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 FM AMEMBASSY BRASILIA
 TO SECSTATE WASHDC PRIORITY 7921
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 AMCONSUL RIO DE JANEIRO
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PASS TO USDOC FOR PTO KIRK AND

USDOC FOR 4330/IEP/WH/OSA/PETER FIELD AND

USDOC FOR 4300/IEP/WH/DAS ANN HUGHES

USTR FOR AMBASSADOR SMITH AND CHRISTINA LUND AND JON ROSENBAUM

GENEVA FOR USTR

E.O.12356: DECL:OADR

TAGS: ETRD, EINV, PREL, BR, US

SUBJECT: PHARMACEUTICALS: PROPOSED STRATEGY FOR
 SECTION 301 CASE ON PHARMACEUTICALS

1. ~~CONFIDENTIAL~~ - ENTIRE TEXT.
2. SUMMARY: THE MISSION'S PROPOSED STRATEGY FOR
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CONDUCTING THE SECTION 301 PHARMACEUTICALS CASE IS TWO
 PHASED. IN THE SHORT RUN OUR STRATEGY SHOULD FOCUS ON

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UNITED STATES DEPARTMENT OF STATE
 REVIEW AUTHORITY: NORMAN M. BOUTON
 DATE/CASE ID: 19 DEC 2001 200000143

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PREVENTING THE EROSION OF RECENT PROGRESS ON REGISTRATION AND PRICING ISSUES AND ON AVOIDING THE ENSHRINEMENT OF NON-RECOGNITION OF PATENT PROTECTION IN THE BRAZILIAN CONSTITUTION. THE SECOND PHASE, WHICH WOULD BEGIN AFTER THE CONSTITUENT ASSEMBLY FINISHES ITS WORK, WOULD STRESS EFFORTS WHICH WOULD: ASSURE THE GOB THAT LOW INCOME GROUPS WOULD NOT SUFFER FROM THE INTRODUCTION OF MORE SERIOUS NATIONAL COMPANIES TO SUPPORT PATENT RE-INTRODUCTION; AND EDUCATE MEDICAL ASSOCIATIONS TO THE BENEFITS OF SEVERAL COMPETITIVE TREATMENTS FOR A PARTICULAR DISEASE. OUR ASSUMPTION IS THAT PMA'S DAMAGE ESTIMATES OF 20 MILLION DOLLARS PER YEAR DOES NOT PROVIDE THE BASIS FOR MUCH MORE THAN SYMBOLIC RETALIATORY MEASURES THAT PROVIDE LITTLE OR NO LEVERAGE FOR RESOLVING THE ISSUE. WE APPRECIATE COMMENTS AND SUGGESTIONS RECEIVED FROM CONGENS RIO AND SAO PAULO WHICH STRENGTHENED THE MISSION'S OVERALL PRESENTATION. END SUMMARY.

3. THE MISSION'S PROPOSED STRATEGY FOR HANDLING THE SECTION 301 PHARMACEUTICAL CASE IS BASED ON TWO ASSUMPTIONS: FIRST, THAT RETALIATION WOULD PROVIDE US WITH LITTLE LEVERAGE IF IT IS DIRECTLY COMMENSURATE TO THE PMA MEMBER COMPANY ANNUAL DAMAGES OF 20 MILLION DOLLARS -- ABOUT 1-2 PERCENT OF TOTAL SALES -- IN THE 1979-1986 PERIOD. SECOND, RESOLVING THE ISSUE AMICABLY WILL TAKE CONSIDERABLE TIME AND WILL REQUIRE PMA INVOLVEMENT IN LAUNCHING AN EDUCATIONAL CAMPAIGN AND DEVELOPING ECONOMIC INCENTIVES TO ADOPTING PATENT PROTECTION WHILE WE MAINTAIN A POSITIVE INTER-GOVERNMENT DIALOGUE.

