Certain Internet sites and electronic mail are growing avenues of information for providers and should be used by the DES National Education Campaign to reach physicians, nurse-practitioners, physician assistants, and nurses. For example, the "Brown Book" for physicians should be made available from the NCI Cancer Net site.

Changes to the Proposal for Formative Research included the following:

Audience Segmentation

- , Symptomatic sons should not be included in focus groups.
- , The group recommended that at least one focus group be held with DES sons, in addition to individual interviews.

Age Ranges for Formative Research

- , The focus groups should include participants pregnant or born during the entire range of years of exposure 1938-1971.
- , Topics for focus groups with women who were pregnant between 1938-1971 should include questions concerning their children's health.
- , Participants recommended including a mix of ages in at least one of the focus group for women born between 1938-1971. This group would include cohorts of women still in the reproductive phase of their lives and those dealing with issues related to menopause. Focus group questions should be planned to explore a range of issues as they occur across life stages.

Recruitment for Focus Groups

- , Recruits for formative research from advocacy groups should be screened to eliminate participants who are very knowledgeable about current DES research and treatment.
- , Cancer survivors who are DES daughters should not be included in focus groups for formative research.

In-person Focus Groups with Consumers

- , Working group members endorsed the use of telephone focus groups for consumers. They felt that such groups facilitated the geographic distribution of participation. However, they indicated that if in-person groups are desired, pockets of DES exposed persons can be found beyond locations where DES was widely distributed. Enough people could be gathered in these locations to hold in-person focus groups.

Telephone Focus Groups with Providers

- , Participants in provider focus groups should represent a range of practice types.
- , Nurses should be added to the groups of target audiences and recruits for formative research. They serve as filters for office information and play a major role in patient care and education.
- , Nurse midwives and nurse practitioners can be combined in the same focus groups.

Nest Steps

As the next steps for the national education campaign, participants in the working group were encouraged to participate in the following up-coming activities:

- , Reviewing the moderator guides for the focus groups
- , Serving as observers to the focus groups

The next meeting of the working group has been tentatively scheduled for the first week of November to review the *Strategic Communication Plan for DES National Education Campaign*. The campaign timeline and meeting schedule may have to be altered if required approvals and funding take longer than anticipated.

INTRODUCTION

On April 26, 2000, members of the DES National Education Campaign Working Group and campaign partners met for the third time since August, 1999. Earlier meetings had focused on the development of campaign goals, audiences, and partners (August 24, 1999), and consensus concerning lessons learned from the DES pilot studies that formed recommendations for the national campaign (January 27, 2000). Participants at the April 26th meeting convened to consider a *Campaign Development Proposal* and a *Proposal for Formative Research* developed by creative contractor, Porter Novelli, for the DES National Education Campaign. Both plans had been distributed to participants before the meeting with a set of discussion questions that would be the primary focus of the meeting's agenda.

This report will describe responses to each question as they occurred during the meeting. Specific changes or modifications that emerged from discussion of each question will be highlighted at the end of each section.

DISCUSSION OF CAMPAIGN DEVELOPMENT PLAN

Edward Maibach, Director of Social Marketing at Porter Novelli, presented the *Campaign Development Proposal (CDP)*. The presentation described campaign goals, audiences, strategies, and planning process. An outline of the presentation, complete with Power Point slides, is included in materials, *Building the Framework for the DES National Education Campaign*, distributed to participants at the April 26th meeting. A discussion followed, focusing on both the agenda questions and other issues raised by the participants.

QUESTION 1: ADDITIONS TO STAGE ONE

The first goal of the *Campaign Development Plan* is to build upon previous DES educational efforts and materials. Stage One explains how recommended goals, audiences, and expanded formative research have been based on reviews of Working Group meeting reports, the *Summary Report*, and pilot study materials. Is anything missing from Stage One that would enhance campaign planning?

Including Men's Health Care Providers as Target Audiences

The first issue that was raised concerned DES sons. One participant stated that, in addition to obstetrician-gynecologists, other primary care providers, such as family practice physicians should be targeted to reach men. Research conducted at the University of Wisconsin showed that

urologists know little about DES, but are receptive to these messages. Some messages about potential health risks found in animal studies may be better directed toward providers of DES sons rather than to consumers (increased, long-term risk of testicular cancer and the risk of prostatic utricle cancer).

Others responded that, at the last meeting, it was decided to focus on DES sons as a consumer audience, but not to target men's health care providers. Instead, women's health care providers should be prioritized in this effort, because there is more information to give to them in terms of clinical guidance. In addition, focusing on women's health care providers as a target audience can help to build momentum for all campaign target audiences. Also, less is known from previous campaigns about men's health seeking behaviors regarding DES. There were some indications from the pilot studies that reaching wives, mothers, sisters, and girlfriends may help to reach DES sons as well.

