

For Alan
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PRESENTATION ON SURGEON GENERAL'S ADVISORY COMMITTEE ON
SMOKING AND HEALTH
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PREFACE

At the dawn of the twenty-first century, the United States of America stood alone as the world's greatest super-power, unveiling new scientific and technologic advances in medicine each day for the prevention, cure and elimination of disease.

In stark contrast, the country was mired in the quick sand of a medical disaster it largely created for itself. That tobacco-induced medical disaster, although now somewhat lessened in the United States, continues to rage unabated worldwide, consuming the lives of 4,900,000 people each year.

SLIDE 1

During the 19th century, chewing of tobacco began in the United States and became the dominant tobacco use into the 20th century along with pipe smoking. Cigarettes were largely unknown in the United States until the 1860's, when rolling one's own cigarette became a fad in the southwest.

At the beginning of the twentieth century, Americans developed mass manufacturing and mass distribution of cigarettes and the epidemic of cigarette-caused cancer, heart disease and emphysema was launched. The epidemic spread rapidly in the U.S. aided by the addicting quality of cigarettes during World Wars I and II.

The disastrous increase in tobacco-caused diseases forced numerous evaluations of the problem by a number of professional and voluntary agencies including the Royal College of Physicians (of London) and by the U.S. Public Health Service at the beginning of the last half of the twentieth century.

The first truly comprehensive evaluation was the 1964 Advisory Committee report to the Surgeon General on Smoking and Health. That report, based only on the existing medical and scientific evidence produced before 1962, has been followed by four decades of the most thorough and intensive investigation in the history of medicine, confirming and greatly expanding the conclusions of the 1964 report. The knowledge gained in those four decades has been translated into “a downward trend in tobacco use since the 1964 report (that) has been described by the Institute of Medicine as one of the 10 greatest achievements in public health in the 20th century.”¹

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As a result of this trend in the United States, the prevalence of smokers has dropped from 78% in 1964 to 20% in 2006. Unfortunately, a plateau has been stabilized at 20%.

Well then why should we be concerned that a plateau has been reached with one in five Americans as smokers? Let’s look quickly at the facts and estimates

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¹ Ending the Tobacco Problem: A Blueprint for the Nation. Institute of Medicine. Report Brief, May 2007

The decline that has stabilized at one out of five adults (44.5 million) produced about 1.5 million new cancer cases each year result in about 400,000 deaths per year from tobacco caused disease. Tobacco use remains the No. 1 preventable cause of death in the U.S. Today tobacco causes 30% of all cancers, (including 87% of lung cancers), 25 % of heart disease and 89% of emphysema in the U.S.

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If current rate of use continues:

Worldwide: 21st Century 1,000,000,000 deaths. Tobacco is the second leading cause of death

SLIDE 5

Fate of Smokers

Those who began as teens: One-half will die prematurely from a disease caused by tobacco. One-half will die in middle age, losing on average 20 to 25 years of life expectancy.

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Causes of disease by tobacco:

Cancer 30%

Lung Cancer 87%

Emphysema: 89%

Heart and Cerebrovascular disease: 25%

SLIDE 7

Addiction: Requires only 3-4 packs (or equivalent lifetime use of about 100 cigarettes)

Similar to cocaine and heroin in strength and physiological mechanism

I believe all will agree with the recent President's Cancer Panel that we still have a serious problem.

Let's take a retrospective look at the prolonged anti-smoking movement that began in the 15th century.

HISTORY OF THE ANTI-SMOKING MOVEMENT

The protest began quickly in an unusual way. The first recorded legal proceeding against a smoker was initiated on ecclesiastical grounds in the 15th Century. Rodrigo deJerez, a member of Christopher Columbus' expedition, who learned to smoke in Cuba, lit up for the first time back in Spain. The people were so alarmed by the smoke streaming from his mouth they assumed he had been possessed by the devil. He was promptly imprisoned by the Inquisition. In the centuries to follow, rulers have tried unsuccessfully in various ways, including brutal punishment, decapitation, ex-communication and torture to eliminate the use of tobacco. The first anti-tobacco movement began in the United States began in the 1830's and continues today in 2006 with some limited success.²

² Smithsonian Magazine, July 1989 pp. 107-108, 110-117
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Looking back to the early 1900's in the U.S., lung cancer was such a rare medical phenomenon that only 134 cases could be found in the entire U.S. scientific literature. Nonetheless, some Americans were forming opinions based on their personal experience. Thomas A. Edison wrote to "Friend Ford" on April 26, 1914.

