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USTR FOR JON ROSENBAUM AND CHRISTINA LUND
USDOC FOR 4330/IEP/WH/OSA/PETER FIELD AND
- 4300/IEP/WH/DAS/ANN HUGHES

E.O. 12356: DECL: OADR
TAGS: ETRD, EINV, PREL
SUBJECT: PHARMACEUTICAL CONSULTATIONS: SOME THOUGHTS
- ABOUT THE ISSUES

- REF: (A) SAO PAULO 1776
- (B) SAO PAULO 1560
- (C) BRASILIA 3291
- (D) BRASILIA 8229
- (E) SAO PAULO 0472
- (F) SAO PAULO 2672 (NOTAL)
- (G) RIO DE JANEIRO 4707 (NOTAL)

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2. INTRODUCTION AND SUMMARY. THIS MESSAGE SETS OUT

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UNITED STATES DEPARTMENT OF STATE
REVIEW AUTHORITY: NORMAN M. BOUTON
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THE MISSION'S THINKING ON THE UPCOMING BILATERAL CONSULTATIONS ON PHARMACEUTICALS AND THE MAJOR ISSUES OF CONCERN. OUR MEETING WILL TAKE PLACE IN AN ENVIRONMENT IN WHICH GOB POLICYMAKERS WILL BE GRAPPLING WITH A HOST OF ECONOMIC PROBLEMS AND DIGESTING THE RESULTS OF THE NOVEMBER 15 ELECTIONS. ON THE PHARMACEUTICAL FRONT, THE GOB FEELS BELEAGUERED AND DEFENSIVE. PRESSURE FROM THE U.S. AND OTHER COUNTRIES, ESPECIALLY THE FRG, HAVE LED TO REPEATED GOB DECLARATIONS ESCHEWING A MARKET RESERVE. BUT THE GOB HAS NOT SORTED OUT ITS OWN THINKING ON BRAZIL'S PHARMACEUTICALS. SOME GOB POLICYMAKERS CLEARLY WANT THE "FOR PROFIT" COMPANIES OUT OF THE BUSINESS; OTHERS WILL SETTLE FOR GIVING THE NATIONAL COMPANIES A LEG UP ON THE MULTINATIONAL COMPETITION.

3. THE MISSION BELIEVES THIS MEETING WILL BE LARGELY AN INFORMATION GATHERING EXERCISE. THE GOB WILL SEEK A BETTER INDICATION OF OUR CONCERNS, DOCUMENTATION AND DEMANDS. THE GOB IS UNLIKELY TO GO BEYOND EXISTING POSITIONS AT THIS MEETING. WE BELIEVE WE SHOULD USE THIS ENCOUNTER TO CLARIFY THE DIRECTIONS OF FUTURE GOB PHARMACEUTICAL POLICY, DEFINE OUR CONCERNS, EXPLORE PROBLEMS, AND ESTABLISH BENCHMARKS THAT THE GOB CAN USE TO EVALUATE OUR REACTION TO FUTURE GOB POLICY INITIATIVES.

4. WE HAVE INDICATED WE WISH THE CONSULTATIONS TO FOCUS ON PATENT PROTECTION, PROFITABILITY (PRICES), REGISTRATION AND FUTURE POLICY. WE BELIEVE THE GOB WILL FIND MOVEMENT ON PATENT PROTECTION DIFFICULT; OUR

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ARGUMENTS WILL BE MOST EFFECTIVE IF WE CAN DOCUMENT THE OPPORTUNITY COSTS OF NO PROTECTION. ON PRICES, WE SHOULD PRESS FOR INDIRECT RELIEF NOW WHILE INSISTING ON TRANSPARENCY AND NON-DISCRIMINATION IN PRICE-SETTING POLICIES WHEN THE CRUZADO PLAN IS MODIFIED. THE CONSULTATIONS SHOULD PUT PRESSURE ON THE GOB TO SPEED-UP REGISTRATION OF NEW AND REFORMULATED PRODUCTS; A USG OFFER OF POSITIVE COOPERATION IN THE PROCESS WOULD INCREASE THIS PRESSURE. ON SECTORAL POLICIES, WE SHOULD SEEK, AMONG OTHER THINGS, CLARIFICATION AS TO WHAT EXTENT AND HOW THE

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GOB INTENDS TO PROMOTE ITS NATIONAL COMPANIES. WE
FURTHER RECOMMEND CONTINUATION OF MULTILATERAL
PRESSURES ON GOB PHARMACEUTICAL POLICIES. END
INTRODUCTION AND SUMMARY.