Another participant mentioned that the DES National Education Campaign (DES NEC) will partner with primary care providers other than ob/gyn groups. The campaign is already building relationships with other groups such as the American Academy of Family Physicians (AAFP), and the Society of Internal Medicine (ACP-ASIM). However, campaign messages will be staged so that men's primary care providers will not be a primary audience at the outset of the campaign, but may be added later. Discussion followed which indicated that staging for the provider campaign should be decided based upon the findings of the formative research.

One participant asked about the reason for deciding not to focus on men's primary care providers at this time. Is it too expensive? Or is it more effective to target women's health care providers first? The reason that Porter Novelli decided to focus more on women's health care providers was due to effectiveness. Porter Novelli's staff is trying to develop messages geared toward the highest priority actions and audiences.

Another participant noted that targeting men's health care providers may not be the most efficient channel for reaching men because most men do not visit providers on a regular basis. Another person mentioned that messages for men's providers are less clear and compelling than messages for women and their providers.

One participant indicated that a chapter in *Infertility in the Male* (1997), "The Effects on Men of Prenatal Exposure to Diethylstilbestrol," would be a useful reference for developing messages for men's health care providers. Others suggested that messages for men's health care providers could be incorporated into existing prostate cancer campaigns as news. Messages should include the results of animal studies showing that exposure to DES may increase the risk of developing a rare cancer of the prostatic utricle.

Priority Audiences and Messages

One participant noted that the DES NEC is an ambitious project which could easily lose focus. Therefore, the campaign must focus on the priority audiences and the most important messages. This participant thought that the most important groups to reach are those for whom knowing their DES exposure status would change their health care. By this criteria, DES daughters are the most important audience. Knowledge of DES exposure requires changes in their health care

regarding fertility, high risk pregnancies, and ongoing cancer screening. Exposure status does not change screening guidelines for mothers. However, they may be effective channels for reaching daughters and sons with health information. The channels to reach DES sons and grandchildren of women who took DES need to remain open. Even though current scientific studies have not identified risks for these audiences comparable to those for DES daughters, the potential for future studies to identify health risks is ongoing.

Other participants indicated that the campaign cannot present too much information, and that messages must be kept simple. Campaign messages should direct audiences to the NCI website or to DES advocacy organizations for more information and regular updates. Campaign materials will not be able to include all the information that audiences will need to make decisions about their DES exposure status or health care. The campaign can, however, raise people's awareness of resources for more information and assistance.

Limiting the Age Range for DES Daughters

The *Proposal for Formative Research* proposes to limit the age range for participants included in formative research to women and men born between 1948-1967 (or pregnant then). The decision to narrow the age range was made to include a critical mass of those exposed in the formative research, not to limit the target audiences. A study published by Smith and Smith in the *Journal of Obstetrics and Gynecology* (1948) marks the rise in DES prescriptions. An 1973 study published in *Cancer* on DES prescription patterns indicates that DES use declined after 1967. However, participants in the meeting felt that it was important to include the younger cohort of women in formative research because these women would still be in an active reproductive phase of their lives. One participant thought that from her work with younger DES daughters, women born between 1960-1971 have different perspectives and concerns than the older cohort, requiring different messages to reach them. Also, providers need to become aware that many DES-exposed persons were born in 1971 and 1972, and not dismiss younger patients' concerns about DES exposure. It is also important to include the older cohort of women in the research because some DES mothers are now in their 80s. The messages should convey to the youngest and oldest cohorts that they are still at risk. Participants agreed that the decision to exclude the early and later years of the DES exposure for the audience research may have been a mistake. Participants decided that the formative research should include the entire age range of possible exposure so that issues across different life stages are explored. One participant wondered if the exclusion had been based on concern about finding enough participants exposed to DES from 1938-1948 and 1967-1971. Even though prescriptions for DES declined nationally after 1967, many young people who were exposed to DES can still be found in New York, California, and Philadelphia. These locations could serve as sites for focus groups with younger cohorts.

Issues to Address in the Formative Research

Discussion concerned topics for exploration during formative research. One participant suggested that some of the questions for the formative research might be better addressed by key-informants. For example, officers and counselors from advocacy groups have abundant information about the emotional reactions of DES mothers, daughters, and sons who learn about

their exposure. Representatives from DES Action, DES Cancer Network, and DES Sons Network have heard from many individuals and can serve as key informants so that the issue will not have to be explored directly with the target audiences. The DES NEC can build on the information from key informants, designing messages to adapt to those reactions and testing them in focus groups.

