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SUBJECT: PROPOSED CONSULTATIONS ON PHARMACEUTICALS
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1. ACTION REQUESTED. USG AGENCIES REQUEST EMBASSY TO

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INITIATE CONSULTATIONS IMMEDIATELY WITH APPROPRIATE GOB OFFICIALS REGARDING BRAZIL'S LACK OF PATENT PROTECTION, MARKET RESERVE POLICY, NEW PRODUCT REGISTRATION AND PRICING PRACTICES.

2. DOC STRIKE FORCE REPORT ON LATIN AMERICAN PHARMACEUTICALS IDENTIFIED A NUMBER OF OPTIONS, INCLUDING 1) CONSULTATIONS WITH SELECTED LATIN COUNTRIES ON A BROAD RANGE OF U.S. INDUSTRY PHARMACEUTICAL TRADE AND INVESTMENT PROBLEMS AND 2) A SELF-INITIATED SECTION 301 CASE AGAINST BRAZIL'S PHARMACEUTICAL POLICIES. NO DECISION HAS BEEN MADE AT THIS TIME WITH RESPECT TO A GOVERNMENT-INITIATED 301 CASE AGAINST BRAZIL'S PHARMACEUTICAL POLICY, PENDING LEGAL REVIEW BY THE TPSC SECTION 301 SUBCOMMITTEE (SCHEDULED FOR THIS WEEK) AND APPROVAL BY THE WHITE HOUSE ECONOMIC POLICY COUNCIL. HOWEVER, USG AGENCIES SUPPORT AS A FIRST STEP INITIATING CONSULTATIONS WITH GOVERNMENT OFFICIALS IN APPROPRIATE AGENCIES REGARDING BRAZIL'S LACK OF PATENT PROTECTION, MARKET RESERVE POLICY, NEW PRODUCT REGISTRATION, (DRAFT LEGISLATION AS WELL AS PORTARIA 4) AND DISCRIMINATORY PRICING PRACTICES.

3. WASHINGTON AGENCIES HAVE SINCE JANUARY CONSULTED WITH THE PHARMACEUTICAL MANUFACRERS ASSOCIATION (PMA) TO DISCUSS INDUSTRY PROBLEMS IN LATIN AMERICA AND POSSIBLE WAYS TO OBTAIN RELIEF. THE U.S. INDUSTRY IS CONCERNED ABOUT BRAZIL IN PARTICULAR BECAUSE IT REPRESENTS THE LARGEST MARKET IN LATIN AMERICA, WHICH WAS ESTIMATED AT 1.3 BILLION DOLLARS LAST YEAR. OF THIS, THE UNITED STATES EXPORTED 68.7 MILLION DOLLARS IN

PHARMACEUTICALS TO BRAZIL. TOTAL U.S. INVESTMENT OF PHARMACEUTICAL COMPANIES IN BRAZIL WAS APPROXIMATELY 1.1 BILLION DOLLARS. THIS FIGURE HAS DECLINED SOMEWHAT IN THE PAST YEAR, DUE TO RECENT U.S. CONSOLIDATIONS AND SELL OUTS. U.S. COMPANIES WHICH HAVE INVESTED IN BRAZIL REPORT THAT THEIR RETURN ON NET WORTH HAS DECLINED SIGNIFICANTLY, DROPPING FROM NEARLY 31 PERCENT IN 1983 TO 12.2 PERCENT IN 1984, IN PART BECAUSE OF GOVERNMENT PRICING POLICIES.

4. USG AGENCIES ASKED PMA MEMBERS IF THEY HAD CONSIDERED

INITIATING A 301 PETITION ON THEIR OWN. PMA HAS NOT YET RULED OUT THIS OPTION AND, IN FACT, HAS SAID THAT THE SITUATION IN BRAZIL DID NOT "AFFORD OUR MEMBERS TIME TO REMAIN IDLE." PMA PLANS TO "RESUME INDEPENDENT EFFORTS TO ATTAIN THE RELIEF" THEY FEEL IS NECESSARY, AND HAVE BEGUN TO STEP UP LOBBYING EFFORTS IN THE U.S. CONGRESS. HOWEVER, PMA BELIEVES THAT A SELF-- INITIATED 301 CASE WOULD HIGHLIGHT THE IMPORTANCE OF INTELLECTUAL PROPERTY RIGHTS PROTECTION TO THE PRESI-DENT'S TRADE POLICY, AND THAT THE GOB WOULD TAKE INDUSTRY COMPLAINTS MORE SERIOUSLY IF THE USG PURSUED THE CASE "SIDE-BY-SIDE" WITH U.S. COMPANIES.