CLIMATE

5. THE NOVEMBER 20 CONSULTATIONS WILL TAKE PLACE
AGAINST A RICH BACKGROUND OF GOB DEFENSIVENESS, CONCERN,
AND PREOCCUPATION WITH DOMESTIC PROBLEMS. OUR REQUEST
FOR CONSULTATIONS HAS PROVOKED CONCERN. THE NATIONAL
PHARMACEUTICAL INDUSTRY, THE NCCS, FEARS THAT A BETTER
DEAL FOR THE MNCS AND ANTI-PIRACY MOVES WILL REDUCE
THEIR LIMITED SHARE OF THE PHARMACEUTICAL MARKET. SOME
GOB HEALTH OFFICIALS, SUCH AS DIMED'S SUELI ROZENFELD,
SHARE THIS CONCERN. MINISTER OF INDUSTRY AND COMMERCE
JOSE HUGO CASTELO BRANCO HAS STATED THAT BRAZIL DOES
NOT INTEND A "MARKET RESERVE" IN PHARMACEUTICALS AND

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USTR FOR JON ROSENBAUM AND CHRISTINA LUND

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

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FINE CHEMICALS. OTHERS CHALLENGE THE COMPANIES' ASSERTIONS OF DAMAGE. DOMESTICALLY, THE GOB WILL BE PREOCCUPIED WITH DIGESTING POLITICALLY THE RESULTS OF THE NOVEMBER 15 ELECTIONS AND THE WIDELY-EXPECTED ADJUSTMENTS IN THE CRUZADO PLAN. OUR BILATERAL TRADE AGENDA ALSO COMPLICATES GOB CONSIDERATIONS: THE INFORMATICS PROBLEM; THE FOLLOW-UP TO THE PUNTA DEL ESTE MINISTERIAL; THE USG REQUEST FOR CONSULTATIONS ON VIDEO-CASSETTES; THE EXPECTED USG DECISIONS ON GSP AND ORANGE JUICE.

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6. THE CONSULTATIONS WILL TAKE PLACE AGAINST A BACKGROUND OF DIVERSE THINKING ON GOB INVOLVEMENT IN PHARMACEUTICALS AND RELATED HEALTH CARE. INDUSTRY SOURCES ALLEGE THAT CEME, AND ITS REGISTRATION AUTHORITY, DIMED, ARE CONTROLLED BY ULTRA-LEFTISTS, DIRECTING POLICIES ACCORDING TO THEIR PERSONAL IDEOLOGIES. THEY OPPOSE THE PARTICIPATION OF FOR-PROFIT PRIVATE DRUG COMPANIES IN THE BRAZILIAN MARKET AND ADVOCATE THAT BASIC MEDICAL CARE BE FREELY AND EQUALLY ADMINISTERED THROUGH A NATIONALIZED HEALTH SYSTEM. AS ARGUED BY