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"Friend Ford

The injurious agent in cigarettse comes principally from the burning paper wrapper. The substance thereby formed, is called "Acrolein." It has a violent action on the nerve centers, producing degeneration of the cells of the brain, which is quite rapid among boys. Unlike most narcotics this degeneration is permanent and uncontrollable. I employ no person who smokes cigarettes.
*Yours, Thos. A. Edison."*³

The increasing interest, and focus, on cigarettes and health in the U.S. accelerated through the 1950's and into the 1960's, spreading public awareness and concern to new heights.

In 1962, the pressure upon the United States Government for clarification of its position on the controversy reached its peak following publication of the 1962 Royal College of Physicians of London report.

The British Government failed to take positive action, despite widespread support among leaders in Parliament. The tobacco lobby had once again quelled the call for action. The impact of this report could not be contained to Great Britain and it was to have a lasting effect upon the course of events in the United States.

³ Personal communication. Dr. Peter V. V. Hamill to Dr. Charles LeMaistre. Letter Thomas A. Edison to "Friend Ford," April 26, 1914, MDACC archives
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Let's now focus on the events that led to the creation of the Advisory Committee to the Surgeon General on Smoking and Health.

Without question the Advisory Committee was born amidst public controversy. In the U.S., the tobacco companies repeatedly brushed aside all of the evidence as "mere statistical association that provided no evidence of causation." This cavalier response was to be their sole mantra and their defense. But many others were not excited about a new study.

- (1) In 1962, there was no clarion call for a new study, as only 38% of Americans believed that smoking caused lung cancer.
- (2) The Food and Drug Administration, empowered by the 1960 Federal Hazardous Substances Labeling Act determined cigarettes did not qualify as hazardous.
- (3) An adversarial Congress, heavily influenced by the tobacco lobby, and a less than enthusiastic governmental hierarchy, were not anxious to confront the issue.
- (4) The White House, early in the Kennedy administration, and with high priority items such as civil rights and tax cuts, did not want to lose the support of the southern congressmen by embracing the tobacco controversy. However, the outcry for clarification of the role of tobacco in causation of chronic diseases would not be silent.

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The presidents of the American Cancer Society, the American Heart Association, National Tuberculosis Association and the American Public Health Association wrote to President John F. Kennedy on June 1, 1961 requesting that he appoint a presidential commission to evaluate the health consequences of tobacco.⁴ On June 6, the White House sent a memorandum to the Secretary of Health, Education and Welfare, Abraham Ribicoff, asking for the Department's advice and guidance in preparing a reply. The Undersecretary replied on June 27 attaching a draft of a letter for the President stating that a "new commission would be inconsistent with the president's policy to abolish a number of independent commissions and advisory committees." The President approved the draft and sent the letter on June 29, to the presidents of the voluntary health agencies.

The rejection by bureaucratic "double talk" did not dismay Dr. Harold S. Diehl, the recently elected President of the American Cancer Society. Dr. Diehl wrote on September 5, 1961 to the new Secretary of Health, Education and Welfare, Anthony Celebrezze, requesting a meeting for the four voluntary agencies.

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Four months later, in early January, 1962 the Secretary shuffled the letter to the Surgeon General for "appropriate action." Clearly up to this point no one in the Executive Branch was interested in embracing this hot potato. The recently appointed Surgeon General, Luther Leonidas Terry, born in Red Level, Alabama, and named for his physician father's closest friend, Sen. Lister Leonidas Hill, was ready for the challenge. Of course he had

⁴ Letter to President John F. Kennedy from Ms. Marion Sheahan, John W. Cline, Oglesby Paul, Herbert C. De Young, June 1, 1961 (representing 4 voluntary health agencies)

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been well prepared. He had his first two years of medical education at The University of Alabama Medical School here in Tuscaloosa!

Surgeon General Terry met with the voluntary health agencies on January 4, 1962 and on February 1 1962 proposed to Secretary Celebrezze creation of a “national commission” to assess the available evidence on smoking and health. No immediate response occurred. Two months later, on April 16, 1962, Surgeon General Terry pushed by Senator Maurine Neuberger’s solo, relentless, anti-tobacco campaign sent a redrafted, more detailed proposal calling for re-evaluation of the Public Health Service’s position taken by Surgeon General Burney in 1959.⁵

The proposal continued to languish in Secretary Celebrezze’s office from April 16 to the last week of May.

It is a matter for speculation as to whether Surgeon General Terry’s proposal would have been acted upon without an unanticipated event at President Kennedy’s May 23, 1962 press conference.⁶

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Towards the end of a lengthy press conference, an investigative reporter for the *Washington Evening Star*, L. Edgar Prina asked: “Mr. President, there is another health

⁵ Report of the Advisory Committee to the Surgeon General. Pp. 7, 1/11/64 Gov. Printing Office

⁶ News Conference 34. President John F. Kennedy. State Department Auditorium, May 23, 1962. 4:00 p.m. EDT

problem that seems to be causing growing concern here and abroad, and I think this has largely been provoked by a series of independent scientific investigations, which have concluded that cigarette smoking and certain types of cancer and heart disease have a causal connection.