5. PMA LATIN AMERICA SUBCOMMITTEE MEMBERS HAVE CONSULTED WITH THEIR CEOS AND OBTAINED UNANIMOUS SUPPORT FOR "ANY TRADE ACTION THE USG DEEMS APPROPRIATE, INCLUDING UNDERTAKING A SELF-INITIATED SECTION 301 ACTION." IN THIS REGARD, THE PMA HAS OFFERED TO ASSIST THE USG IN ANY WAY IT CAN.

6. SPECIFICALLY, THE PARENT U.S. COMPANIES COMPLAIN THAT THEIR PROBLEMS STEM FROM:

-- THE SPECIFIC DENIAL OF PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS;

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ER RONEROUS, UNREALISTIC AND BIASED PRICE CONTROLS LACKING ANY METHODOLOGY;

-- IMPORT TAXES WHICH, WHILE NOT EXCLUSIVE TO THEIR INDUSTRY, COMPOUND THEIR MEMBERS' FINANCIAL PROBLEMS;

-- NO NE PRODUCT REGISTRATIONS, WITHOUT WHICH THE PHARMACEUTICAL INDUSTRY -- WHICH IS DEPENDENT ON RESEARCH AND DEVELOPMENT -- CANNOT SURVIVE;

-- INCREASED STATE COMPETITION THROUGH CEME WHICH IS ASSUMING A GREATER ROLE IN THE PRODUCTION AND DISTRIBU-TION OF DRUGS;

-- THE BRAZILIAN GOVERNMENT'S AVOWED INTENT TO PROVIDE FOR INCREASED LOCAL PRODUCTION OF CHEMICAL/PHARMACEUTI-

CALS BY NATIONAL COMPANIES; AND EXCLUDE FOREIGN-OWNED COMPANY PARTICIPATION.

7. PMA AND ITS MEMBERS BELIEVE THAT IN THE SHORT RUN, PRICING RELIEF AND THE RESUMPTION OF EXPEDITIOUS PRODUCT REGISTRATION ARE ESSENTIAL; HOWEVER, MANY OF ITS PROBLEMS WOULD BE RESOLVED IN THE LONG RUN IF BRAZIL AFFORDED ADEQUATE INTELLECTUAL PROPERTY PROTECTION. (COMMENT: IT IS THE PARENT COMPANIES THAT DETERMINE PRIORITIES AMONG TRADE AND INVESTMENT CONCERNS, IN CONTRAST TO THEIR SUBSIDIARIES, WHICH ARE MORE OFTEN CONCERNED WITH SHORT-TERM PROBLEMS, SUCH AS PRICING, WHICH AFFECT QUARTERLY PROFIT/LOSS STATEMENTS.) USTR'S INITIAL ASSESSMENT OF THE "301 ACTIONABILITY" OF BRAZIL'S PHARMACEUTICAL POLICIES SUGGESTS THAT THE LACK OF PATENT PROTECTION WOULD FORM OUR STRONGEST CASE.

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PERHAPS WITH ACTUAL EXPERIENCES RELATED TO MARKET RESERVE. HOWEVER, THE INDUSTRY'S CONCERNS ABOUT MARKET RESERVE POLICES ARE BASED TO SOME EXTENT ON PROSPECTIVE LEGISLATION, WHICH IS NOT ACTIONABLE UNDER SECTION 301. IN ADDITION, PRICE CONTROLS AND TARIFFS ARE NOT PRIMA FACIE UNFAIR; WE SHOULD BE PREPARED TO DEMONSTRATE DISCRIMINATORY PRICING PRACTICES AGAINST U.S. COMPANIES. AS MENTIONED ABOVE, THE TPSC SECTION 301 SUBCOMMITTEE WILL BE REVIEWING THESE ISSUES NEXT WEEK, TO DETERMINE THE LEGALITY OF THE CASE.

