

THE WHITE HOUSE

WASHINGTON

April 1, 1976

MEMORANDUM FOR: DICK PARSONS
FROM: SPENCE JOHNSON *SA*
SUBJECT: Legal Questions raised by the PMA
regarding the production of influenza
vaccine.

Attached is the testimony of the Pharmaceutical Manufacturers Association, on the President's influenza immunization program, as presented before the House Health Subcommittee yesterday.

The testimony raises two policy issues: product liability immunity and antitrust immunity.

Committee staff has requested policy guidance in this area and I would appreciate any suggestions you might have as soon as possible.



TESTIMONY OF
C. JOSEPH STETLER, PRESIDENT
PHARMACEUTICAL MANUFACTURERS ASSOCIATION
BEFORE THE
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT
HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
PRESIDENT'S VACCINATION PROGRAM

MARCH 31, 1976

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

I AM C. JOSEPH STETLER, PRESIDENT OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION. TESTIFYING WITH ME TODAY ARE BRUCE J. BRENNAN, PMA VICE PRESIDENT AND GENERAL COUNSEL, AND JOHN G. ADAMS, PH.D., PMA VICE PRESIDENT FOR SCIENTIFIC AND PROFESSIONAL RELATIONS.

WE ARE PLEASED TO APPEAR BEFORE YOU TODAY TO DISCUSS THE PROPOSED PROGRAM TO INOCULATE ALL AMERICANS AGAINST AN EXPECTED EPIDEMIC INFLUENZA. WE ARE NOT IN A POSITION TO, NOR WOULD WE, ATTEMPT TO QUESTION THE SCIENTIFIC DECISION THAT THE COUNTRY IS THREATENED WITH A SERIOUS EPIDEMIC. OUR MISSION IS TO OUTLINE AS ACCURATELY AS POSSIBLE THE ESTIMATED CAPACITY OF THE PHARMACEUTICAL INDUSTRY TO PRODUCE AND DELIVER THE VACCINE NEEDED FOR A TOTAL IMMUNIZATION PROGRAM. WE ALSO WANT TO RAISE SOME EXTREMELY IMPORTANT QUESTIONS WHICH HAVE NOT BEEN CONSIDERED AND WHICH MUST BE FACED UP TO BY THE GOVERNMENT BEFORE THE MANUFACTURERS CAN PROCEED FULLY.

BEARING IN MIND THAT, GIVEN THE NUMBER OF UNANSWERED QUESTIONS THAT REMAIN, NO ONE CAN PROVIDE ABSOLUTELY RELIABLE DATA ON THESE MATTERS. LET ME DESCRIBE THE SITUATION AS WE SEE IT TODAY.



THERE ARE FOUR PHARMACEUTICAL COMPANIES IN THIS COUNTRY WHICH ARE PRESENTLY PRODUCING INFLUENZA VACCINES. TWO OTHER FIRMS ARE LICENSED, BUT THEY HAVE NOT BEEN PRODUCING VACCINES RECENTLY, AND IT IS UNLIKELY THAT THEY COULD GET INTO PRODUCTION QUICKLY ENOUGH TO PARTICIPATE IN THE PROGRAM. IF THERE IS ANYTHING FORTUNATE ABOUT THE PRESENT SITUATION, IT IS THAT THE FOUR PRIMARY PRODUCERS HAVE JUST COMPLETED PRODUCTION OF REGULAR VACCINES. THE FIRMS HAVE ALREADY BEGUN PRODUCTION OF EXPERIMENTAL BATCHES OF THE A-SWINE STRAIN, AND CAN BE PRODUCING SOON ON AN AROUND-THE-CLOCK BASIS.

IT IS ESTIMATED THAT INITIAL BATCHES WILL BE TURNED OVER TO THE GOVERNMENT FOR CLINICAL EVALUATION BEFORE APRIL 15. THOSE STUDIES WILL DETERMINE THE POTENCY OF THE VACCINE, AND ENABLE THE GOVERNMENT TO SET THE NECESSARY STANDARDS. ONLY WHEN THAT INFORMATION IS IN HAND, PROBABLY BY THE FIRST OF MAY, WILL IT BE POSSIBLE TO ESTIMATE THE PRODUCTION YIELD WITH ACCURACY, AND PREDICT THE TOTAL NUMBER OF DOSES THAT CAN BE PRODUCED. IT MUST BE UNDERSTOOD THAT DESPITE OUR EXPERIENCE WITH OTHER KINDS OF INFLUENZA VACCINE, WE DO NOT KNOW, AND CANNOT KNOW UNTIL MAY, HOW MUCH YIELD WE CAN EXPECT OF A STRAIN WE HAVE NEVER PRODUCED BEFORE.