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SPOKESPERSONS SUCH AS DIMED DIRECTOR SUELI ROZENFELD, THE NUMBER OF MEDICATIONS AVAILABLE IN BRAZIL SHOULD BE LIMITED TO THE WORLD HEALTH ORGANIZATION'S LIST OF 700-ODD ESSENTIAL DRUGS, WHICH SHOULD BE PRODUCED IN STATE-OWNED LABS. HER VISION MAY BE AS MUCH BEHIND THE SLOWDOWN IN REGISTRATION AS THE WELL-DOCUMENTED LACK OF STAFF AND EXPERTISE. LESS RADICAL BRAZILIANS, SUCH AS THE PLANNERS THAT ELABORATED THE DRAFT POLICY DECREE PUBLISHED LAST JULY (REF A), FORESEE A ROLE FOR THE PRIVATE SECTOR IN PHARMACEUTICALS, BUT WANT THE MAJOR IMPETUS TO COME FROM THE NCCS. FEW DEFEND THE STATUS QUO, AT LEAST PUBLICLY. THE QUESTION, OF COURSE, IS WHICH CONCEPT REPRESENTS GOB POLICY. ARE SUELI'S ANTI-"FOR PROFIT" DRUG COMPANY VIEWS A PERSONAL VISION, OR DO THEY REPRESENT GOB POLICY? TO WHAT EXTENT ARE THE NATIONALISTIC VIEWS OF THE DRAFT POLICY DECREE REPRESENTATIVE OF GOB DECISION-MAKERS? DOES THE DRAFT POLICY DECREE SIMPLY CONSOLIDATE EXISTING THINKING, AS SOME HAVE ARGUED? OR WILL MORE MODERATE VIEWS, THAT RECOGNIZE AND ACCEPT A PRIMARY ROLE FOR THE PRIVATE SECTOR AND THE MNCS, PREVAIL? THESE QUESTIONS SHOULD BE EXPLORED WITH OUR GOB INTERLOCUTORS. THE ANSWERS

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WILL BE IMPORTANT IN DETERMINING THE POSSIBILITIES FOR PROGRESS ON THE SPECIFIC ISSUES UPON WHICH THE CONSULTATIONS WILL FOCUS.

 THE ISSUES

7. WE HAVE INDICATED TO THE GOB THAT WE WISH TO DISCUSS FOUR SPECIFIC ISSUES: PATENT PROTECTION, INADEQUATE PROFITS (READ PRICES), REGISTRATION PROBLEMS, AND GOB INVESTMENT POLICIES. BELOW, WE OFFER SOME OBSERVATIONS ON THE SCOPE OF THE ISSUES, HOW WE MIGHT ADDRESS THEM, WHAT WE MIGHT SEEK TO OBTAIN, AND THE NATURE OF THE PROBABLE GOB RESPONSE. IN GENERAL, WE BELIEVE THE GOB WILL SEEK TO USE THIS MEETING TO GET A BETTER INDICATION OF OUR CONCERNS, OUR DOCUMENTATION, AND THE CHANGES WE DESIRE. THE GOB IS UNLIKELY TO GO BEYOND EXISTING POSITIONS AT THIS MEETING. NEVERTHELESS, WE BELIEVE THE CONSULTATIONS CAN SERVE TO CLARIFY

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AREAS OF CONCERN AND ESTABLISH BENCHMARKS THAT THE GOB CAN USE TO EVALUATE OUR POSSIBLE REACTION TO FUTURE POLICY CHANGES. WE SHOULD SEEK ALSO TO ESTABLISH A FRAMEWORK FOR FUTURE CONSULTATIONS.

PATENT PROTECTION

8. AT THE TOP OF OUR AGENDA IN THE PHARMACEUTICAL CONSULTATIONS WILL BE THE LEGAL DENIAL, CODIFIED IN ARTICLE 9 OF LAW 5772 OF DECEMBER 21, 1971, OF PATENT

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USTR FOR JON ROSENBAUM AND CHRISTINA LUND

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

- 4300/IEP/WH/DAS/ANN HUGHES

E.O. 12356: DECL: OADR

TAGS: ETRD, EINV, PREL

SUBJECT: PHARMACEUTICAL CONSULTATIONS: SOME THOUGHTS

PROTECTION FOR PHARMACEUTICAL AND CHEMICAL PRODUCTS. SOME MNCS REPORT SIGNIFICANT LOSSES BECAUSE OF WIDESPREAD PIRACY OF EASY-TO-COPY PRODUCT LINES. OTHERS CLAIM THIS IS NOT A MAJOR PROBLEM FOR THEIR PARTICULAR PRODUCT LINES. A PARTIAL SURVEY CONDUCTED BY CONGEN SAO PAULO OF 16 PHARMACEUTICAL FIRMS INDICATED THAT IT WOULD NOT BE UNREASONABLE TO ESTIMATE DAMAGES TO U.S. FIRMS DUE TO PIRACY AT 1 BILLION DOLLARS OVER A 10-YEAR PERIOD (REF B). WE UNDERSTAND THAT THE PMA IS CONDUCTING A MORE COMPLETE SURVEY OF THESE LOSSES.

