This opened the Modern Era of CVD Epidemiology. Good for Dod! AK

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March 23, 1972

M E M O R A N D U M

TO: Fellows, Council on Epidemiology

FROM: Henry W. Blackburn, M.D., Chairman

SUBJECT: Arteriosclerosis - A Report by the National Heart and Lung Institute Task Force on Arteriosclerosis and the Duff Memorial Lecture by Dr. Theodore Cooper

The enclosed Task Force report is one long awaited by our Council. It calls for a national effort commensurate with the problem and gives appropriate priority for preventive measures, with a broad program for research, its applications, and health education.

The other document, Dr. Cooper's Duff Lecture in Anaheim, (also enclosed) is evidence of the direction NHLI is taking to implement the Task Force recommendations.

The recommended Heart and Lung Advisory Committee is in formation, contracts for trials are released, and new major legislation to support this program has just been introduced into Congress.

Volume II of the Task Force report will soon be available. Anyone interested in receiving a copy should send requests to Mr. Leonard P. Cook at the American Heart Association.

HB: aw
Enc.

G. Lyman Duff Memorial Lecture
"Arteriosclerosis - Policy, Polity and Parity"
By Theodore Cooper
Tuesday, November 9, 1971
Anaheim, California

At first it was difficult for me to satisfy my conscience that I could accept Dr. McGill's invitation to present the Duff Memorial Lecture on Arteriosclerosis. I am not expert in the subject. (Broken Heart Slide) I can offer no new data - no new theories. I cannot even recount for you extensive clinical experience to dramatize the results of application of the new technologies. It was easy enough, however, to satisfy my vanity - and to rationalize the opportunity as follows:

From time to time it is necessary that someone accept responsibility (even in the absence of authority) for the allocation of public resources for the solution of public health problems. Within present polity, that is within the present form of government, the current method of doing federal business, this responsibility falls in part upon me. In exercising this responsibility it often appears that I speak for you, the scientists and physicians interested and involved in any way in diseases of the heart, particularly in arteriosclerosis, and of the lungs. I speak, or I appear to speak, as your representative and sometimes as your advocate. I am aware and sensitive to the fact that this is not representation by participatory selection. Hence, it is not only appropriate -- it is vital that we talk about
Slide 1 policy -- and that you disagree as you see fit and disown if need be (Only Child Slide).

In a similar fashion, I am not infrequently called upon to speak for the public, the patients, or as they are now popularly called, the
Slide 2 consumers. They did not elect me either, only a few of them know that anyone speaks on their behalf in the matter of heart disease. (Penquin Slide)

Nonetheless, until our polity changes (and by this I do not mean whether the Institute remains a part of NIH or whether NIH remains in the Department of Health allied with Education and Welfare or finds other bedfellows in the Presidentially proposed cabinet streamlining so that we become a part of the Department of Human Resources. I do mean that as long as the public chooses to support health research as a function of the federal government) that until our polity changes, some bureaucrat will be speaking for you and for the consumers. It thus seemed worthwhile for me to discuss with you what our policy is and what is or may be involved in parity.

Many of you, I am sure, feel that our decisions are fatuous. I read about it regularly in my mail. Some of you, and some of the consumers, feel that I am ill informed, biased by certain lobbyists, politicians and vested interests, including the scientific interests of our distinguished intramural scientists. I may be all these, but as you see I have learned at least something during my 3 years as Director, for in 4 paragraphs I have converted my ignorance and my possible errors into the reasons why it was proper for me to accept Dr. McGill's invitation and to give this lecture. Vanity has often subdued conscience in the past but we in Washington have elevated it to such a fine art
Slide 3 that an heraldic symbol has been designed to depict it. (Two Headed Eagle) As Lytton has said, "Men are valued, not for what they are, but for what they seem to be".

As an example of this let me consider, for a moment, the changes which I am sure would have been vigorously nurtured by Dr. Duff himself were he still with us, as they present in the current possibilities for recoupling of morphology--descriptive pathology with clinical physiology and biochemistry.

Slide 4 The next four slides show classic patterns of arteriosclerosis as pathologists have known them for years. The first shows lipid rich atheroma formation.

Slide 5 The next shows a section of a coronary artery with profound intimal thickening and severe stenosis. The next, also shows profound atheroma development and

Slide 6 stenosis with the lesions being predominantly those of lipid cores covered by fibrous layers, and the fourth demonstrates a striking degree of lipid

Slide 7 rich atheroma formation with some superficial fibrous cap development. The clinical histories of these four patients also follow classic lines. The first was a 55 year old white diabetic female who had previously suffered a stroke. The second was a 65 year old white male, a known hypertensive for many years, who died relatively suddenly. The third was a 42 year old white male who had had severe angina for 7 years and class IV heart disease for much of that time. The fourth was a 63 year old woman who died 8 days after massive infarction and without any previous cardiac symptoms or any of the now accepted "risk" factors. Stories such as these are well known.