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SHORT TERM STRATEGY - DAMAGE LIMITATION

4. OUR SHORT-TERM STRATEGY SHOULD BE FOCUSED ON PREVENTING THE NON-RECOGNITION OF PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS AND PROCESSES FROM BEING ENSHRINED IN THE CONSTITUTION, ON RENEWING IMPROVEMENTS IN PRICING AND REGISTRATION ISSUES AND ON BEGINNING A CONSTRUCTIVE DIALOGUE WITH THE GOB ON THE PATENT ISSUE.

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PRICING AND REGISTRATION

5. WHILE NOT PART OF THE SECTION 301 ACTION, WE BELIEVE THE U.S. GOVERNMENT SHOULD CONTINUE TO PRESS THE GOB FOR PROGRESS IN THESE AREAS. THE MOMENTUM THAT HAD BEEN BUILT UP EARLIER THIS YEAR ON THESE ISSUES QUICKLY DISSIPATED AFTER THE JUNE 11 PMA FILING. TALK ABOUT ESTABLISHING A TRANSPARENT SEMI-AUTOMATIC PRICING SYSTEM LINKED TO AN INFLATIONARY TRIGGER HAS HALTED. WHILE DIMED HAS A NEW, SEEMINGLY MORE PRAGMATIC HEAD, LOCAL PHARMACEUTICAL COMPANIES REPORT NO NOTICEABLE INCREASE IN NEW DRUG REGISTRATIONS. THE NATIONAL HEALTH COUNCIL, DESIGNED TO FACILITATE DRUG APPROVALS, HAS NOT MET. THE MISSION WILL CONTINUE ITS EFFORTS TO INITIATE, WITH FULBRIGHT COMMISSION SUPPORT, A DIMED-FDA EXCHANGE PROGRAM.

CONSTITUENTE

6. THE FIRST DRAFT OF THE NEW BRAZILIAN CONSTITUTION CONTAINS A PROVISION WHICH STATES THAT BRAZIL DOES NOT

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PASS TO USDOC FOR PTO KIRK AND

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GENEVA FOR USTR

E.O.12356: DECL:OADR

TAGS: ETRD, EINV, PREL, BR, US

SUBJECT: PHARMACEUTICALS: PROPOSED STRATEGY FOR

RECOGNIZE THE RIGHT OF EXCLUSIVE USE WHEN AN INVENTED
 ITEM DEALS WITH LIFE, NUTRITION AND HEALTH. WE BELIEVE
 THAT GROUPS WITH AN IDEOLOGICAL ORIENTATION IN FAVOR OF
 ENHANCED STATE PARTICIPATION IN THE HEALTH SECTOR COULD

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USE USG PHARMACEUTICAL PUBLIC HEARINGS AND PUBLIC
 STATEMENTS AS EVIDENCE OF U.S. PRESSURES AGAINST
 BRAZIL'S CONSTITUENT ASSEMBLY. PUBLIC HEARINGS IN
 SEPTEMBER, WHICH WE UNDERSTAND ARE LEGALLY MANDATED,
 UNFORTUNATELY COINCIDE WITH PLENARY DEBATE ON THE
 CONSTITUTIONAL DRAFT. THE EMBASSY, IN CONJUNCTION WITH
 THE LATIN AMERICAN WORKING GROUP (LAWG), IS CONSULTING
 WITH THE GOB AND INDIVIDUAL CONGRESSMEN ON THE ISSUE OF
 ENSHRINING PATENT NON-RECOGNITION OF PHARMACEUTICALS IN
 THE CONSTITUTION.