I have two questions. Do you and your health advisors agree or disagree with these findings, and secondly, what if anything should or can the Federal government do in the circumstances?"

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The President responded "That matter is sensitive enough and the stock market is in sufficient difficulty—(laughter)—without my giving you an answer which is not based on complete information, which I don't have, and therefore perhaps we could—I would be glad to respond to that question in more detail next week."⁶

Eleven months had transpired since the four voluntary health agencies initiated action. Now a restatement of Surgeon General Terry's April 16, 1962 proposal was being sent to the White House at the White House's request as a consequence of the May 23, 1962 press conference. The White House, under pressure from the Press, approved Surgeon General Terry's proposal. President Kennedy assured Surgeon General Terry that there would be no political interference and instructed him to form a committee to undertake the task.

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⁶ Ibid

On June 19, 1962, Surgeon General Luther L. Terry issued the following. "It is timely to undertake a comprehensive review of all of the data. I have decided to appoint an expert advisory committee to study the evidence (on smoking and health), evaluate it and make whatever recommendations may be appropriate. This advisory group will be made up of a panel of experts selected after consultation with the Federal agencies concerned, non-governmental professional groups, health organizations and the tobacco industry.

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Represented at the first meeting on July 24, 1962 were the American Cancer Society, the American College of Chest Surgeons, American Heart Association, American Medical Association, the Tobacco Institute Incorporated, the Food and Drug Administration, the National Tuberculosis Association, the Federal Trade Commission and the President's Office of Science and Technology

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A second meeting on July 27 compiled a list of names of more than 150 (approximately 155) scientists and physicians. During the next month, the nominee lists were screened by the same representatives including the Tobacco Institute, Inc. They were given instructions to eliminate names "for whatever reason" and return the approved list to the Public Health Service by August 3. The group meeting on July 24 had agreed that those individuals who had already taken a strong public position pro or con on the controversy

were not to be chosen and none were. None could be the representative of any organization or group.

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The honed list of 150 names was available in late August 1962 and approved by Surgeon General Terry. Dr. Hamill was assigned the task of recommending to the Surgeon General the final list of those who would be invited to serve. Dr. Hamill submitted only 10 names to Surgeon General Terry who approved all of them and forwarded them to the White House for final approval.

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In addition, the groups meeting on July 24th and 27th approved a far more comprehensive and more thorough study than had ever been attempted before. According to Dr. Terry, the study would be concerned with not only with tobacco, but also with all other factors which might be involved in causing cancer such air pollution, automobile exhaust, occupational hazards, etc. The study was expected to get underway by mid-September “with a first phase hopefully completed in approximately six months.”

The estimated completion in six months by Dr. Terry raised the expectations of the Congress and the public. The six-month expectation was not presented to the Advisory Committee as a completion date; indeed the Committee was assured several times by Dr. Terry there would be no time limit.

On August 24, 1962, another press release was issued.⁷ Surgeon General Terry announced two staff appointments to his Advisory Committee on Smoking and Health. Dr. Terry announced that: "Herman F. Kraybill, Ph.D. will be the Executive Director of the study. Dr. Peter V.V. Hamill, will be the Medical Coordinator."

At this point, no contact had been made with the nominees who were unaware that they had been nominated. Dr. Terry authorized Dr. Hamill to make exploratory contact with each of the chosen candidates and confirm his (Dr. Hamill's) judgment on the merits of each nominee. Dr. Terry had full confidence in Dr. Hamill's judgment. If he felt so inclined, he was authorized to offer a verbal commitment of a position on the Advisory Committee.

The recruitment did not go smoothly. Although the nominees had not been aware they were being considered, they were aware of the controversial nature of the topic to be considered.

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First, they also knew that recent studies in the U.S. and Great Britain had failed to produce conclusions sufficient to settle the controversy. Second, some had had experiences with government studies. Third, the scientific evidence available was far from perfect and gaps in information could be anticipated. Much of the evidence, scattered in different disciplines, had never been correlated so the work would not be easy. Fourth, judgments would be necessary on the strengths of the casual association

⁷ Press Release. Surgeon General Terry, August 24, 1962, NARA II, College Park, MD

from the diverse categorical areas, including evidence from experimental, epidemiological, clinical and pathological data. Fifth, the invitation to serve, while maintaining their full-time academic appointments, was considered unrealistic as all were carrying full academic loads. Sixth, perhaps the most difficult hurdle would be to establish creditable, new criteria for causal significance of the associations found among the several categories of evidence. All of the nominees realized that without creation of new operational standards for causation, conclusions by a new committee would likely not stop the controversy. Many excellent committees in the U.S. and Great Britain had produced clear, concise answers to the relevant role of tobacco in the causation of human disease but the controversy continued. So there was little reason to expect that the results from yet another study using past criteria for causation would be persuasive.