8. THE PURPOSE OF THE CONSULTATIONS SHOULD BE TO CONVEY TO THE GOB U.S. CONCERNS REGARDING THE BROAD RANGE OF PROBLEMS FACED BY THE U.S. PHARMACEUTICAL COMPANIES, TO ASCERTAIN HOW INTERESTED THE GOB IS IN ADDRESSING THESE CONCERNS AND TO OBTAIN FURTHER INFORMATION ON HOW THE GOB'S POLICIES HURT U.S. COMPANIES. OF PARTICULAR INTEREST ARE SPECIFIC INSTANCES WHERE COMPANIES HAVE EXPERIENCED PROBLEMS DUE TO THE LACK OF PATENT PROTECTION. KEEP IN MIND THAT WE NEED EVIDENCE TO SUPPORT SECTION 301 ACTION, NOT JUST ALLEGATIONS.

9. THE EMBASSY SHOULD STRESS THAT INTEREST IN THE U.S. PHARMACEUTICAL INDUSTRY'S PROBLEMS IN BRAZIL IS BUILDING, IN THE EXECUTIVE BRANCH AND IN THE U.S.-CONGRESS. WE WOULD PREFER TO OBTAIN PROMPT AND

GENUINE RELIEF WITHOUT RESORTING TO A SECTION 301 CASE. HOWEVER, U.S. INDUSTRY IS SUFFERING SIGNIFICANT ECONOMIC LOSSES FROM BRAZIL'S PHARMACEUTICAL POLICIES, AND WILL NOT BE ABLE TO SUSTAIN OPERATIONS IN BRAZIL ABSENT RELIEF. THE GOB'S WILLINGNESS TO SERIOUSLY ADDRESS THE INDUSTRY'S PROBLEMS IN A TIMELY MANNER WILL INFLUENCE THE RESPONSE OF BOTH THE U.S. GOVERNMENT, AS WELL AS THAT OF THE PHARMACEUTICAL COMPANIES.

10. CONSULTATIONS COVERING THE SAME ISSUES WILL BE

HELD WITH THE BRAZILIAN EMBASSY IN WASHINGTON. WE WILL FOLLOW THE CONSULTATIONS WITH A DEMARCHE OR NON-PAPER THAT REITERATES THE CONCERNS RAISED IN BRAZIL. (FYI: A SIMILAR STRATEGY WILL BE PURSUED IN OTHER LATIN COUNTRIES.)

11. USG AGENCIES APPRECIATE EMBASSY'S EFFORTS TO PROVIDE WASHINGTON AGENCIES WITH REQUESTED INFORMATION. WE WOULD FURTHER WELCOME INFORMATION REGARDING NON-U.S.,-FOREIGN-OWNED PHARMACEUTICALS COMPANY PROBLEMS AND WHETHER THEIR EMBASSIES WOULD BE INTERESTED IN COLLABORATING WITH THE USG IN OBTAINING RELIEF OR COSIGNING A DEMARCHE TO THE GOB.

12. SEPTEL CONTAINS TEXT OF MARCH 25 STRIKE FORCE PAPER ON GOB PHARMACEUTICAL POLICIES FOR EMBASSY'S USE DURING CONSULTATIONS.

13. TALKING POINTS

-- AS WE HAVE INDICATED IN PAST BILATERAL MEETINGS AND INFORMAL CONSULTATIONS, THE UNITED STATES IS EXTREMELY CONCERNED OVER THE DIRECTION IN WHICH YOUR SPECIALTY CHEMICAL POLICIES APPEAR TO BE GOING.

-- THELACK OF ADEQUATE PATENTPROTECTIONDISCOURAGES NOT ONLY FOREIGN MANUFACTURERS BUT BRAZILIAN RESEARCH LABS FROM ENGAGING IN THE COSY RESEARCH AND DEVELOPMENT NECESSARY FOR SCIENTIFIC ADVANCE. THE LACK OF PATENT PROTECTION ENABLES PIRATE PRODUCERS TO IMPORT AND/OR

