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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Henry Kissinger and the UGDP

If you read my posting a few years back on the UGDP you will know this story, but if you have not it bears repeating in this age of “we want your data”.

The University Group Diabetes Program (UGDP) was a secondary prevention trial done to determine if any of the commonly used agents for type 2 diabetics were useful in preventing the morbidity associated with the condition.

The trial spanned 21 years. Enrollment started early 1961 and the last followup visit was done August 1975. The first publication came in 1970 in relation to a decision by the investigators to stop tolbutamide because of ill-effects. The presentation of results in the summer of 1970 at the American Diabetes Association Meetings and the publication that followed produced a firestorm of criticisms.

The Committee on the Care of the Diabetic (CCD) was formed the same month the results were published as a counter force to efforts of the FDA to relabel the drug.

Members of the CCD regarded the UGDP as badly flawed and reasoned that if they were to gain access to raw data of the trial they would be able to reanalyze and show where we went wrong.

In the fall of 1975 the CCD files suit against David Mathews, Secretary of Health, Education, and Welfare for access to UGDP raw data under the Freedom of Information Act (FOIA) in the United States District Court for the District of Columbia (denied; appealed to higher court).

About the same time, William Safire of the New York Times filed a request for Henry Kissinger's telephone notes from 21 January 1969 through 12 February 1971. That request was followed by one from the Military Audit Project and one from the Reporters Committee for Freedom of the Press. Those two requests were for telephone notes while Kissinger was Secretary of State.

Safire's request was denied but courts did order the State Department to produce Kissinger's telephone notes for the other two requests.

The CCD's request and the two for Kissinger's telephone notes were heard at the same time by the US Supreme Court (argued 31 October 1979; decided 3 March 1980).

The ruling in the Kissinger case was 4 to 2 against the requestors.

The ruling in the UGDP was 7 to 2 that:

Written data generated, owned, and possessed by privately controlled organization as grantee of funds from HEW, held not accessible as 'agency records' under Freedom of Information Act when HEW never obtained data.

The entire opinion is posted to trialsmeinertsway.com; tab "Historical Archive".

The opinion in the UGDP hinged primarily on the fact that the NIH did not ask for data when the trial was ongoing. The ruling might well have been different if the trial had been done under contract with the NIH and subjected to closer monitoring by the agency.