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The nominees selected for the Advisory Committee, from the date of the invitation to join and for weeks before the first meeting, had frequent and in-depth discussions with Dr. Hamill at their academic home base. Convinced he had the right ten men, he vigorously pursued their acceptance. The 10 selected are pictured with Dr. Guthrie standing by me on the far right of the second row.

Dr. Hamill's strategy worked surprisingly well. He obtained agreement upon the general area of the study, albeit only after considerable give and take. Each member agreed to accept responsibility for evaluation of at least one major area, some working in two or more areas simultaneously. All members agreed to become generally familiar with the

total massive scientific, clinical, pathological and epidemiological evidence from the past, and to accept primary responsibility for preparing an in-depth report in at least one assigned area. The final report on each area would be reviewed and approved by the entire Advisory Committee. All of Dr. Hamill's negotiations were completed with the chosen ten before he recommended the names to Dr. Terry. Six of the ten were users of tobacco in some form. Four of the six smoked cigarettes.

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Surgeon General Luther L. Terry on October 28, 1962 announced the appointment of ten members to his Advisory Committee on Smoking and Health.⁸ Dr. Terry would be Chairman of the Committee.

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"Advisory Committee members and their fields of professional competencies were: Louis F. Fieser, Ph.D., Sheldon Emory Professor of Organic Chemistry, Harvard, field of chemistry of tobacco smoke; Emmanuel Farber, Chairman, Department of Pathology, University of Pittsburgh, field experimental and clinical pathology; Dr. Maurice Seevers, Ph.D. M.D., Chairman, Department of Pharmacology, University of Michigan, Ann Arbor, field pharmacology of anesthesia and habit forming drugs; Leonard M. Schuman, M.D., Professor of Epidemiology, University of Minnesota School of Public Health, Minneapolis, field health and its relationship to the total environment; Charles A.

⁸ Press Release. Surgeon General Terry. October 28th, 1962. NARA II, College Park, MD.

LeMaistre, M.D., Medical Director of Woodlawn Hospital and Professor of Medicine, U.T. Southwestern Medical School, Dallas, TX, field internal medicine, chest and infectious diseases, preventive medicine; Jacob Furth, M.D. Professor of Pathology, Frances Delafield Hospital New York, field cancer biology; Walter J. Burdette, Ph.D., M.D., Head of Department of Surgery, University of Utah School of Medicine, Salt Lake City, fields clinical and experimental surgery genetics; John B. Hickam, M.D., Chairman, Department of Internal Medicine, University of Indiana, Indianapolis, fields internal medicine, physiology of cardiopulmonary disease; William G. Cochran, M.A., Professor of Statistics, Harvard, field mathematical studies with special applications to biologic problems; Stanhope Bayne-Jones, M.D., LLD (retired) former Dean, Yale School of Medicine 1935-1940, former President, Joint Administrative Board, Cornell University, New York Hospital Medical Center, 1947-52, former President, Society of Bacteriologist 1929 and the American Society of Pathology in bacteriology 1940, field nature and causation of disease in human populations. Dr. Bayne-Jones would also serve as a Special Consultant to the Committee staff.” Dr. James Hundley would be Vice Chairman. Dr. Guthrie, Staff Director and Dr. Peter V.V. Hamill, Medical Coordinator pictured here with Don Shopland who would later become Director of the Clearinghouse on Smoking and Health.

This press release contained a reference to Dr. Herman Kraybill. Dr. Kraybill, who was named the Committee's Executive Director, was forced to step down when he told a reporter back home that he believed the evidence "definitely suggests that tobacco is a

health hazard.”⁹ The position of Executive Director was never filled. It should be noted that Surgeon General Terry stated for the second time his expectation that the review would be completed by the summer of 1963. Unfortunately his “expectation” was seized upon as a “promise” by many, and this became a statement that would haunt Dr. Terry in mid-1963 and perhaps was responsible for the pressure on the Public Health Service for an early completion.

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It is worthy of note that Dr. Hamill in his oral history for the Kennedy Library stated that there were difficulties in getting the 10 members of the Committee to accept his offer. He said “none of them were looking for a job like this; they were all overcommitted as it was. They had all served on a lot of committees in the past. Quite a number of them had initially turned it down. I was able to sell them when I told them the point was that the Surgeon General had offered almost unconditional support. Literally he said, “You name it and we will do it.” A couple of them still said “we’ve heard this before,” “I was able to get across the Surgeon General’s absolute promise that this was really something different.”

