NATIONAL TOXICOLOGY PROGRAM

BOARD OF SCIENTIFIC COUNSELORS

April 14 and 15, 1992

Summary Minutes

National Toxicology Program
Board of Scientific Counselors
April 14-15, 1992
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SUMMARY MINUTES
NATIONAL TOXICOLOGY PROGRAM
BOARD OF SCIENTIFIC COUNSELORS MEETING
April 14 and 15, 1992

The National Toxicology Program (NTP) Board of Scientific Counselors, its Technical Reports Review Subcommittee, its Reproductive and Developmental Toxicology Program Review Subcommittee (the Board), and several ad hoc expert consultants met on April 14 and 15, 1992, at the National Institute of Environmental Health Sciences (NIEHS), Research Triangle Park, North Carolina. (Attachment 1: Federal Register Meeting Announcement; Attachment 2: Agenda and Roster of Members and Expert Consultants.) All members of the Board were present except Drs. Gary Carlson, Rebecca Sokol, and George Szczech. The purpose of the meeting was to have the Board review and provide recommendations to the Program Director and NTP Executive Committee on specific issues of the operation or function of the NTP. Dr. Kenneth Olden, NTP Director, has as one of his major goals to assure that the Program serves the public health by strengthening its role as the nation's premier toxicology research and testing program. To accomplish this goal, he asked for advice on four specific issues of the function or operation of the NTP as to how:

(1) to assure that emphasis is placed on studies of the mechanisms of toxicity and carcinogenicity;

(2) to develop and validate better assays that may reduce the need for long-term testing in animals;

(3) to improve the quality of chemicals nominated for testing by assuring that they have the greatest public health significance; and

(4) to improve the procedures for alerting regulatory agencies and the public about test results on chemicals (particularly data which suggest potential hazard to humans from chemicals of widespread importance).

The issues concerned with mechanistic studies, alternate assays and chemical nominations were considered endpoint-specific, and in the case of the first two, principally research oriented issues. To obtain endpoint-specific advice on the first three issues, the work of the Board was divided among three work groups for carcinogenesis, reproduction and heritable effects, and other toxicities and disposition (Attachment 2). Because the fourth issue, the release of test results was a generic operational issue independent of the type of data, the NTP Executive Committee was asked to review this topic separately.

Plenary Session I

I. Introduction and Charge to the Board: Dr. Olden said that since his appointment as Director of the NTP (and the NIEHS) in June 1991, he had visited most of the agencies represented on the Executive Committee of the NTP and had received mostly positive comments about the Program. However, there were thoughts that a review of certain aspects of the Program might be useful with the view of strengthening it. Dr. James Mason, Assistant Secretary for Health, agreed that the NTP continued to be the Nation's premier toxicological research and testing program but concurred that a review was in order. Dr. Olden said the decision was made that the NTP Board of Scientific Counselors, supplemented by expert consultants, was the appropriate body to conduct the review. He reiterated the four issues (listed above) to be studied and noted that the findings and recommendations of the Board would be published in the Federal Register with a request for public comment. Following this, a public meeting would be held in Washington, DC, to allow for additional comments on the issues and recommendations of the Board. The Executive Committee would meet subsequently to discuss the issue of early data release.

Dr. Olden briefed the Board on the reorganization of the NIEHS which was in process and was intended to improve the quality of science. He said that the reorganization, when completed, should enhance interactions among laboratories and branches and enable better use of limited resources. He noted that each of the three current intramural research divisions was a focus for one of three components of modern toxicology research -- classical toxicology, mathematical modelling, and molecular biology. Reorganization should facilitate more interdisciplinary cooperation on various projects.

II. Comments from the NTP Executive Committee: Dr. J. Donald Millar, Director of the National Institute for Occupational Safety and Health (NIOSH), and current Chairman, NTP Executive Committee, stated that he and the Committee were strongly supportive of the review and expressed gratitude for the Boards' participation. He commented that during a 1981 Congressional hearing chaired by Representative Albert Gore, Jr. (D-Tenn.) to review the NTP, he had testified that the Program was the best example of collaboration in government that he had seen. Now, eleven years later his assessment had not changed. In reviewing the background books provided for the Board, he was struck by the observation that NTP studies on 29 different chemicals had had an impact on rule making by the Occupational Safety and Health Administration (OSHA). Dr. Millar said the Committee would look forward to receiving and commenting on the Boards' final report.