WE ARE HOPEFUL THAT THE FIRST BATCHES OF THE SPECIFIED VACCINE WILL BECOME AVAILABLE FOR TESTING AND DISTRIBUTION IN JULY OR AUGUST AND OF COURSE PRODUCTION WILL CONTINUE THROUGH THE FALL. AT THIS MOMENT, IT IS IMPOSSIBLE TO GIVE ASSURANCE THAT SUFFICIENT VACCINE TO INOCULATE ALL AMERICANS (213 MILLION DOSES) CAN BE PRODUCED BY THE TARGET DATE OF OCTOBER OR NOVEMBER. THE PROBABILITIES ARE THAT IT CANNOT. HOWEVER, THERE IS ALSO NO ASSURANCE OR LIKELIHOOD THAT EVERYONE WILL WANT TO BE INOCULATED OR THAT THE PROCESS

FOR COUNTRY-WIDE ADMINISTRATION CAN BE FULLY ESTABLISHED. WE CAN PROMISE OUR MOST DILIGENT EFFORTS. IT IS OUR PRESENT BELIEF THAT IF THE ABOVE SCIENTIFIC ISSUES ARE SOLVED WITHOUT UNANTICIPATED DELAYS, AND IF THE REMAINING LEGAL PROBLEMS ARE SOLVED, WE CAN SUPPLY THE VOLUME OF VACCINE NEEDED ON SCHEDULE.

IT SHOULD BE EMPHASIZED AS WELL THAT THE SWINE FLU IS NOT THE ONLY INFLUENZA STRAIN THAT MAY STRIKE THIS YEAR. FEDERAL OFFICIALS HAD PREVIOUSLY AUTHORIZED A VACCINE FORMULA FOR THE 1976-77 FLU SEASON COMPOSED OF "A-VICTORIA" AND "B-HONG-KONG" STRAINS, AND THE PRODUCTION OF THOSE VACCINES HAS BEEN COMPLETED. MANY INDIVIDUALS IN OLDER AGE GROUPS WHO MAY HAVE PARTIAL IMMUNITY TO THE SWINE VIRUS, WILL BE VULNERABLE TO THE HONG KONG VIRUS, WHICH HAS ALREADY HIT IN SOME EUROPEAN COUNTRIES. THE GOVERNMENT IS PRESENTLY AUTHORIZING THE PRODUCTION OF "A-VICTORIA" VACCINES ALONE, OR IN COMBINATION WITH THE NEW SWINE VIRUS. THIS LEAVES A QUESTION AS TO WHETHER THE MASS INOCULATION PROGRAM OUGHT TO INCLUDE VACCINATION AGAINST THE HONG KONG STRAIN AMONG SUSCEPTIBLE GROUPS. HAVING AUTHORIZED AND ENCOURAGED ITS PRODUCTION AND GIVEN THE REMAINING THREAT OF AN INFLUENZA PROBLEM FROM THIS STRAIN, THE GOVERNMENT MUST GIVE EARLY CONSIDERATION TO THIS QUESTION.

IN ADDITION TO THE ABOVE SCIENTIFIC AND PRODUCTION PROBLEMS, THERE ARE MAJOR LEGAL QUESTIONS WHICH MUST BE ANSWERED NOW. WE KNOW FROM EXPERIENCE THAT THEY CANNOT BE LEFT HOPEFULLY FOR LATER CONSIDERATION. ANY IMPLEMENTING OR APPROPRIATIONS LEGISLATION



SHOULD PROVIDE A LIMITED EXEMPTION FOR PARTICIPATING MANUFACTURERS FROM APPLICABLE ANTITRUST LAWS. THIS LIMITED EXEMPTION IS NECESSARY NOW DUE TO THE BASIC NATURE OF THE PROPOSED PRODUCTION PROGRAM AND THE LIMITED NUMBER OF MANUFACTURERS THAT WILL PARTICIPATE. IF A LIMITED STATUTORY EXEMPTION IS NOT PROVIDED FOR PARTICIPATING COMPANIES, THEY WILL BE UNABLE TO JOINTLY DISCUSS MATTERS SUCH AS OPTIMUM ALLOCATION OF PRODUCTION QUOTAS, MATTERS RELATING TO PRODUCTION AND FORMULATION TECHNIQUES, JOINT RESEARCH AND TESTING AND RELATED MATTERS. WE UNDERSTAND THAT THE APPROPRIATION STATUTE IS LIKELY TO AUTHORIZE THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE TO ESTABLISH PRODUCTION QUOTAS AND PRICES. UNDER SUCH CIRCUMSTANCES, THE STATUTE SHOULD FURTHER PROVIDE A LIMITED EXEMPTION TO PARTICIPATING MANUFACTURERS FROM THE ANTITRUST LAWS IN CONNECTION WITH PRODUCTION, FORMULATION, SALE AND DISTRIBUTION OF THE SWINE INFLUENZA VACCINE, ALONE OR IN COMBINATION WITH THE OTHER STRAINS.

ALSO, SINCE THE MANUFACTURERS WILL PRODUCE THE VACCINE IN ACCORDANCE WITH GOVERNMENT SPECIFICATIONS, SELL IT TO THE GOVERNMENT WHO WILL DICTATE AND COORDINATE ITS METHOD OF DISTRIBUTION IT IS REASONABLE THAT THE GOVERNMENT SHOULD INDEMNIFY THE MANUFACTURER FOR LIABILITIES EMANATING FROM OR ASSOCIATED WITH THE USE OF THE VACCINE. WE ARE NOT SUGGESTING THAT THE MANUFACTURER BE INDEMNIFIED AGAINST FAILURE TO PRODUCE A QUALITY VACCINE MEETING STRICT GOVERNMENT SPECIFICATION.



