



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Re: Part 16 Hearing -
John H. Hopkinson III, M.D.

Gentlemen:

I am enclosing a copy of my decision concluding that Dr. Hopkinson should not be disqualified from receiving investigational new drugs. By this letter, I am providing a copy of my decision to the Dockets Management Branch to be placed on display in the Public Reading Room.

Sincerely yours,

Arthur Hull Hayes, Jr.

Arthur Hull Hayes, Jr., M.D.
Commissioner of Food and Drugs

Enclosure
cc: Dockets Management Branch

IN THE MATTER OF:
JOHN H. HOPKINSON, III, M.D.
Regulatory Hearing

The purpose of this proceeding is to determine, pursuant to 21 CFR 312.1(c)(1) and 21 CFR Part 16, whether John H. Hopkinson, III, M.D., a clinical investigator, will be disqualified from receiving investigational-use drugs. Associate Commissioner for Health Affairs, Stuart Nightingale, M.D., presided over the regulatory hearing on October 14, 1980, November 5, 1980 and January 14, 1981.

My decision is based on the administrative record. Under 21 CFR 16.80, the record includes the transcript of the hearing, the draft report of the Presiding Officer, the comments of the parties on that Report, the pre- and post-hearing statements submitted by the parties, the exhibits submitted by the parties, the assurances of Dr. Lippmann, the Final Report, other relevant materials. I adopt the Final Report of the Associate Commissioner for Health Affairs dated February 28, 1983 [attached].

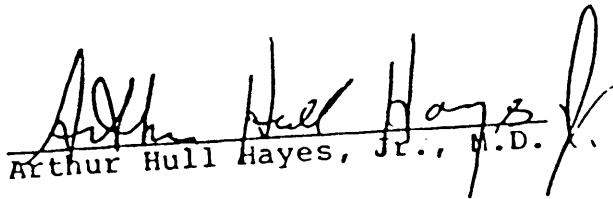
My review has established that, as set forth in the Final Report, Dr. Hopkinson has repeatedly and deliberately failed to comply with regulations covering the conditions for exemption of new drugs for investigational use. In this

connection, I note that the National Center for Drugs and Biologics (NCDB) submitted no comments on the Presiding Officer's findings and conclusions respecting the evidence at the hearing. There has been no substantive change in those findings and conclusions in the Final Report.

My review has also resulted in the conclusion that, as the Final Report sets forth, Dr. Hopkinson has provided adequate assurances that the conditions for exemption will be met in the future. I accept those assurances.

In this connection, I find that it was appropriate for the Associate Commissioner for Healty Affairs to reconsider his views on this matter after his initial draft report had been circulated to the parties and the comments of Dr. Hopkinson were received. It has been the consistent policy of the Food and Drug Administration that disqualification of a clinical investigator is not necessary if adequate assurances are provided. It would have been preferable for Dr. Hopkinson to have provided adequate assurances prior to the issuance of the draft report. However, it was not improper for the Associate Commissioner to accept Dr. Hopkinson's comments offering to make his assurances subject to other reasonable conditions.

I understand the reluctance of the NCDB to "re-open" the matter of Dr. Hopkinson's assurances, having been advised that it had proven its case and that the assurances tendered as of that time were inadequate. Notwithstanding its objections, the NCDB commented on the proposed assurances and the assurances incorporated into the final report respond to most of the NCDB's comments. I believe that the public is adequately assured that Dr. Hopkinson will meet the conditions for exemption in the future. Accordingly, Dr. Hopkinson is not disqualified from receiving investigational new drugs.


Arthur Hull Hayes, Jr., M.D.

Dated:

June 3, 1983