III. NIEHS/NIH Perspective: Dr. Richard Griesemer, Deputy Director, NIEHS, said this was the first time that the entire Board had met together. He reviewed the history of the NTP beginning with its formation in 1978, and listed the four overall objectives: (1) broadening the spectrum of toxicology information which is obtained on

selected chemicals; (2) increasing the number of chemicals studied, within funding limits; (3) developing and validating assays and protocols responsive to regulatory needs; and (4) communicating plans and results to governmental agencies, the medical and scientific communities, and the public. Dr. Griesemer discussed the two oversight bodies for the NTP -- the Executive Committee and the Board of Scientific Counselors -- and their roles. With regard to the Advisory Review, he noted that the proceedings, the findings and recommendations of the Board and Executive Committee, and background papers representative of current NTP program activities and future plans prepared by NTP agency staff will be published in an appropriate journal, possibly in Environmental Health Perspectives.

IV. NCTR/FDA Perspective: Dr. William Allaben, Associate Director for Scientific Coordination, NCTR, and FDA Liaison to the NTP, spoke to the FDA's initial and continuing involvement in the NTP through the NCTR, including on-site conduct of prechronic and chronic rodent toxicology and carcinogenesis studies, genetic toxicology screening, participation in reproductive and developmental toxicology testing and methods development, and development of a toxicology data management system. Dr. Allaben pointed out that the FDA Commissioner serves on the NTP Executive Committee and that FDA has membership or representation on several NTP committees and working groups, including the NTP Board of Scientific Counselors and its Technical Reports Review Subcommittee. He noted that in 1986 because of federally-mandated Gramm-Rudman budget cuts, NCTR was forced to withdraw its funding of NTP projects and the completion of several long-term rodent studies were then funded, in significant part, through a separate Interagency Agreement (IAG) with the NIEHS. Dr. Allaben said that the FDA has relied upon NTP for testing needs when industry sponsored studies were not possible; moreover, the FDA has utilized NTP's expertise to assist with pathology review of some NDA's and food petitions; and NTP has provided staff to serve on FDA Carcinogenesis Assessment Groups. He noted that currently NTP continues scientific exchange with NCTR through interagency agreements for special research or testing needs. With regard to future FDA needs, Dr. Allaben said the Agency supports the need for more flexible protocol design for bioassays and encourages supportive mechanistic studies to provide data useful for the Agency in bioassay interpretation, risk assessment/risk benefit analysis and risk management. He then acknowledged the presence of seven FDA scientists who would serve as consultants to the three work groups and provide input regarding regulatory needs.

V. NIOSH/CDC Perspective: Dr. Janet Haartz, Division of Biomedical and Behavioral Science (DBBS), NIOSH, discussed the NIOSH role in the NTP and noted that the differences in the primary focus of the three parent agencies, CDC -- prevention, FDA -- regulation, and NIH -- research, enabled staff of the three NTP agencies to bring different perspectives to looking at needs and problems, which could be valuable. The main focus of the NIOSH participation in the NTP is research collaboration with the DBBS and the Division of Respiratory Disease Studies (DRDS) through laboratory-based studies. These research studies lead to collaboration with

other divisions of NIOSH in field studies of exposed workers. Dr. Haartz described the importance to research interactions of the NTP interagency working groups at the staff level in neurotoxicology, immunotoxicology, and reproductive and developmental toxicology. She discussed the major NIOSH toxicology program emphases: (1) methods development for laboratory and human studies -- including increasing attention to biomarkers of exposure and effect and development and validation of animal models; (2) in vivo studies -- which are aimed at specific workplace hazards; e.g., teratogenesis resulting from the combined insults of radiofrequency radiation and solvents; (3) cellular and genetic toxicology; and (4) the development of alternate test systems; e.g., the use of Drosophilia as a screen for adverse reproductive/developmental toxicology effects.

At the conclusion of the plenary session, Dr. Olden presented certificates and acknowledged the contributions of retiring members of the Board and its Subcommittees, Drs. Garman, Goodman, Hayden, Hughes, McKnight, Miller, Sanborn, Szczech, and Welsch.