One participant noted that advocacy organizations have focused their messages on years of exposure (i.e., "Were you born or pregnant in the years Y@") rather than by age. This approach should be tested in the focus groups to determine whether people respond more strongly to a risk message based on age or by years of exposure.

One participant thought that the formative research could be an important forum for considering tactics that work for health care providers. Many providers think that DES is an old issue and ignore it in their practices. What communication strategies can make DES relevant for these providers? One tactic that worked in the pilot projects was motivating physicians to learn about DES by using other physicians as channels. Participants indicated that new approaches were needed and should be explored in the formative research. The research will consider specific messages, as well as the most effective channels and sources to reach the providers.

Changes to the Proposals Based on Responses to Question 1

- , Staging of the provider campaign will be determined on the bases of findings from the formative research.
- , The population included in formative research will be expanded to include the widest range of exposure dates 1938-1971.
- , Members of patient advocacy groups will serve as key informants on the emotional reactions of patients to news of DES exposure.

QUESTION 2: INTEGRATING DES MESSAGES INTO ASSOCIATED HEALTH COMMUNICATION EFFORTS

The proposal includes a plan to integrate DES messages into associated health communication efforts. What do you see as the advantages and the disadvantages of this approach? How can integration be accomplished without diluting the goals of the DES campaign?

One participant asked how the DES NEC planned to develop the relationships that are described in the proposal. The participant has worked for years to convince the Pennsylvania Breast Cancer Coalition to include DES as a topic in their programs and materials but has been unable to establish the relationship.

Porter Novelli's staff suggested that the DES NEC has two new assets that advocates in the field have not previously enjoyed:

1. AMight makes right@B when multiple organizations come together (as has happened with the DES working group), they are taken more seriously than when individuals or individual organizations seek changes and partnerships.
2. Investing in the development of engaging messages can have a positive impact on getting to the gatekeepers and through the gates. When people understand that messages have been developed through a formal process of audience research and testing, individuals are more willing to include those messages in their own channels and forums.

However, one participant was concerned about the potential for diluting messages. Her organization had conducted campaigns including a rigorous process of message testing with target audiences. She wondered about the impact of interfering with that careful process by adding an additional message, untested on her target audience. Organizations may not be willing to incorporate DES messages into their content because it may dilute the impact of the organizations= own messages.

According to Porter Novelli's staff, encouraging other organizations to incorporate DES messages into their own campaigns may be affected by how messages are packaged for different audiences. Humans have the ability to process fragmented ideas into coherent wholes. It makes sense to try to incorporate the DES messages into pre-existing campaigns because the information will have a longer life than if the DES NEC tried to develop a one-time campaign from the ground up. One effective tactic is to convince gatekeepers of related campaigns that DES messages are important and relevant to their own campaigns. For instance, breast cancer campaigns use a risk model for women. Including DES exposure as a risk factor for breast cancer should not require changing existing messages substantially.

One participant expressed surprise that the risk of DES has not already been incorporated into breast cancer messages. Other participants suggested the omission might be due to economic influences. Breast cancer campaigns are influenced by the pharmaceutical industry that promotes preventative drugs and influences providers=treatment decisions. DES education includes a warning that drug companies do not want to promote B the unknown long-term effects of drugs. It may be easier to incorporate DES messages into educational materials from non-profit organizations which are not associated with the pharmaceutical industry.

The participants seemed to agree that an abundance of related educational efforts now exist which the DES NEC can build on. The next step for the formative research is to identify clear, effective, compelling messages that will serve as calls-to-action. The existing contacts of the DES working group can be used to help develop a network to coordinate messages and ensure that everyone is moving in the same direction. According to Porter Novelli staff, the campaign development plan builds in flexibilityBallowing DES messages to be adapted in different formats for dissemination through a variety of organizations.

One participant added that the use of existing channels to disseminate DES messages should provide a foundation for distributing future information about on-going DES research. Although the current focus of DES education is on health risks for DES daughters, future messages may include additional risks for DES sons or third generation exposed persons (the grandchildren of women who received DES prescriptions). It is important to keep the channels of communication open so that the results of on-going research with the DES cohorts can be disseminated. New information should slide in behind existing information rather than having to start up a new campaign effort. It is important to develop the DES campaign as a story that continues to unfold.

Changes to the Proposals Based on Responses to Question 2

- , Although question #2 stimulated considerable discussion, the session did not produce modifications in the *Campaign Development Proposal*.

QUESTION 3: TARGETING THE AT-RISK PUBLIC

The plan proposes targeting the at-risk public (unknown exposure/without symptoms) as audience segments who are most disposed to learn about health information. Appendix A (in the CDP) describes those groups. Given your experience, what implications will such an approach have on: Who is reached and how well?