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As promised by Dr. Hamill, Dr. Terry backed up his commitments to Dr. Hamill and to the Committee in the first meeting, November 1962, and again in the second meeting and again the third meeting. He repeatedly said in one form or another “no one, absolutely

⁹ Ref. Smoke Screen: Tobacco and the Public Welfare, Page 9, Chapter 1, published by Prentice Hall Incorporated, 1963

no one will dictate to this Committee, certainly not as for how to proceed with the study, how long it takes or any of its conclusions. It determines its own mode of operation.” In addition, Dr. Terry said “I am asking you men to do an extraordinary job for me, the most important job I as Surgeon General have ever asked a committee to do, and perhaps any Surgeon General has asked a committee to do, and perhaps the most difficult. I am asking you to do this for me. In turn, this is what I pledge to you.”

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Unfortunately for Dr. Terry, his boss, Secretary Celebrezze had “foot-in-mouth disease” and announced his opposition to government telling citizens not to smoke. Dr. Terry responded to the Committee: “I know some that some individual Committee members, as well as members of the staff and other people, have quite frankly been disturbed about some things that have been said at high government levels, specifically Secretary Celebrezze’s remarks at the Press Club. Secretary Celebrezze stated he did not consider it “the proper role of the Federal government to tell its citizens to stop smoking.”

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Dr. Terry then read a lengthy letter from Secretary Celebrezze explaining his statement and concluding with: “Should the Surgeon General find that smoking is injurious to health, this information would be rapidly communicated to all segments of the population.” The Advisory Committee was not impressed with Sec. Celebrezze’s letter because it did not endorse the study.

The first three meetings of the Advisory Committee (Nov. 1962, Jan. 1963, March, 1963) were very productive. The review of the massive literature (over 7000 reports) had been largely completed and over one-half of the consultants reports had been submitted, although not yet in final form. The subcommittees of the Advisory Committee, through which most of the work was done, had submitted at least a preliminary report. The upcoming fourth meeting on May 3 and 4 was anticipated to be a critical focus on the process of carcinogenesis and the final unraveling of the process by which cancer of the lung occurred. The first day of the May meeting was disappointing as the evidence presented on carcinogenicity and bioassay, including that from tobacco industry sources, had little pertinence to carcinogenicity in man.

Fortunately, the Advisory Committee had scheduled a subcommittee meeting on lung cancer and carcinogenesis in Toronto, Canada for May with an array of outstanding consultants addressing key topics. Perhaps progress would be made there.

The surprise came on the second day, May 4, six months into the study.

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Opening the second day, May 4, 1963, Dr. Hundley spoke to the need to expedite the work of the Committee in order to have the report finished promptly. No reason for the change in timing was given. One of the options presented by Dr. Hundley was to have the PHS staff prepare the report for the Committee's approval and then go forward.

Another was the Committee could stop its inquiry, prepare the report and sign it now. The time limit was disturbing enough but the two options were absolutely unacceptable.

The Committee was aware that in the early press releases Surgeon General Terry had stated that he expected the report by spring (1963) or mid-summer. Subsequently, however, Dr. Terry had assured the Committee in the presence of Dr. Hundley there was no time limit and he would not allow one to be set other than by the Committee. To say the least, the new message that Assistant Surgeon General Hundley delivered, without reference to Surgeon General Terry's previous assurances, got the committee's undivided attention.

Dr. Hundley's comments were interpreted by the Committee to say "Gentlemen, if you can't do the job, we will do the job, we the Public Health Service." The Committee was stunned by Dr. Hundley's comments and asked for an executive session without Dr. Hundley, Dr. Hamill or the staff present to discuss the dramatic change. They were instructed to stand by on call while the apparent "bait and switch" message was discussed.

The immediate response was temperate and analytical. The Advisory Committee began to analyze the situation unemotionally, asking such questions as: could it be that outside pressure from Congress and/or the White House stimulated by the tobacco interests were attempting to destroy the report? Could it be just a stupid administrative gesture to prod the Committee to work faster? Was Dr. Hundley authorized by Dr. Terry to deliver the time change? No matter what the source or the motivation, the Advisory Committee

became more enraged. After approximately an hour and a half they asked Dr. Hundley to return alone for questioning. His answers to the questions did not disclose reasons or the source for the abrupt change, and despite extensive direct questions with no answers, he maintained his announced position. In effect the word of the Surgeon General was countermanded. The Advisory Committee, realizing that it must address Dr. Hundley's timetable, asked Dr. Hundley to leave, and returned to its executive session. After about 45 minutes, the Committee asked Dr. Hundley and Dr. Hamill to return.