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7. THE (LAWG) RECENTLY RETAINED A LOCAL PUBLIC RELATIONS FIRM (SEMPREL) TO PUBLICIZE THE BENEFITS OF PATENT PROTECTION TO GOB OFFICIALS AND DELEGATES TO THE CONSTITUTIONAL CONVENTION. THE CENTERPIECE OF THIS EFFORT IS A FAIRLY DETAILED 9-PAGE PRESENTATION, WRITTEN BY PFIZER EXECUTIVES AND ATTORNEYS, OUTLINING WHAT MEDICINE PATENTS ARE AND HOW THEY COULD BENEFIT BRAZIL. THIS DRAFT DIFFERS FROM AND IS SUPERIOR TO PREVIOUS WORKS ON THE SUBJECT IN THAT IT DEALS SPECIFICALLY WITH THE HISTORICAL DEVELOPMENT IN BRAZIL OF THE HUMAN MEDICINES INDUSTRY.

8. WHILE THE GOB'S REACTION TO DATE TO USTR'S ACCEPTANCE OF THE PMA'S PETITION HAS BEEN MUTED AND LOW-KEY, THERE APPARENTLY IS AN OPTION BEING DISCUSSED WHICH WOULD HAVE THE GOB LAUNCH ITS OWN INVESTIGATION INTO MNC OPERATIONS IN THE PHARMACEUTICAL SECTOR. THE AIRING OF IRREGULAR MNC PRACTICES WOULD CERTAINLY START OUR GOVERNMENT-TO-GOVERNMENT DIALOGUE ON THE WRONG FOOT.

9. IN THE GOVERNMENT-TO-GOVERNMENT DIALOGUE, WE SUGGEST THAT IN THE SHORT RUN THE USG EXPLORE

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ALTERNATIVES TO THE FOUR POINTS RAISED BY AMBASSADOR MOREIRA IN THE JUNE 8 TALKS - TRADEMARK ENFORCEMENT, QUALITY STANDARDS, INVESTMENT RESTRICTIONS AND INTERNATIONAL COOPERATION ON PATENT PROTECTION. THE MOST INTERESTING POINT COULD BE QUALITY STANDARDS. ALTHOUGH THE GOB COULD NOT LEGALLY ENFORCE EXCLUSIVITY OF PRODUCTS WITHOUT A FORMAL CHANGE IN LAW 5772, WE COULD IMAGINE THAT RIGOROUS QUALITY STANDARDS AND SCRUTINY OF DATA USED TO JUSTIFY PIRATED PRODUCTS COULD RESULT IN LONG DELAYS OF REGISTRATION REQUESTS FOR PIRATED ITEMS.

10. OF THE TOTAL OF AROUND 310 NATIONAL PHARMACEUTICAL COMPANIES IN BRAZIL ONLY ONE, ACHE, IS SIZEABLE. THE REST ARE VERY SMALL (MEDIAN EMPLOYMENT IS ABOUT 300) AND GENERALLY UNDERCAPITALIZED. MODERN QUALITY CONTROL PROGRAMS IN HUMAN MEDICINES MANUFACTURE REQUIRE SUBSTANTIAL AMOUNTS OF DEDICATED EQUIPMENT AND PERSONNEL, AND NATIONAL FIRMS GENERALLY LACK THE VOLUME TO EFFICIENTLY AMORTIZE SUCH AN INVESTMENT. MOST

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NATIONAL FIRMS DO NOT HAVE ANY EMPLOYEES EXCLUSIVELY ASSIGNED TO QUALITY CONTROL. AS A RESULT, IF AS A PREREQUISITE FOR COMMERCIALIZATION THESE FIRMS WOULD HAVE TO PROVE THAT THEIR PRODUCTS MEET INTERNATIONAL QUALITY STANDARDS, THEY WOULD GENERALLY BE UNABLE TO DO SO.

11. WE WOULD ALSO SUGGEST THAT A BILATERAL STUDY GROUP, BE ESTABLISHED EARLY IN THE GOVERNMENT-TO-GOVERNMENT DIALOGUE WHICH COULD SERVE AS A VEHICLE FOR AN EDUCATIONAL CAMPAIGN AS WELL AS A MEANS TO QUANTIFY THE COST/BENEFITS OF ADOPTING PATENT PROTECTION.