The nonsymptomatic public which falls into the age for potential exposure is not as high a priority as the other two, the known-exposed and the symptomatic. One participant asked how this group would be reached, since even focusing on only those that are most receptive to health information would still include two-thirds of the US population.

Porter Novelli staff explained that the *Healthstyles* database has information on media channels used by health-information-seekers and provides some ways to reach the audience segments that are most receptive to health information. *Healthstyles* segmentation information would be used as the basis for screeners to recruit for the at-risk focus group which would have a mixture of the three *Healthstyles* audiences B the Moderates, the Doctor-Dependent Actives, and the Independent Actives. *Healthstyles* will also be used in message development to understand which channels will reach different audience segments and how they seek and receive health information.

The Porter Novelli staff indicated that there are three questions that must be answered for each audience:

- , What message will catch people's attention and make them pay attention to subsequent messages?
- , What can we tell people to do? What is the call to action?
- , What is the in-depth content about their risk that people need to know?

One participant reminded the group that DES (diethylstilbestrol) was prescribed under a variety of names (for example, Astilbestrol®). The participant suggested that the campaign use varied labels for the drug to trigger the memory of exposed persons.

Changes to the Proposals Based on Responses to Question 3

No modifications emerged from this part of the discussion.

QUESTION 4: PARTNERING WITH THE NATIONAL CENTERS FOR EXCELLENCE IN WOMEN'S HEALTH

The proposal includes a plan to integrate DES messages for health care providers in stable educational environments by partnering with the National Centers of Excellence in Women's Health. The role of the Centers of Excellence is outlined on pages 15-16. Do you feel that the use of the Centers of Excellence is an effective way to create educational materials for health care providers? What implications can you see for the credibility of the materials? On their sustainability?

The Office of Women's Health has contracts with 17 National Centers of Excellence in Women's Health. The contracts with a subset of these centers that are interested in the DES project can be modified to create medical and nursing curricula and other training materials to support the provider education campaign. These materials would be incorporated into the programs of the Centers of Excellence and distributed to other campaign partners for dissemination. These materials can include CME courses, grand rounds, clinical essays, or CD-ROM courses. The nature and substance of these materials will be identified through the formative research. The *CDP* identifies five types of projects available to the Centers of Excellence, to be further refined following the formative research: (1) multiple-unit free standing DES courses, (2) computer-based curriculum materials, (3) one shot DES training (CME lectures, grand round sessions, etc.), (4) materials to integrate DES into extant medical and nursing curricula, and 5) A bench to bedside journal articles for specialty publications (how to translate the latest research into recommendations for care). The Centers may approach these tasks as independent projects or work as a teams. The Office of Women's Health will have a better sense of how team efforts might evolve once they see how the centers respond to their statement of work in the proposals. One participant thought that the use of the National Centers of Excellence is an excellent idea. One variant of the proposal would be to create a toolbox to provide to the centers. This set of materials would give the centers a template to individualize so that they would not have to start from scratch with each product. Five or six centers could then coordinate and work as a team, sharing information and resources.

One participant suggested that DES educational materials for providers could be incorporated into provider curricula on other issues that providers perceive to be more current, such as cervical cancer screening. The American College of Nurse Midwives (ACNM) have developed messages through multiple channels and suggested that process as a model. For instance, in a Domestic Violence campaign the ACNM has used journals, annual meetings, a home study curriculum and other materials to deliver its message.

The proposal for the use of the National Centers of Excellence is just one part of the professional education program of the DES NEC. Existing contracts with the Office of Women's Health provide an opportunity of convenience for the DES National Education Campaign. The Centers represent highly skilled operations and know how to reach health professionals. This is a way to have DES education materials developed efficiently and effectively.

One participant thought that the DES NEC could use this opportunity to make a unified, visual impression. The campaign could have a recognizable symbol such as the pink ribbon for breast cancer. This is difficult to achieve when materials are diffused through various channels, because different organizations want to put their own stamp on them. Despite this limitation, the campaign should strive to develop a unified body of materials with a consistent style and tone. Other participants did not agree. The materials will be created by the Centers of Excellence. However, when the materials are transferred for use in other organizations, their organizational imprints should go on the materials. Another participant agreed that the DES materials should not have a central logo. They should be associated with the organization that is disseminating the information since the organization is already respected by members of the target health care provider audience. The information can then be easily tailored to reach their members.

Changes to the Proposals Based on Responses to Question 4

Participants reached a compromise that any materials that are developed centrally should have a similar look and feel. Other organizations can be provided with a template of the information to which they can add their own organizational logo.

QUESTION 5: ETHICAL CONCERNS

The proposal includes evaluation of the ethical impact of the campaign. DES messages have the potential to create anxiety (without resolution), family tension, and other ethical conflicts. As a result, we need to ensure that the campaign can address those problems. Do the steps outlined on page 17 (of the CDP) seem adequate and effective to address potential ethical issues?