VI. Work Group Sessions: The three Board workgroups formed specifically for this meeting convened separately in open session for much of the remainder of the day on April 14 and for most of the morning on April 15. The work group on Carcinogenesis was chaired by Dr. Jay Goodman, Michigan State University. The work group on Reproduction and Heritable Effects was chaired by Dr. Richard Miller, University of Rochester, while that on Other Toxicities and Disposition was chaired by Dr. Curtis Klaassen, University of Kansas. Each workgroup discussed the three issues dealing with the role of mechanistic research, alternate test systems, and chemical nominations as they related to their respective disciplinary areas of toxicology. Scientists from the three participating agencies of the NTP served as resource persons in the work group sessions. The sessions were open to and attended by members of the public.

VII. Public Comment Session: Dr. Richard McKee, senior staff toxicologist, Exxon Biomedical Sciences, spoke on behalf on the Exxon Company, U.S.A. He made several points regarding the four specific issues, summarized as follows: (1) the objective of the NTP program should be to characterize carcinogenic risk rather than simply carcinogen detection; (2) the bioassay should be used for screening purposes only and mechanistic studies should then be used to assess the hazards of certain test chemicals to humans; (3) usage of laboratory animals should be reduced; (4) chemical selection criteria should be modified to consider potential for human exposure and environmental persistence; and finally, (5) communication with the public should be deferred until the human health implications are understood.

VIII. Plenary Session II: Dr. Longnecker began the closing session by asking for public comments. There being none, the three work groups made brief presentations of their deliberations and recommendations. Comments made are summarized as follows:

OVERALL OBSERVATIONS -- Comments by the three working groups were strikingly similar, despite the different disciplines, and recommendations made were generally for refinements to procedures already being used. COMMENTS ON THE ISSUES -- Chemical Nomination and Selection: (1) the process needs to be improved because it is too slow, especially for carcinogenesis studies, and the reasons for selection should be better documented; (2) the NTP needs to be more aggressive in soliciting nominations from both inside and outside the Federal government; (3) nominations need to include toxicity endpoints other than cancer; (4) nominations need to include chemicals for the purpose of elucidating mechanisms of toxicity; and (5) known or potential human exposure should remain a primary reason for nomination of a chemical. Emphasis on Mechanisms of Toxicity: (1) more emphasis should be put on hypothesis driven research to facilitate interpretation of test data; (2) mechanistic data are important for designing better definitive toxicity studies, helping understand animal models, and developing better test systems; (3) there needs to be more collaborative work with other scientists inside and outside of the NTP to expand knowledge of toxicity of chemicals; and (4) resources should remain focused, the NTP cannot work effectively on everything and every manifestation of toxicity. Emphasis on Alternative Test System Development: (1) there are no alternative systems currently available to replace whole animal systems such as the rodent bioassay; (2) alternative systems have important mechanistic applications; (3) the NTP should not be the National center for alternative test development and validation but should continue to be involved in developing and validating alternative test systems; (4) the NTP can provide important focus to the field of toxicology to insure that the development of alternative systems is based on good science and good in vivo data; and (5) an interagency committee should be formed for coordination of efforts to develop and use alternative test systems within the government. OTHER RECOMMENDATIONS -- a national toxicology strategy should be developed with the NTP serving as the nation's principal coordinating center for toxicological issues. At the conclusion of the meeting, the Chairman of the Board and the Chairmen of the three work groups drafted a report which was sent to all members of the working groups for review and comment. The edited working group reports along with an executive summary by the Board Chairman, Dr. Longnecker, were incorporated into a final report of the advisory review which was transmitted to the Director, NTP, Dr. Olden. Copies of the report were then sent to all reviewers as well as members of the NTP Executive Committee and their staff. The report was published in the Federal Register in July 1992 with a request for comments from the public. To provide further opportunity for public input, an open meeting will be held in the first floor auditorium of the Hubert Humphrey Building, 200 Independence Avenue SW, Washington, D.C., September 11, beginning at 9:00 a.m.

To receive a copy of the final report of the advisory review by the NTP Board of Scientific Counselors please write to: Dr. Larry G. Hart, National Toxicology Program, P.O. Box 12233, Research Triangle Park, NC 27709.