MATERIALS AS WELL AS FINISHED PRODUCTS AT LESS

THAN THE ORIGINATOR'S FULL COST OF PRODUCTION.
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-- AN EXAMPLE OF THE EFFECT OF INADEQUATE PATENT PROTECTION IS THE RECENT CLOSING OF THE MONSANTO AGRICULTURAL RESEARCH CENTER IN SAO PAULO. MONSANTO LOST $16 MILLION IN POTENTIAL SALES OF ITS MAJOR HERBICIDE SOLD IN BRAZIL -- A PRODUCT THAT COST $30 MILLION AND 15 YEARS TO DEVELOP -- AFTER A BRAZILIAN FIRM COPIED THE INTERMEDIATE PRODUCT AND MARKETED IT AS ITS OWN. (REFTEL SAO PAULO 00719) MONSANTO CAN NO LONGER AFFORD TO CONTINUE RESEARCH ON NEW PRODUCTS THAT ARE UNPROTECTED BY PATENTS, COPIED AND SOLD MORE CHEAPLY.

-- MOREOVER, YOUR OCTOBER REGULATIONS (PORTARIA 4) APPEAR TO RESERVE THE MARKET FOR BRAZILIAN PRODUCERS, WHETHER OR NOT THOSE PRODUCERS PROVIDE GOODS AT COMPETITIVE PRICE AND QUALITY.

-- YOUR DRAFT LAW (PROFARMA) CONTAINS ELEMENTS THAT WOULD DISCRIMINATE AGAINST FOREIGN FIRMS, INCLUDING THOSE FROM THE UNITED STATES, WHICH HAVE A SUBSTANTIAL INTEREST IN THE BRAZILIAN MARKET.

-- STRICT PRICE CONTROLS IN BRAZIL HAVE SEVERELY HAMPERED COMPANIES' EFFORTS TO RECOVER THE COSTS OF RESEARCH, DEVELOPMENT AND MARKETING OF PRESENT AND FUURE PRODUCTS. WE REALIZE THAT PRICING IS POLITICALLY SENSITIVE NOW AS A RESULT OF THE NEW ECONOMIC PLAN, BUT THE TIMING CAUGHT AN ALREADY SUFFERING INDUSTRY AT A MOMENT WHEN A PRICE INCREASE HAD BEEN APPROVED BUT NOT IMPLEMENTED.

-- I BELIEVE SUCH POLICIES WILL NOT ASSIST YOU IN ACHIEVING YOUR LAUDABLE OBJECTIVES OF SUPPLYING LOW COST, HIGH QUALITY CHEMICALS AND PHARMACEUTICALS TO THE BRAZILIAN MARKET.
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-- RATHER, THEY WILL DISCRIMINATE AGAINST INVESTORS WHO HAVE BEEN RELIABLE SUPPLIERS TO BRAZIL AND IMPEDE THE ADDITIONAL FLOWS OF FOREIGN DIRECT INVESTMENT WHICH COULD HELP MEET SOME OF BRAZIL'S CAPITAL NEEDS AND DEVELOPMENT OBJECTIVES. MOREOVER, SUCH POLICIES WILL DRIVE OUT THE BASIC RESEARCH AND DEVELOPMENT.

-- I URGE YOU TO RECONSIDER YOUR CURRENT POSITION ON PROTECTION OF PHARMACEUTICAL PATENT RIGHTS AND TO COMBAT PIRACY TO ENSURE THAT U.S. PRODUCERS RECEIVE

ADEQUATE PROTECTION AND FAIR RETURN ON THEIR PRODUCTION COSTS IN BRAZIL.

-- I URGE YOU AS WELL TO RECONSIDER YOUR POLICIES IN THE SPECIALTY CHEMICALS AREA: THE NEGATIVE IMPACT OF THOSE IN PLACE OR BEING CONTEMPLATED ON U.S. TRADE AND U.S. INVESTORS CAN NOT HELP BUT BE NOTICED AMONG POLICYMAKERS IN THE UNITED STATES.

-- INTEREST IN OBTAINING RELIEF FOR U.S. PHAR MACEUTICALS IS INCREASING, BOTH WITHIN THE U.S. GOVERN-MENT AND FROM OUR INDUSTRY. A RESPONSE BY YOUR GOVERN-MENT TO OUR CONCERNS WILL SERVE TO EASE THIS PRESSURE

-- BUT ONLY IF THE RESPONSE IS TIMELY AND PROVIDES GENUINE RELIEF TO OUR INDUSTRY.

14. RESPONSE TO BRASILIA 03291, COOPERATION ON DRUG REGISTRATION, WILL FOLLOW IN SEPTEL. SHULTZ

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