Raising Fears

One participant felt that the concern raised in the *CDP* about frightening target audiences might be misplaced. Sometimes fear can trigger action, creating a need to learn more about health issues. This participant thought that a more important issue concerned sending consumers to physicians who do not have current DES information about health risks. Although the campaign should not raise questions about exposure that cannot be resolved, the campaign can identify specific actions that people can take and resources for information and counseling. In addition, the members of the symptomatic group are likely to be relieved to find out about DES. If they are already dealing with health problems, identifying the source of their problems may direct individuals' efforts for follow-up and information.

Another participant agreed. From her perspective, learning of DES exposure does not cause emotional devastation in most people. Instead, the majority deal with their exposure status very well. The campaign is less likely to raise unnecessary fears if the messages are stated in a straightforward manner, followed by more information.

Other participants indicated that a certain amount of fear may be a motivating agent, but too much fear may lead to avoidance. Sometimes persons who have just become aware of a risk react by choosing not to deal with the message. Some may not be ready to act and may respond with wishful thinking that the message does not apply to them. Various audiences react differently, depending upon their attitude toward health information and risks. Messages should be created which stimulate action, rather than avoidance. The campaign should aim to increase consumers' confidence and efficacy when dealing with their exposure.

Other Ethical Concerns

Participants thought that the following were ethical issues related to the national education campaign:

- Raising awareness among consumers, then sending them to providers who are not aware of current DES research and up-to-date health risks associated with DES.
- Ensuring that DES-exposed persons are concerned about symptoms and undergo screening procedures that are supported by scientific study, rather than raising concerns about issues which have not been documented as associated with DES.
- Raising questions about menopause or the potential risks of using hormone replacement therapy when insufficient study of these issues has been conducted to guide decision-making.

Participants spoke at length about menopause and the possible impact of DES exposure on hormone replacement therapy. Several participants indicated that, on issues such as menopause,

people can be empowered by asking questions, even if there are no straight forward answers. The participants stated that a lack of research about DES-related effects on menopause does not mean a lack of risk. The group concurred that the DES NEC should work closely with the NCI scientists conducting follow-up studies on the DES cohorts, so that emerging findings can be incorporated into DES messages. As research continues, the need for the campaign to sustain channels for DES messages is critical.

Another issue discussed by the group was considered more political or economic, rather than ethical. Campaign organizers should be aware that the campaign may generate some fallout. Pharmaceutical companies that marketed DES have downplayed the drug's side-effects. Drug companies may feel threatened that increased awareness of DES exposure will lead to increased litigation from DES-exposed persons. As a result, some backlash from the pharmaceutical industry is possible.

One participant concurred that increased litigation is a likely outcome of the campaign. She conducted a recent search for DES on the Internet and found a link to an attorney specializing in DES cases. As consumers discover their exposure status, they may discover channels of legal recourse. Even though the national education campaign will not refer people to legal

services, advocacy organizations may choose to provide that service to callers. DES Action has a list of attorneys to whom it makes referrals.

Changes to the Proposals Based on Responses to Question 5

Participants concurred that the campaign should encourage DES daughters to talk with health care providers about DES effects on menopause and hormone replacement therapy. Even though studies in these areas have not yet been completed, women should be encouraged to consider the possible implications and discuss their individual risks with providers.

QUESTION 6: EDUCATIONAL MATERIALS FROM PILOT STUDIES

Appendix C (of the CDP) includes a list of consumer and provider educational materials from the pilot studies that will likely be tested with target audiences in the formative research. At our January meeting we recommended that the number of brochures be decreased, that the information in the Talking about DES® brochure be integrated into other formats, and that the provider brochure be updated. Are there other recommendations about these materials that can guide the contractors as they prepare for the formative research?

Changes to the Proposals Based on Responses to Question 6

The participants had the following corrections, comments, and suggestions for the educational materials:

- One of the brochures **Were you born between 1938 and 1964?** is identified in the *CDP* as targeted to DES mothers. However, the brochure was designed for all target audiences.
- The chapter, **The Effects on Men on Prenatal Exposure to Diethylstilbestrol**, in the urology textbook, *Infertility in the Male* (1997), can serve as an important educational resource and should be reviewed by the contractors.
- Participants requested that an easily reproducible, three-fold format brochure be developed as part of campaign materials.
- Since many persons do not have access to the Internet, materials should be distributed through additional channels. Public libraries can be a valuable resource for disseminating print materials to the public.
- Certain Internet sites and electronic mail are growing avenues of information for providers. For example, the **Brown Book** for physicians should still be available from the NCI Cancer Net site.