0791. Copies may be obtained from: Dr. Richard Weaver, Executive Secretary, Advanced General Dentistry Review Committee, room 8C–15, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6837.

Dated: March 19, 1992.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 92–6874 Filed 3–24–92; 8:45 am]

BILLING CODE 4160–15–M

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Meeting, National Advisory Board for Arthritis and Musculoskeletal and Skin Diseases

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Board for Arthritis and Musculoskeletal and Skin Diseases on April 13, 1992. The meeting will be held at the Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, Virginia 20202. The Board will meet April 13, 8:30 a.m. to approximately 3 p.m.

The meeting, which will be open to the public, is being held to discuss the Board's activities and to continue evaluation of the National effort to combat arthritis and musculoskeletal and skin diseases. Attendance by the public will be limited to space available.

Ms. Geraldine B. Pollen, Executive Director, National Advisory Board for Arthritis and Musculoskeletal and Skin Diseases, 1801 Rockville Pike, suite 500, Rockville, Maryland 20852, (301) 496–6045, will provide on request an agenda and roster of the members. Summaries of the meeting may also be obtained by contacting her office.

Dated: March 17, 1992.

Susan K. Feldman,

NIH Committee Management Officer.

[FR Doc. 92–6903 Filed 3–24–92; 8:45 am]

BILLING CODE 4140–01–M

Public Health Service

National Toxicology Program (NTP) Board of Scientific Counselors' Meeting To Review Specific Aspects of the Function and Purpose of the NTP

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the National Toxicology Program (NTP) Board of Scientific Counselors, U.S. Public Health Service, to review and give advice to the Program Director and NTP Executive Committee on four specific aspects of the function or purpose of the NTP. The meeting will be held on April 14 and 15, 1992, in the Conference Center, Building 101, South Campus, National Institute of Environmental Health Sciences (NIEHS), 111 Alexander Drive, Research Triangle Park, North Carolina. The meeting will begin on April 14, at 8:30 a.m. and end at approximately 5 p.m. The meeting will begin on April 15 at 8:30 a.m. and continue until adjournment. The meeting is open to the public with attendance limited only by space available.

The Director, NTP, has as one of his major goals to assure that the program serves the public health by strengthening its role as the nation's premier toxicology research and testing program. To accomplish this goal, he has asked for advice on four specific aspects of the function or purpose of the NTP as to how:

(1) To assure that emphasis is placed on studies of the mechanisms of toxicity and carcinogenicity;

(2) To develop and validate better assays that may reduce the need for long-term testing in animals;

(3) To improve the quality of chemicals nominated for testing by assuring that they have the greatest public health significance; and

(4) To improve the procedures for alerting regulatory agencies and the public about test results on chemicals (particularly date which suggest potential hazard to humans from chemicals of widespread importance).

To obtain endpoint-specific advice on the first three issues, the work of the Board will be divided among three subcommittees for carcinogenesis, reproductive and heritable effects, and other toxicities and chemical disposition.

The preliminary agenda with approximate times are as follows:

April 14

8:30 a.m.–10 a.m.—Introduction and charge to the Board and presentation of NTP agency perspectives.

10 a.m.–4 p.m.—Subcommittee work sessions to discuss the four issues.

4 p.m.–5 p.m.—Public comment and discussion.

April 15

8:30a.m.–11 a.m.—Continuation of subcommittee work sessions.

11 a.m.–12 p.m.—Public comment and discussion.

1 p.m.–Adjournment—Continuation of public comment and discussion session.

The NTP seeks comments and views on the four issues. Suggestions of other activities to improve the NTP also are welcomed. Comments should be as brief as possible and should be addressed to the Chairman of the Board as follows: Chairman, NTP Board of Scientific Counselors, c/o Dr. Lazrry G. Hart, Executive Secretary, NIEHS, P.O. Box 12233, Research Triangle Park, North Carolina 27709.

Every effort will be made at the meeting on April 14–15 to consider comments received by c.o.b. Friday, April 10. Oral comments may be made during the public comment sessions and may not exceed 5 minutes in length. Preferably, oral comments should not duplicate written comments.