LONGER TERM

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12. WE DO NOT BELIEVE THE GOB WILL CHANGE ITS POSITION

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USTR FOR AMBASSADOR SMITH AND CHRISTINA LUND AND JON ROSENBAUM
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E.O.12356: DECL:OADR
 TAGS: ETRD, EINV, PREL, BR, US
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ON PATENT PROTECTION UNTIL IT CAN BE PERSUADED THAT:
 THE NATIONAL PHARMACEUTICAL INDUSTRY WILL SURVIVE AND
 HAVE REASONABLE PROSPECTS FOR GROWTH; PRICES WILL NOT
 BE PROHIBITIVE, ESPECIALLY FOR LOW-INCOME GROUPS; AND

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THE GOB CAN PREVENT ABUSE OF A STRONG MARKET POSITION.

13. USING THE BILATERAL STUDY GROUP AND PERIODIC
 CONSULTATIONS, WE EXPECT THAT SOLUTIONS CAN BE
 DEVELOPED. WE WILL NEED PMA PARTICIPATION TO SHAPE
 SOME OF THE SOLUTIONS. FOR EXAMPLE, PMA MIGHT WANT TO
 CONSIDER THE POSSIBILITY OF CREATING AN ECONOMIC
 INCENTIVE FOR SOME OF THE SERIOUS NATIONAL FIRMS IN
 EXCHANGE FOR SUPPORT OF PATENT PROTECTION. THIS MIGHT
 BE DONE BY CREATING JOINT VENTURES, JOINT MARKETING, OR
 LICENSING ARRANGEMENTS TO HANDLE THE INTRODUCTION OF
 PATENT DRUGS. THE PMA MIGHT SURVEY ITS MEMBERSHIP TO
 DETERMINE HOW INVESTMENT LEVELS MIGHT INCREASE WITH
 PATENT PROTECTION.

IDENTIFYING POTENTIAL ALLIES

14. THE OWNER OF THE LARGEST AND MOST INFLUENTIAL
 NATIONAL PHARMACEUTICALS COMPANY, ACHE, IS REPORTEDLY
 IN FAVOR OF ADOPTION OF PATENT PROTECTION UNDER CERTAIN
 CONDITIONS. LIKE MOST MEDICINES COMPANIES HERE, GOB
 PRICE CONTROLS HAVE DRIVEN ACHE TO THE BRINK OF
 INSOLVENCY. LAST MONTH THE FIRM LAID OFF 30 PERCENT OF
 ITS WORKFORCE. ACHE EXECUTIVES THINK THAT ADOPTION OF
 A PATENT REGIME COULD PERMIT LUCRATIVE LICENSING DEALS
 THAT COULD RETURN THE FIRM TO PROFITABILITY. INHERENT
 IN THIS IDEA IS THE UNTESTED ASSUMPTION THAT PMA MEMBER
 FIRMS ARE WILLING TO HOLD OUT SOME "CARROTS" IN

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EXCHANGE FOR ADOPTION OF A PHARMACEUTICALS PATENT REGIME.

15. A FACTUALLY BASED EDUCATIONAL CAMPAIGN MIGHT INDUCE OTHER NATIONAL FIRMS TO LINE UP WITH ACHE. THE IDEA

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THAT THE ADOPTION OF A PATENT REGIME WILL DRIVE THE NATIONAL COMPANIES OUT OF EXISTENCE IS PERHAPS THE MOST DAMAGING OF THE MANY MISCONCEPTIONS PREVALENT HERE. THE FACT IS THAT ONLY 3 OR 4 OF THE 400 MEDICINES ON THE "RENAME" LIST OF ESSENTIAL MEDICINES ARE CURRENTLY UNDER ACTIVE PATENT. THE U.S. AND OTHER INDUSTRIALIZED COUNTRIES THAT RECOGNIZE PHARMACEUTICALS PATENTS HAVE BILLION DOLLAR INDUSTRIES THAT DO NOTHING BUT MANUFACTURE GENERIC DRUGS. ON-PATENT DRUGS ARE RESPONSIBLE FOR NO MORE THAN 2 PERCENT OF TOTAL DRUG SALES IN BRAZIL. IN TERMS OF EFFECT ON THE ECONOMIC VIABILITY OF THE NATIONAL DRUG INDUSTRY, THE ADOPTION OF PATENT PROTECTION PER SE IS NEUTRAL.