NEXT STEPS

The final two questions on the discussion of the campaign development plan were held until the afternoon discussion.

Question 7. A tentative timeline is included as Appendix B of the *CDP*. What, if any changes, would you like to see in this schedule?

Question 8. The proposal is built around a six-stage Health Communication Process. At which stage(s) is your organization/agency most likely to be involved in DES campaign development activities? What role is your organization best equipped to play?

Discussion of Formative Research Proposal

Purnima Chawla, Associate Director for Research and Strategic Planning at Porter Novelli, presented highlights from the *Formative Research Proposal* including desired outcomes, audience segmentation, recruitment methods, research methodologies, discussion topics, reporting procedures, and timeline. A discussion followed focusing both on the agenda questions

and other issues raised by the participants.

QUESTIONS/COMMENTS FROM PARTICIPANTS

Socio-economic Status of the Exposed

The afternoon discussion began with questions concerning the target audiences. One participant mentioned that prior work with DES-exposed populations assumed they were primarily middle class and Caucasian. That may have been true for the earliest exposures (before 1955), but is not true for all of the exposed population. DES was widely used in the military and distributed in clinics associated with urban hospitals. As a result, a significant number of people of lower socio-economic status may have been exposed.

According to DES Action, recent calls to the group's hotline provide further evidence that DES exposure may have been more widespread than originally thought. A recent segment on a CBS's news program, *Day and Date*, gave the hotline number for DES Action. The number of calls that followed the program were too numerous for the group to handle. A total of 6,300 incomplete calls (hang-ups) came in the week after the episode aired. Many of the calls did not come from the major centers of exposure, raising questions about previous assumptions regarding points of DES dissemination and the demographic profiles of exposed populations.

Another participant said she had read a review of DES prescription patterns from the 1960's. In that study almost one-third of pregnant women prescribed DES were non-white, identified as African-American and Puerto Rican. Porter Novelli staff indicated that one way to reconcile this difference is to use the *Healthstyles* information, rather than using demographic or socio-economic profiles. For instance, the Doctor-Dependent Actives are ethnically the most mixed population segment. Another participant suggested reaching a socio-economically mixed population by partnering with military doctors provider organizations. Many military personnel, even those who are retired, continue to receive health care through the military. NCI also has a number of special population networks that focus on cancer awareness and control. These networks can be used as a vehicle to get the DES message to minority and underserved populations (including an Appalachian network that focuses on Caucasians of lower socio-economic status).

QUESTION 1: AUDIENCE SEGMENTATION

The proposal segments public target audiences into:

- , **Known-exposed**
- , **Exposure Unknown (but experiencing symptoms that are consistent with DES exposure)**
- , **Exposure Unknown, (but born/pregnant during periods that put them at risk for exposure)**

Does this segmentation capture the most important groups of potential audiences?

Symptomatic Audiences

Participants discussed whether there should be a separate focus group with symptomatic sons. They were concerned about the difficulty of targeting men based on specific health problems. *De facto* fertility is not a symptom for men. Cohort studies showed that, at 25 years of age, exposed men had lower sperm counts than other men. However, by age 40 no differences in actual fertility were found. Exposed sons do have an increased risk of urogenital abnormalities and epididymal cysts, but it would be difficult to recruit focus group participants on these criteria. The group discussed holding a focus group of those with testicular cancer as the Asymptomatic sons@group, but thought that the link between exposure and testicular cancer was not well enough established to support that decision.

Participants then considered symptomatic mothers and daughters. Some participants wondered whether having focus groups with symptomatic mothers would be helpful, since that would only include older women with breast cancer. There was consensus that symptomatic daughters constitute a useful group for formative research since symptoms include the inability to maintain a pregnancy and increased risk for ectopic pregnancies. Such a group could be convened through infertility clinics.

DES Sons

Participants wondered why formative research with known-exposed sons only included interviews and not focus groups. Porter Novelli indicated that the decision was based on information from a contact who has conducted focus groups with DES exposed individuals. She recommended a conservative strategy with DES sons because they may be reluctant to discuss their reproductive health in a group context. In contrast, another participant indicated that DES Action has held some focus groups with DES sons and found that sons are often eager to talk with other exposed persons. The group decided that Michael Freilick of the DES Sons Network would be the appropriate contact to discuss the feasibility of focus groups with known-exposed men. Some participants suggested a mix of focus groups and interviews with DES sons.

One participant wondered why men should be given equal weight in the formative research if the priority for the campaign is DES daughters. Others replied that since the campaign will be staged, it makes sense to conduct the research now on all populations that will be targeted. The formative research may find that men are not receptive to messages targeted directly to them. If so, the campaign for sons may need to piggyback on messages to mothers and daughters. In addition, since an equal number of male and female children were exposed to DES in utero, it is important to conduct audience research now in case ongoing research reveals health problems for DES sons in the future.