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Response

Dr. Hundley was told that the unanimous position of the Advisory Committee was that the Public Health Service would not be allowed to use their names in a report they did not write or approve, not only every conclusion, but every word. There would be no minority report. The Advisory Committee was willing to continue only under the assurances originally given by Surgeon General Terry to do the report on a timetable that the Committee set with no outside interference. If this was not acceptable, the Advisory Committee would submit their resignations today and let the chips fall where they may and the Public Health Service could explain its decision to the public and the press. In effect the Advisory Committee placed the decision in the hands of the Public Health Service. If the Advisory Committee was to continue, the Committee would be in control of the content and the timing of the report.

The Advisory Committee forced the Public Health Service to choose the only course open to them: the Committee would continue under the mandates and assurances given

to them by Surgeon General Terry. The stance taken by the Advisory Committee during the Executive Session was stated in 14 written conclusions, which reflected the iron will of the Advisory Committee to conduct and control its own study from this date forward.

Thus by late spring, 1963 two major hurdles had been successfully overcome:

- 1. The Committee had adopted a successful and productive work pattern which was going smoothly.*
- 2. The integrity and independence of the Advisory Committee was clear to all, never to be challenged again during the conduct of the report.*

From a low point in May, the Advisory Committee had one of its most important cornerstones in place within a month.

Criteria for Causation

As stated earlier, it was patently clear that the Advisory Committee would have to find a new approach to the evaluation of existing scientific evidence if its conclusions were to be creditable. Creation of new criteria for the scientific proof of causation was absolutely necessary for underpinning the studies conclusions. There was no alternative: creditable criteria for scientific proof of causation must be created, or the report would fail.

Dr. Hamill addressed this concern in June 1963 by assembling Dr. Leonard Schuman, Professor William G. Cochran, Dr. Johannes Ibsen, and Dr. Ruel A. Stallones, for a

three-day epidemiologic brainstorming retreat in Saratoga Springs, NY, which focused on the criteria necessary for the proof of causation in multifactorial chronic diseases.

On the third day, after two days of productive debate, at the last dinner meeting, Dr. Hamill relates: “Stoney (Stallones) took out his pack of Lucky Strikes, pushed the cigarettes aside and with his left hand scratched down four criteria on the inner wrapper of the cigarette package and said isn’t this what we’ve been talking about?” “Stoney handed the paper to me. I read it to the group. All knew we had succeeded upon hearing the simple brilliant language. Stallones summarized the criteria and succeeded far better than I had anticipated. Super discussion for three days.”

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Dr. Stallones wrote on the white inner wrapper that causation should depend upon:

- The consistency of the statistical association,
- The strength of the association,
- The specificity of the association,
- The coherence of the association.
- The others present quickly agreed and in the discussion added one more:
- The temporal relationship of the association.

Dr. Stallone’s succinct, clear criteria ended the long debate and focused the intention of all present upon testing each of the criteria for operational validity for cigarette smoking and lung cancer.

The new criteria submitted to the Advisory Committee were reviewed, debated and unanimously adopted. The basic criteria used in the 1964 report were adopted subsequently for widespread use in epidemiological studies as the criteria for determining causation.¹⁰

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*Three decades later, Dr. Hamill stated: "It revolutionized the field of epidemiology at the time. It was a paradigmatic change. Sir Austin Bradford Hill borrowed our criteria and smoothed them over one year later (1965) for a major address in England."*¹¹

*Since our two reports, almost every textbook on epidemiology contains some version of the criteria with explanations and examples.*¹²

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The Advisory Committee stood firm on its decision that there would be no minority report issued. This of course led to lengthy debates on a number of issues because the Committee had decided that they must be unanimous in every segment of the report and on every word. As shown on the next slide there were five often contentious discussions. In the interest of time, I'll not comment further on these at this time.

¹⁰ Hamill, Peter V.V., Letters to the editor. American Journal of Epidemiology. 1997 Vol. 6, pg. 527

¹¹ Hill, A.B., The environment and Disease: Association or Causation? Proc. Soc Med.; 56:295-300, 1965

¹² Hamill, P.V.V., Personal communication to C. A. LeMaistre

Contentious Discussions

- Constitutional theory of causation
- Habituation vs. Addiction
- Lung Cancer: Progression of Cell Changes in bronchi
- Challenges to epidemiological data
- Causation and Emphysema

Subcommittee on Lung Cancer and Carcinogenesis

Two highly productive meetings were held by the Subcommittee on Lung Cancer and Carcinogenesis in May, 1963 in Toronto, Canada. The first, held in early May, was led by Dr. Furth and Farber. The topic was "Anatomic Aspects of the Diagnosis of Lung Cancer." Dr. Furth defined the two major problems pathologists have "in this problem of smoking and health" are the criteria for diagnosis of lung cancer based on pathological changes and the sequence of cell change as lung cancer is established.

For the first time, consensus was reached on criteria for the pathological diagnosis of adenocarcinoma, for squamous cell carcinoma and for the mixed type and as to gradation in mitotic activity, all topics lacking clarity in the literature. Still much confusion centered about the early stages of carcinogenesis and the meaning of the terms metaplasia, pre-cancerous, carcinoma-in-situ, etc.

