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Subject: 09/27/99 letter R.L. Garwin to J.D. Holum.

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September 27, 1999
(Via FAX to 9-1 (202) 736-4397)

The Honorable John D. Holum
U.S. Department of State
2201 C Street, N.W., Room 7208
Washington, DC 20520

Dear John,

Subject: Productive 09/20/99 meeting with Roy Vagelos.

Meselson, Scheinman, Sherman, Teplitz, Warnke, and I met with the former Merck CEO for two hours on BW inspections. Highlights of the particularly encouraging and productive meeting are:

--Vagelos said, in effect, that he was glad to be helpful, that he continues to have very good access within the industry, but that his power to persuade was limited by his reputation for unorthodox ideas.

--He said that none of the present pharmaceutical CEO's have a technical background and therefore tend to be overcautious about visits for verification, which is a subject they don't understand. This lack of understanding is compounded by the fact that the CWC precedent of including industry representatives from the beginning in verification planning was not followed with the BWC.

--He suggested some retired technical experts whom he believes could help design a verification regime in which industry would have reason for confidence. A good solution to our BWC difficulties could be to revisit the verification issue with some kind of a joint government-industry body. While this might make an agreement by the end of 2000 unlikely, an acceptable and ratifiable agreement based on our current position seems even less likely. The first step in such an approach should be unofficial contact with such technical experts.

--Vagelos said that the information element that most

needed protection was not pharmaceutical processes, but

rather that of "target molecules." The major question in fighting a disease is what specific molecule to attack in order to treat the disease. Once that is decided there is usually more than one (patentable) way to attack that molecule. At the patent stage, the target molecule becomes public and ability to beat competition is mostly lost. The advantage time is on the order of 5 years. Further loss of secrets (in, e.g., processes) is real but impossible to prevent.

--This led to agreement that inspection procedures should be devised so as to provide maximum protection to R&D labs, minimum for the production facilities, and, likely, high protection for pilot plants, depending on specifics. The latter tend to be 1/10 to 1/100 scale and hence of lesser BW risk.

--Industry fear of losing secrets, however, is broad and deep, especially in the earlier stages before actual marketing.

--There is a different sort of concern with regard to countries (including China, Russia and India) where we lack enforceable patent protection. Once a product and processes are patented, industry is protected in countries with appropriate patent law, but at that stage the information is widespread and products are routinely imitated in non-patent countries.

--The industry is accustomed to inspection by FDA, with which relations are relatively good, thanks in large measure to recent upgrade in quality and stature of the FDA inspectorate. Provision for high technical competence in the BW inspectorate would be a useful step.

--The USG has not engaged in detailed discussion with high-level industry process engineers and R&D chiefs on the inspection issue.

--The USG has presented the inspection issue as a political one of satisfying Allies and others, but has not made clear to the industry the rationale for having both routine inspections of declared facilities and challenge inspections of undeclared facilities in order to raise the risk to the violator of cheating.

--It was agreed that it would be desirable to have discussion of technical aspects of inspection issues by members of the National Academy of Sciences who have had senior positions in industry, together with a number of people, such as ourselves, who are more familiar with the government's goals and national security needs in the BWC. Vagelos, Meselson and I agreed to talk to NAS President Alberts on the subject. Such NAS discussions could be

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