Changes to the Proposals Based on Responses to Question 1

- , Symptomatic sons will not be included as a focus groups.
- , The group recommended that at least one focus group be held with DES sons, in addition to individual interviews.

QUESTION 2: AGE RANGES FOR FORMATIVE RESEARCH

The proposal recommends formative research with DES mothers daughters and sons / pregnant/born between 1948 and 1967.¹ Does using 1948-67 as inclusive dates allow formative research to focus on the critical mass of DES daughters, mothers, and sons? What is lost or

¹ These dates were chosen as representing the period in which DES prescriptions for pregnant women were at their height. In 1948 Smith & Smith published their empirical study on the positive results of 632 pregnant women taking DES to prevent pregnancy loss. The 1948 study appears to be the start of the widespread use of DES. A study of DES prescription patterns published in 1973 Cancer notes that DES prescription rates declined after 1967.

gained by not including children born 1938-1947 and 1967-1971 (or women who were pregnant then)?

The rationale for using 1948-67 to define DES exposure for participants in formative research was to find a critical mass of the exposed population. However, as discussed earlier in the *Campaign Development Plan* session, the group prefers to open the focus groups to the whole age range of exposure.

Participants explored whether it was necessary to hold different focus groups for an older and a younger cohort of daughters. Different messages may be needed to reach each age cohort. Older daughters are likely to be concerned about menopause, while younger daughters (1960-1971) may still be concerned about fertility. A third focus groups for exposed women could be for mothers (regardless of age). These women would be asked questions regarding their children's health, in addition to exploring health risks for the women themselves.

Several participants indicated that having focus groups including a mix of older and younger women might be beneficial to facilitate discussion of a range of topics across the life span.

Changes to the Proposals Based on Responses to Question 2

- , The focus groups should include participants pregnant or born during the entire range of years of exposure 1938-1971.
- , Focus groups for mothers should include questions concerning their children's health.
- , Participants recommended including a mix of ages in focus groups for DES daughters and those who fall within the daughters age cohort group.

QUESTION 3: RECRUITMENT FOR FOCUS GROUPS

The plan proposes to recruit representatives of public audiences (known-exposed and exposure-unknown-but-experiencing- symptoms-related-to-DES) through advocacy groups and physicians. Breast cancer support groups, infertility clinics, DES Action, DES Sons Network, DES Cancer Network are likely to be recruiting channels.

What are the advantages and disadvantages of using such resources? How else might you propose to reach participants in those groups? Are Working Group members willing to assist with these recruiting activities? In what ways?

Disadvantages

Several participants were concerned that individuals who belonged to advocacy groups may be more involved in DES issues and more knowledgeable than the general known-exposed population.

Advantages

The advocacy groups have thousands of members, including many who are not active. For example, most DES Action members subscribe to the newsletter and are on the mailing list but do not have much involvement beyond that. As a result, they are likely to be typical of the target audience of known-exposed for focus groups. In addition, sons may be especially difficult to find without contacting those known to DES Action or the DES Sons Network. Finding the known-exposed through other mechanisms (for example, through physicians) could run into barriers of patient confidentiality.

Discussion

Participants indicated that confidentiality is an issue no matter what the source. The DES advocacy organizations would not provide the names of their members directly to Porter Novelli for recruitment. Instead, they would act as an intermediary between Porter Novelli and advocacy group members. They would send letters to their members and invite them to contact Porter Novelli if members would like to participate in focus groups.

Another suggestion was to recruit participants for the focus groups through the National Women's Health Network. Individuals in the network are not necessarily exposed to DES, but they are not getting the health information they want from their providers. As a result, they may be interested in participating in the formative research. The network could send a notice about the research to their members or send contact information on its website.

One participant thought that recruiting knowledgeable participants may not be a problem for the formative research. The focus groups are not designed to test the limits of the participants' knowledge, but rather to ensure that messages are compelling and not offensive. Other participants disagreed, saying that having less informed, known-exposed participants in the research may be important to gather information about those that feel that DES is no longer a concern for them. These individuals may be a different audience than those currently involved in advocacy organizations. Focus groups could explore messages that cause these individuals to understand that DES as a continuing health risk. Individuals who have let their membership in the advocacy groups lapse may be an appropriate group for recruiting to focus group.

One participant explained that individuals whose memberships have lapsed do know how to get in touch with the advocacy organizations if they feel a need. In New York, many known-exposed DES daughters do not seek follow-up screening at the DES screening clinic, but are on the clinic mailing list and call periodically for updates. They stay peripherally involved. There is a range of knowledge among the known-exposed population, and the formative research should look at what misperceptions exist within the group. The most important misinformation to address is the misperception that there is an age at which cancer risks for DES daughters end.