The second meeting in late May focused on tobacco and lung cancer and the process of carcinogenesis. Chaired by Dr. Walter Burdette with Drs. Farber, Furth and Hamill

present, the two-day meeting was attended by nine carefully selected experts on the topics.

The report from this subcommittee meeting to the Advisory Committee was extremely valuable, under-girding the indictment of cigarettes as the major cause of lung cancer.

Among the conclusions reported from this meeting enabled statements such as:

When the evidence from the clinical, epidemiologic, histologic and the pathologic disciplines was finally correlated, the Advisory Committee was unanimous in its conclusion that "Cigarette smoking is casually related to lung cancer in men; the magnitude of the effect of cigarette smoking far outweighs all other factors."

From a historical standpoint, the second Toronto meeting produced the strongest histopathological evidence linking cigarette smoking to lung cancer in man.

The following month another subcommittee of the Advisory Committee achieved another milestone.

Sixth Meeting of the Advisory Committee
July 11-12, 1963

One last major hurdle remained. Professor William Cochran, Dr. Leonard Schuman had been working diligently on seven prospective epidemiologic studies related to cigarette smoking and occurrence of disease.

At the July 1963 Advisory Committee meeting, they made their final report. The combined results from these massive seven studies demonstrated a high mortality ratio for cigarette smokers and for cancer of the lung, bronchitis and emphysema, cancer of the

larynx, oral cancer and cancer of the esophagus. In all seven studies coronary artery disease was the chief contributor to the excess deaths among smokers. The Advisory Committee unanimously endorsed the thorough analysis of the prospective studies. The final cornerstone of the evidence had been laid, utilizing unequivocal evidence from clinical, pathological, experimental, and epidemiologic findings to conclude that cigarette smoke was a health hazard of sufficient importance to the United States to warrant remedial action.

The work of the Advisory Committee had culminated in a fundamental understanding of the relation of smoking to health. General agreement had been reached on the major issues, cancer, chronic bronchitis and emphysema and cardiovascular diseases. The remaining meetings of the Advisory Committee in October and December of 1963 were devoted to final agreement on every word in the draft.

The November 1963 meeting had been scheduled for the Committee to approve the text before final printing. The dates chosen were in the last week of November, the latest that the deadline allowed for printing by the end of the year.

I was at Parkland Hospital on that fateful day when President Kennedy, who had authorized our study, was assassinated. Mrs. Kennedy asked that we proceed with our scheduled meeting as the President was very much interested in having the study released as soon as possible.

The November meeting was held in Washington and the final wording approved, adjourning only during the funeral procession down Pennsylvania Avenue.

Dr. Guthrie delivered the manuscript to the U. S. Government Printing Office as a “top secret” document. Dr. Guthrie was told this was the first civilian document ever printed under top secret security.

The report release date was scheduled for January 11, 1964 at the State Department Auditorium, a Saturday when the stock market was closed. The report was delivered in an armored truck at 7:00 a.m. to the State Department Auditorium. A single copy for President Johnson was delivered to the White House at the same hour.

Each Committee member was assigned a numbered seat on the stage as was Surgeon General Terry, and his staff. Ironically, the West Auditorium of the State Department is the same location at which President Kennedy’s May 23, 1962 press conference was held.

At 8:30 a.m., in a separate locked room, the press and media had received numbered copies of the report and were given 90 minutes for review. They had been instructed that they would not have telephone access or be allowed to leave until the press conference concluded. The large auditorium was indeed filled to capacity and, even so, the silence was impressive, as all waited intently for the presentation of the findings and conclusions, plus the opportunity to ask questions.

The auditorium stirred in anticipation of the conclusions as Surgeon General Terry commented on the preparation of the report: "I want to express our great gratitude to the distinguished members of the Committee. The unstinted devotion with which they applied their scientific skills to the preparation of this report has provided us with the most comprehensive compilation and analysis ever undertaken on the relationship between smoking and health. Two decades later in a personal letter to me, Dr. Terry expanded his assessment: "To my mind, the report of the Surgeon General's Advisory Committee has and is the outstanding medical document in modern American medical history."¹³

Dr. Terry continued: "At the time I requested this group of ten eminent scientists to undertake this evaluation neither they, nor I, fully appreciated the immensity of the task on which they would be embarked. Nor did any of us realize the demands on time and effort that would be exacted by the evaluation. To them, to the many consultants who assisted, and to the Committee staff, we are immeasurably indebted.

When you note the vast amount of data which had to be considered and analyzed by the Committee, it is amazing to me that such a massive and detailed study could have been accomplished in so brief a period of time."