What is now available and what seems to me should strike a spark of renewed excitement in descriptive pathology is the opportunity to link pathological data with the increasingly precise clinical and laboratory data such as coronary arteriography and lipid fractionation. To capitalize on new opportunities we need changes in resources, in ways of working together, in crossing traditional discipline boundaries, in approaches to problems, and last, but far from least, in our attitudes, to finance these activities we need to have a program or policy that the public can evaluate and choose to accept.

The decision to try to formulate a national program or policy and the determination as to the size of such a program should depend upon 3 considerations:

Slide 8 (Apart from the following, of course, Miss Peach Slides I and II). The size

Slide 9 and the content of the program should bear a direct relationship to:

1) The magnitude of the problem
2) The importance that the public attaches to the problem
3) And the scientific, social and if you will, political possibilities for significant change in the acquisition of new knowledge and the application of it.

No one in this room doubts the magnitude of the public health problem which is Arteriosclerosis and Arteriosclerotic Heart Disease. All of you know that some 200,000 people die each year between the ages of 15 and 65 with what we have called premature coronary heart disease but which might better be called

Slide 10 unnecessary heart disease and heart disease deaths. (Slide) You also know that for every one such person dying before 65 years of age, 3 will die after that age of complications of arteriosclerosis and a far from trivial number will be

Slide 11 disabled from these diseases prior to death. (Disability Slides) None of you will

Slide 12 be surprised to see (Next Slide) that diseases of the circulatory system account for the lion's share of worker disability allowances, and that these 228 million man years of work lost by members of the labor force due to cardiovascular disease amounted to $1.1 billion*. Health expenditures for cardiovascular disease in

Slide 13 1969, that is for care and treatment cost an additional $7 billion (Next Slide). In a word, the magnitude of the problem is enormous.

*Task Force Report, Page 61

Many members of the medical community and a corresponding number of laymen may believe that there are no promising leads to prevention or cure at this time, no possibilities for a "breakthrough" to use the current jargon - and thus attention (dollars) should be directed elsewhere.

Thus we are forced to acknowledge that policy and parity are highly related. In deciding one, the other is often preset if not defined. Concepts of parity are based on "how much cost when viewed in relation to other things available for purchase". By discussing parity - I really want to discuss the problem of deciding how many of your dollars go, or
Slide 15 should go, into which program. (Dollar Slide)

I have no intention of getting into a discussion of the relative importance of domestic issues vs foreign ones. The Attorney General's office in Washington has been quoted as advising those of us who speak as members of the Executive Branch: "Don't worry about the microphone, speak directly into the salt shaker." Apart from that, it does not seem to me particularly profitable to pit one disease against another. Pain, suffering and death are pain, suffering and death regardless of etiology. Furthermore, as a physician I, like you, have been trained to try to alleviate disease by working toward that which has the highest probability. All of our information, all of our thought processes are geared toward making the most probable diagnosis and prescribing the therapy which is most likely to relieve the signs and symptoms.

But decisions on resource allocation are largely determined by people whose background is in law, public administration or business administration. These people, particularly lawyers, are trained to consider <u>all</u> the possibilities and to accept that the best advocate will be judged the winner and his proposal implemented. This put physicians in a disadvantageous position when attempting to hammer out with other members of the federal government, a large number of whom are lawyers, the content, form and priority of a particular health program. In effect this means that skill in advocacy can, and
Slide 16 sometimes is, an overriding force in policy determination. (Opening Remarks Slide) But, even if this were not so, I would still feel that a disease problem such as arteriosclerosis should have consideration as a <u>health</u> problem and should have the concomittant allocation of national resources determined on the dispassionate, factual basis - the magnitude of the problem and what can be done about it.

This brings to me our present policy in arteriosclerosis. As I indicated earlier we have such a policy, a program; we have been thinking about it (Slide
Slide 17 of Publications): and, as you see on this slide, we have been soliciting the opinions of the scientific community as to the most optimal form and nature of such a program. There are those, and some of them, I believe, are in this audience, who feel that our past activities are more closely related to that Washington phenomenon, the filibuster, than to the industrial/academic phenomenon, planning. I do not consider these discussions, debates and publications as either unnecessary or excessive. It is one thing to risk one's own time and hence at least some of one's own money in as experiment which fails by virtue of improper design or execution. It is quite something else to take the time of many investigators, to utilize scarce and expensive manpower, and to do it with large amounts of the taxpayer's dollars in a study that fails to provide needed answers to important questions, fails by virtue of poor design, poor timing, or improperly assigned priority.