The group decided that DES daughters who are cancer survivors should not be included in focus groups with women who have not developed gynecological cancer associated with DES

exposure. This mix could skew the discussion. People may be reluctant to discuss their *fear* of developing cancer with cancer survivors. Participants indicated that it is important to remember that people who have been exposed to DES do not all have related health problems. Group members suggested that the DES Cancer Network could help later in recruiting cancer survivors for message testing.

Changes to the Proposals Based on Responses to Question 3

- , Recruits for formative research from advocacy groups should be screened to eliminate participants who are very knowledgeable about current DES research and treatment.
- , Cancer survivors who are DES daughters should not be included in focus groups for formative research.

QUESTION 4: IN-PERSON FOCUS GROUPS WITH CONSUMERS

The plan proposes to use telephone and in-person focus groups for formative research. For DES Sons and Office Staff telephone interviews are recommended. All formative research with known-exposed and unknown-exposed-with-symptoms is proposed as telephone interviews or focus groups because this group is more difficult to recruit and may not be concentrated enough in one area to use in-person groups effectively. Does the Working Group believe that it is possible to recruit enough people in the exposed and symptomatic segments to hold a focus group in person, on location?

Participants indicated that the DES exposed population has dispersed beyond the population centers where it was originally administered. Many DES exposed people currently live in the South/Midwest and in Florida. Participants agreed that capturing the geographic dispersion of DES exposure is important. As a result, formative research should be conducted in areas beyond the locations that have previously been studied. Using telephone focus groups with consumers will allow contractors to attain a greater geographic distribution of participants to reflect a more representative range of concerns.

Participants asked how the telephone focus groups are conducted. According to Porter Novelli staff, in a telephone focus group, the person can sit at home to receive the call without special equipment. Although moderators cannot see the participants' non-verbal responses, in previous focus groups people compensated by verbally clarifying their responses. Since part of the aim of the group will be to test messages and formats, visual materials will be mailed to participants prior to the group so that everyone can respond to examples. Most groups have between 8 and 9 participants.

Changes to the Proposals Based on Responses to Question 4

Working group members felt that telephone focus groups with consumers could be valuable to obtain opinions from participants who are geographically distributed across the country. However, they indicated that if in-person groups are desired, there are pockets outside of known DES centers where enough people could be gathered on location for in-person focus groups.

QUESTION 5: TELEPHONE FOCUS GROUPS WITH PROVIDERS

The plan also proposes to use telephone focus groups with health care providers because these audiences are very busy and difficult to recruit to a central location where in-person groups can be held. Our Working Group includes a number of representatives of health care provider organizations. Do telephone focus groups seem like the best way to solicit health care providers= participation? Does this differ with physicians, nurse-practitioners, or physician assistants? What are the advantages and disadvantages to this approach?

Cost of Telephone Focus Groups

Participants asked if telephone focus groups were less expensive than in-person groups. According to Porter Novelli staff, telephone focus groups do not cost substantially less than in-person focus groups since the primary cost of focus group research is in recruiting and paying for the moderator. Also, in telephone focus groups, Porter Novelli uses a sophisticated telephone system that permits the moderators to know who is speaking at any given time. Telephone focus groups do save travel costs and they allow more people to listen to the discussion. They are approximately 20 percent less expensive than face-to-face focus groups. The total cost depends on how recruitment occurs, how Porter Novelli reaches the audiences, and how much help they receive in recruitment.

Research with Health Care Providers

The participants recommended that a mixture of practice types be represented in focus groups for health care providers (various managed care models, private practice, etc.). Different practice types use different channels and process information in varied ways.

Participants also wanted to know whether office nurses were included in the formative research.

Nurses often serve as office staff and gatekeepers in many types of providers= offices. They should be included in focus groups to explore their roles in patient education/counseling, in-take, and as gatekeepers to physicians.

Changes to the Proposals Based on Responses to Question 5

- , Participants in provider focus groups should represent a range of practice types.
- , Nurses should be added to the groups of target audiences and recruits for formative research. They serve as filters for office information and play a role in patient care and education.
- , Nurse midwives and nurse practitioners can be combined in the same focus groups.

NEXT STEPS

Participants were invited to participate in the formative research activities by 1) reviewing the moderator guides for the focus groups, and 2) serving as observers to the focus groups. The next meeting will be held in the first week of November after Stage 5 on the timeline to review the *Strategic Communication Plan for DES National Education Campaign*. The meeting may have to be rescheduled if required approvals and funding take longer than anticipated. More information will follow on the listserv.