16. PMA MEMBER FIRM EXECUTIVES HERE READILY ADMIT THAT THEY HAVE UP TO NOW DONE A POOR JOB OF EDUCATING THE LOCAL INDUSTRY, THE GOB, OR THE GENERAL PUBLIC ON FACTS SUCH AS THE ABOVE CITED ONE AND FEEL THAT AN EDUCATIONAL CAMPAIGN IS NECESSARY. THUS THE BILATERAL STUDY GROUP COULD SERVE AS THE FORUM FOR SUCH A CAMPAIGN, AS WELL AS PROVIDE A WAY OF DRAWING THE ABOVE MENTIONED POTENTIAL ALLIES INTO THE DEBATE.

17. ANOTHER POTENTIAL RESOURCE THAT COULD BE TAPPED FOR THIS EDUCATIONAL CAMPAIGN IS INTERPAT. THIS IS A PHARMACEUTICALS PATENT LOBBY BASED IN SWITZERLAND AND FUNDED BY MNC MEDICINES COMPANIES. THE CURRENT PRESIDENT, MICHAEL JACKSON (WHO IS WITH THE U.K.-BASED WELLCOME FOUNDATION), WAS IN BRAZIL RECENTLY AND SPOKE WITH SEVERAL MEMBERS OF ABIFARMA. JACKSON REPORTEDLY EXPRESSED HIS PERSONAL OPPOSITION TO THE PMA 301 FILING. HOWEVER, NOW THAT THE FILING IS A FAIT ACCOMPLI INTERPAT CAN BE COUNTED ON TO WORK WITH PMA MEMBER FIRMS AND THE USG TO PUT FORTH THE POSITIVE CASE FOR ADOPTION OF PATENTS.

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18. TO ALLAY FEARS OF PROHIBITIVE PRICES DENYING
 LOW-INCOME GROUPS ACCESS TO NEEDED NEW MEDICINES, WE
 RECALL THAT THE LAWG ONCE APPROACHED THE FORMER
 FIGUEREIDO GOVERNMENT WITH A PROPOSAL TO SELL A
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SPECIFIED QUANTITY OF DRUGS TO THE FEDERAL MEDICINES
 CENTER (CEME) AT COST IN EXCHANGE FOR MARKET PRICES FOR
 PHARMACY PURCHASES. PERHAPS A VARIATION OF THIS IDEA
 MIGHT BE CONSIDERED.

19. IN TERMS OF MARKET ABUSE, WE MIGHT BRIEF THE GOB ON
 OUR ANTI-TRUST LEGISLATION AND EXPERIENCES IN THE
 PHARMACEUTICAL INDUSTRY.

THE NEGATIVE EXAMPLE

20. WE BELIEVE THAT A FAILURE TO OBTAIN PATENT
 PROTECTION IN THIS CASE COULD SET A VERY NEGATIVE
 EXAMPLE IN THE GLOBAL CAMPAIGN TO STRENGTHEN
 INTELLECTUAL PROPERTY RIGHTS. CONSEQUENTLY, WE BELIEVE
 CONSIDERABLE EFFORT SHOULD BE EXERTED TO DEVELOP A
 PACKAGE OF INCENTIVES THAT MIGHT CHANGE THE GOB'S FIRM
 CONVICTION THAT PATENTS ARE NOT IN BRAZIL'S INTEREST.
 SHLAUDEMANN##

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