To enchance the utilization as well as the development of this new knowledge, I endorse the concepts of a coordinated system of groups of scientists interested in various facets of the problems embraced under arteriosclerosis. In order to provide national resources for this activity we recently initiated our Specialized Centers of Research in Arteriosclerosis.

In the resolution of many problems, there comes a time when a variety of forms of organized activity can contribute. Knowledge is accumulated and formulated into hypotheses of causality of disease. To test these hypotheses may require the cooperation of large numbers of people over long periods of time. Among the current hypotheses dealing with arteriosclerosis none rates greater attention than the lipid hypothesis.

I think we need to get on with testing whether lowering blood lipids will prevent arteriosclerotic vascular disease in man -- perhaps, put in another way -- we need to learn in which people lowering of the lipids would prevent or retard the development of the vascular disease.

More needs to be known of the prevalence and distribution of what are considered blood lipid abnormalities in the population at large -- in their own envirmonments. Many epidemiological studies have given an excellent basis for this. These data should emerge from our lipid metabolism clinics in cooperation with some of the SCORS. The characterization of the population will be an important step in the selection of the appropriate people for the human clinical trials which are needed.

It has long been recognized that clinical trials (particularly in this area) are costly. Part of the expense is based on the requirements of cohort size which in turn is based on end point measurement. To be able to evaluate inception, distribution, progression, and regression of vascular lesions has been long indentified as a critical need in this field. To do this we are seeking new non-invasive methods. New non-invasive techniques would also contribute greatly to the ability of physicians to detect disease earlier. Arteriography and stress-testing already offer possibilities for the refinement of endpoints.

Thus, a great deal of information could evolve from a longitidinal study of patients already characterized as being at high risk because of a metabolic disorder--using the more sophisticated diagnostic end points. Such a study in patients with Type II hyperlipoproteinemia has been initiated at the Institute in Bethesda.

The test of the lipid hypothesis using the usual clinical endpoints should be extended to a large scale trial in patients at high risk because of their lipid characterization. Such trials should strive for maximal lowering of lipids by any methods available, effective, appropriate to the patient situation and safe, be it diet, drugs, surgery or any combination thereof. The test is therefore not of diet <u>or</u> drugs <u>or</u> of surgery--rather it is a test of the <u>lipid</u> hypothesis. This distinction is most important. As you know, the Institute has been urged to endorse and undertake a national study of the effect of alteration of the diet on the course of heart disease. All diet studies that have been initiated or proposed would be expected to reduce lipid levels to some extent. We now know that the reduction from a single dietary regimen would not be expected to constitute optimal clinical management in all patients.

sociological approach to rehabiliation of patients who have suffered heart attacks and strokes. And we surely need to be more effective in the areas of professional and public education. The children should learn to take care of their heart as well as their teeth.

Thus the national program in arteriosclerosis should take into account the magnitude of the problem, appropriate cost benefit analysis, and the opportunities to effect a prevention and a therapeutic "breakthrough". The decisions should reflect parity within the disease entity, between disease entities and between competing domestic and social problems. Of necessity, those that make decisions should recognize current realities of polity and make due allowance for educating not only the scientists and the physicians but the comsumers as well. It is also well to be prepared for the problems which will arise simply by virtue of semantics. In a country such as ours with well-springs in so many different cultures and languages one must be constantly alert to understand as well as to hear. There are those who say "no" while really meaning "yes": a simple "no" may indicate a desire for further negotiation. Contrarywise a qualified "yes" might be interpreted and indeed--intended to be a polite refusal. There are many stories that can serve to illustrate "semantic difficulties".

> During the first World War, Marshal Haig, a notorously austere and reserved officer, attempted to be friendly with a solitary private by the roadside in France. Marshal Haig inquired, "Well, my man, where did you start the war?" Private (pale to the teeth), "I swear to God, sir, I never started no war."
>
> In more recent times a liberated young mother decided to be entirely frank and "tell it like it is" to her daughter. Her four year old inquired one day. "Mother, do you and Daddy have sex relations?" "yes dear", replied the mother, "Daddy and I have lovely sex relations". "Then why don't they ever come to visit us?" asked the little girl.

It is not enough to formulate a national policy, to obtain expert opinions and contributions to it. One must be prepared to communicate this in an intelligible fashion to consumers and producers alike. This communication must be reasonably lucid, otherwise its validity cannot be assessed. We must resist absolutely the temptation to oversimplify complex issues and to treat every issue as a crisis understandable only by a scientific elite. We must take our plans to the people for in the final analysis it is the people, and the people who represent them, that make the priority decisions upon which the dollars and the programs depend.

I have tried to indicate to you the needs as I see them and the feasible approaches as I understand them. I hope that this has not been solely an exercise in assuaging my vanity. I hope that I have at least stimulated you to think about a national program in arteriosclerosis, about how it can be implemented, and if you feel that my vision has been obscured by ignorance, how my darkness can be illuminated.