Dr. Terry, after introductions of the Committee and staff, summarized the report's major finding and major conclusion: "Out of its long and exhaustive deliberations the

¹³ Letter, July 7, 1981. Dr. Luther Terry to Dr. Charles A. LeMaistre
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Committee has reached the overall judgment that cigarette smoking is a health hazard of sufficient importance to the United States to warrant remedial action.”

There was some stirring and murmuring in the audience possibly because of the breadth of the indictment.

Dr. Terry continued: “This overall judgment was supported by many converging lines of evidence as well as by data indicating that cigarette smoking is related to higher death rates in a number of disease categories. In view of the continuing and mounting evidence from many sources, it is the judgment of the Committee that cigarette smoking contributes substantially to mortality from certain specific diseases and to the overall mortality death rate.”

Sensing the audience to be anxious to raise questions, Dr. Terry called for questions.

The first question asked if the report “constitutes the official thinking for the Public Health Service’s beliefs as regards smoking and health?” Dr. Terry replied, “No, this is the report of the Committee to the Public Health Service.” He judged it an excellent report but until his staff could review it and he had the opportunity to “affirm” it, it would not be the official position.

Indeed, only the Advisory Committee, Dr. Guthrie and the staff required to format copy for printing had seen the report prior to release in order to maintain security of the findings.

Numerous questions were asked of the Advisory Committee members and about the reports' findings. The press conference ended after about one hour, and with the doors unlocked, the news reporters ran for the telephones to break their stories. The feature writers and TV anchors sought out Committee members for more background and sound bites. The Saturday evening news and the Sunday papers featured the conclusions of the report on the front pages with high acclaim as did major magazines and periodicals for months..

Three decades later, Dr. Stan Glantz published the "Cigarette Papers" disclosing the internal papers of the tobacco companies. This disclosure proved conclusively that the tobacco companies knew in the 1960's, while the Advisory Committee was meeting, of the harmful effects and the addiction caused by tobacco. One vice president considered that they were in the business of selling an addicting instrument, the cigarette.

In the forward to that book, C. Everett Koop, Surgeon General 1981-1989, wrote "One can speculate, with enormous regret, how different that 1964 Surgeon General's report would have been had the tobacco companies shared their research with the Surgeon General's Advisory Committee. What would have been the history in the United States—and the world—if that report had had the benefit of all the information available on tobacco and held privy to the inner circles of the cigarette manufacturing companies? The contrast of public and private statements from the tobacco industry reveals their deceit." ¹⁴

¹⁴ *ibid.* Preface: XIV
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In the intervening 42 years since that historic report, the original findings have been strengthened by an incredible amount of data against tobacco products, particularly cigarettes, and documented in almost 30 reports of the Surgeon General. Cumulative knowledge from well over 50,000 studies have documented the unprecedented lung cancer epidemic produced by cigarette smoking. In fact few biologic relationships have ever been worked out with such thoroughness as the lethal role that cigarettes and cigarette smoke plays in serious chronic diseases. Historians in years to come will surely shake their heads in disbelief over the persistent prevalence of smoking in the supposedly civilized world of the 20th century and 21st century.

SLIDE 43

The ultimate solution to the tobacco problem in America is threefold: first, protect the non-smoker from air polluted by tobacco smoke through legislation at the local, state and national level; second, free the addicted smoker from nicotine dependence, and third, raise a nonsmoking generation of young Americans.

Looking forward to the year 2025, we stand with an unparalleled opportunity to rid our country—and ultimately all nations—of the disastrous health consequences of smoking. The question is whether we have the will to pass indoor no-smoking legislation, to prevent the taking up of the habit, and free the addicted.

Fortunately the 1964 Advisory Committee's report to the Surgeon General was created despite the controversy and did survive the pressures generated by the tobacco companies. Perhaps its most significant impact was that it provided the impetus for 28 subsequent Surgeon General's reports on the subject.

SLIDE 44

The New York Public Library has another way of measuring impact on society: their selection of the Books of the Century. The 1964 Advisory Committee's report to the Surgeon General on Smoking and Health was selected as one of the ten books with an immediate and lasting impact on the 20th century. It was listed in the category "Nature's realm" along with Einstein's "The Meaning of Relativity" and Marie Curies' "Treatise on Radioactivity."

SLIDE 45

May I conclude with the citation for the 1964 report? It reads: In 1962 President Kennedy's Surgeon General, Luther L. Terry, assembled an Advisory Committee of distinguished medical authorities to investigate the effects of smoking on health. The exhaustive report (387 pages of closely packed text and references, with innumerable charts and graphs) continues to influence medical thought, national and local legislation and social behavior. One could say it is one of the most widely quoted publications ever, cited on every cigarette package and advertisement in the United States.

The tobacco industry and its powerful lobbies continue to discount the finding of smoking and health.