There will be further opportunities for public comment on these four issues as well as on the recommendations of the NTP Board of Scientific counselors and Executive Committee. First, the recommendations of the NTP Board and Executive Committee will be published in the **Federal Register** with a request for public comment. Second, a public meeting will be held in Washington, DC, in the near future (date to be announced in the **Federal Register** to allow for additional comments on the issues and the recommendations of the NTP Board and Executive Committee.

For further information regarding the meeting, please contact Dr.Hart by mail at the above address, by FAX to 919/541–2260 or by telephone at 919/541–3971 or FTS 629–3971. A roster of Board members will be available prior to the meeting.

Dated: March 18, 1992.

Kenneth Olden,

Director, National Toxicology Program.

[FR Doc. 92–6904 Filed 3–24–92; 8:45 am]

BILLING CODE 4140–01–M

HEALTH AND HUMAN SERVICES

Vaccine Information Materials

ACTION: Notice.

SUMMARY: On December 17, 1991, the Food and Drug Administration (FDA) licensed an acellular pertussis vaccine for administration as the fourth and fifth doses given to children. This recent development necessitates a revision of the vaccine information pamphlet entitled, "Diphtheria, Tetanus, and Pertussis: What You Need to Know," which has been developed by HHS as required by the National Childhood Vaccine Injury Act of 1986. A separate Notice of Proposed Rule Making (NPRM) will be drafted to revise the pamphlet, under the rulemaking procedures mandated by 42 U.S.C. 300aa–26.

ATTACHMENT 2

NATIONAL TOXICOLOGY PROGRAM

AGENDA

APRIL 14-15, 1992

AGENDA
BOARD OF SCIENTIFIC COUNSELORS
NATIONAL TOXICOLOGY PROGRAM
ADVISORY REVIEW
April 14 and 15, 1992

Building 101, South Campus
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)
RESEARCH TRIANGLE PARK, NORTH CAROLINA

TUESDAY, APRIL 14, 1992

Plenary Session I
Conference Center

8:30 a.m. - 10:00 a.m.	Introduction and charge to the Advisory Groups	Dr. K. Olden, NIEHS
	Comments from the NTP Executive Committee	Dr. J. Millar, NIOSH
	NIEHS/NIH perspective	Dr. R. Griesemer, NIEHS
	NCTR/FDA perspective	Dr. W. Allaben, NCTR
	NIOSH/CDC perspective	Dr. J. Haartz, NIOSH

Work Group Sessions
Conference Center

10:00 a.m. - 4:00 p.m.	Carcinogenesis	Dr. J. Goodman, Chair
	Room D450 Reproduction & Heritable Effects	Dr. R. Miller, Chair
	Private Dining Room Other Toxicities & Disposition	Dr. C. Klaassen, Chair

Each work group will discuss the following issues as they relate to their respective areas:

1. Chemical nomination
2. Alternate test systems
3. Role of mechanistic research in the NTP

Conference Center

4:00 p.m. - 5:00 p.m.	Public comment and discussion.	Dr. Longnecker, Chair

WEDNESDAY, APRIL 15, 1992

Continuation of Work Group Sessions

8:30 a.m. - 11:00 a.m.	Same rooms and chairpersons as before.	

Plenary Session II
Conference Center

11:00 a.m. - 12:00 p.m.	Public comment and discussion on all issues under review.	Dr. Longnecker, Chair
1:00 p.m. - Adjournment	Continuation of public comment and discussion.	Dr. Longnecker NTP Staff

NATIONAL TOXICOLOGY PROGRAM BOARD OF SCIENTIFIC COUNSELORS
ADVISORY REVIEW
April 14-15, 1992

Chairperson: Dr. Daniel S. Longnecker

CARCINOGENESIS WORK GROUP
NTP Staff Support: Dr. Gary Boorman, NIEHS; Dr. Richard Griesemer, NIEHS; Dr. Raymond Tennant, NIEHS; Dr. William Allaben, NCTR

- **Board of Scientific Counselors Members**

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Mr. Louis S. Beliczky
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Merck, Sharp & Dohme Research
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NTP BOARD OF SCIENTIFIC COUNSELORS
ADVISORY REVIEW

Conference Center, Building 101, South Campus
National Institute of Environmental Health Sciences
Research Triangle Park, North Carolina

April 14-15, 1992