THERE ARE MAJOR PRODUCT LIABILITY PROBLEMS ASSOCIATED WITH MASS IMMUNIZATION PROGRAMS, PARTICULARLY IN LIGHT OF A RECENT DECISION INVOLVING ONE OF OUR MEMBER FIRMS. THAT DECISION HELD THE MANUFACTURER LIABLE FOR AN ALLEGED INJURY IN A COMMUNITY IMMUNIZATION PROGRAM, EVEN THOUGH THE FIRM HAD HAD NO CONNECTION WITH THE PROGRAM OTHER THAN SUPPLYING THE VACCINE AND PROVIDING FULL PRESCRIBING INFORMATION. YET THE SUIT HELD THAT THE COMPANY SHOULD HAVE ADVISED EACH PERSON BEING IMMUNIZED OF THE POTENTIAL HARM THE VACCINE MIGHT CAUSE. CLEARLY, MANUFACTURERS MUST HAVE PROTECTION AGAINST SUCH AN EXAGGERATED INTERPRETATION OF THEIR RESPONSIBILITY IN ANY MASS INOCULATION PROGRAM, AND PARTICULARLY IN ONE OF THE DIMENSIONS WE ARE CONTEMPLATING HERE.

WE HAVE SUPPLIED WITH OUR STATEMENT, SUGGESTED LEGISLATIVE LANGUAGE TO IMPLEMENT THESE RECOMMENDATIONS.

TO CONCLUDE, THE PHARMACEUTICAL INDUSTRY WILL DO EVERYTHING POSSIBLE TO DEVELOP THE NEEDED VACCINES IN THE UNPRECEDENTED QUANTITIES AND IN THE TIME NECESSARY TO MEET THIS PUBLIC HEALTH THREAT, IF THE CONGRESS DECIDES TO PROCEED WITH THIS PROGRAM. WE ARE GIVING THE GOVERNMENT OUR FULL COOPERATION, AND WILL ASSIST THE MEDICAL, PHARMACY AND PUBLIC HEALTH PROFESSIONS IN ASSURING THAT VACCINES ARE AVAILABLE ON AS TIMELY A BASIS AS POSSIBLE. THESE TASKS ARE AMONG THE MOST DEMANDING THAT ANY HEALTH COMPLEX HAS ATTEMPTED. WITH CAREFUL ORGANIZATION, PLANNING, AND IMMEDIATE ATTENTION TO SOME OF THE PROBLEMS I HAVE OUTLINED, WE FEEL THAT THEY CAN BE ACCOMPLISHED.

IF MEMBERS OF THE SUBCOMMITTEE HAVE SPECIFIC QUESTIONS OR A LATER NEED FOR ADDITIONAL INFORMATION ABOUT PHARMACEUTICAL FIRMS'



OPERATIONS IN REGARD TO THIS EFFORT, PMA WILL BE PLEASED TO ACT AS A CONDUIT IN OBTAINING ANSWERS OR SUCH ADDITIONAL INFORMATION.

THAT CONCLUDES OUR STATEMENT, MR. CHAIRMAN. MY ASSOCIATES AND I WELCOME YOUR QUESTIONS.



PRODUCT LIABILITY - IMMUNITY

If any action is brought in any state or federal court based upon any claim that the manufacturer, distributor, or supplier of any vaccine or drug product purchased with or made available through any funds authorized or appropriated under this act is liable for any loss or injury suffered by any person in connection with or as a result of the administration or use of any such vaccine or drug product, the United States shall indemnify such manufacturer, distributor, or supplier against any liability and other costs incurred in connection with any such claim. Provided, that such indemnification shall be made only if such vaccine or drug product was manufactured and labeled in accordance with the specifications and requirements issued by the Secretary of Health, Education, and Welfare. Provided further, that the United States shall have a right to intervene in any such action, and that such manufacturer, distributor, or supplier shall provide the Secretary of Health, Education, and Welfare with timely notice of any such action and shall cooperate fully with the United States in the defense of the action.

Claims for indemnification under this provision shall be submitted to the Secretary of Health, Education, and Welfare, who shall, upon determining that indemnification is due and the amount to be paid, refer such claims to the Secretary of the Treasury. The Secretary of the Treasury shall pay out of moneys in the Treasury not otherwise appropriated the claims referred to him for payment by the Secretary of Health, Education, and Welfare.



ANTI TRUST - IMMUNITY

No person shall be liable for damages, penalties, or other sanctions under the Federal Trade Commission Act (15 U.S.C. 41-77)), or the Antitrust Acts (as defined in section 4 of the Federal Trade Commission Act (15 U.S.C. 44), or under any similar State law, on account of his negotiating, entering into, participating in, or implementing an arrangement providing for the research, development, formulation, manufacture, sale, distribution, or supply of vaccines or drug products purchased with, or made available through, any funds authorized or appropriated under this Act, provided that such activity is undertaken at the request of the Secretary of Health, Education, and Welfare or his delegate.