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HOPEFULLY THE RESULTS OF THE SURVEY AND THE METHODOLOGY EMPLOYED WILL BE AVAILABLE PRIOR TO CONSULTATIONS.

9. PROGRESS ON THE PATENT PROTECTION ISSUE WILL BE VERY DIFFICULT BECAUSE MANY OF BRAZIL'S 490 NATIONAL CAPITAL PHARMACEUTICAL COMPANIES (NCCS) BELIEVE PATENT PROTECTION WOULD THREATEN THEIR VERY SURVIVAL. EVEN REPRESENTATIVES OF LARGE NCCS, SUCH AS ACHE AND FARMASA, HAVE TOLD US BLUNTLY THAT THE LACK OF PATENT PROTECTION IS NECESSARY AND THIS SITUATION WILL CHANGE ONLY WHEN NATIONAL FIRMS ARE STRONGER. WHILE THE ARGUMENT THAT PIRACY LEADS TO STRONGER NATIONAL FIRMS IS AN OBVIOUS NON SEQUITUR, WE MUST BE AWARE THAT PATENT PROTECTION, AT LEAST IN THE MEDIUM-TERM, WOULD REDUCE THE NCC'S CURRENT 20 PERCENT SHARE OF THE PHARMACEUTICAL MARKET. IN ADDITION, PROGRESS WILL BE DIFFICULT BECAUSE PATENT PROTECTION RUNS CONTRARY TO THE INTERESTS OF THE FEDERAL MEDICAL CENTER (CEME). THE NEW HEAD OF CEME, MARTA NOBREGA MARTINEZ, WAS QUOTED BY THE OCTOBER 16 PRESS AS

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ADMITTING, "THE PROGRAM OF NATIONALIZING ESSENTIAL MEDICINES IS POSSIBLE ONLY BECAUSE A PATENT REGIME DOES NOT EXIST IN BRAZIL".

10. WE CAN THINK OF SEVERAL LINES OF DEFENSE THAT THE GOB MIGHT EMPLOY TO STYMIE PROGRESS ON THIS ISSUE. A TIME-HONORED GOB DEFENSE IS THAT THE LACK OF PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS IS NOT INCONSISTENT WITH INTERNATIONAL AGREEMENTS SIGNED BY THE GOB. THE GOB MIGHT POINT OUT (IF THE NUMBERS ARE RIGHT) THAT MOST LDCS DO NOT EXTEND PATENT PROTECTION TO PHARMACEUTICAL PRODUCTS. THE GOB MAY ALSO ARGUE THAT LACK OF PATENT PROTECTION HAS BEEN ON THE BOOKS FOR A

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LONG PERIOD AND MOST MNCS HAVE FOUND WAYS TO ADAPT TO THIS REALITY. THE GOB MAY ALSO CONTEND THAT THE LACK OF PATENT PROTECTION HAS NOT DISCOURAGED FOREIGN INVESTMENT IN THE PHARMACEUTICAL SECTOR WHICH, ACCORDING TO GOB FIGURES, GREW FROM 292 MILLION DOLLARS IN DECEMBER 1975 TO 1.113 BILLION IN DECEMBER 1985. THE PHARMACEUTICAL SHARE OF TOTAL FOREIGN INVESTMENT DURING THIS PERIOD ACTUALLY ROSE SLIGHTLY -- FROM 4.0 TO 4.7 PERCENT. THE GOB MAY POINT OUT THAT FOREIGN COMPANIES (AT LEAST THEIR LOCAL SUBSIDIARIES) HAVE CONSISTENTLY RATED THE LACK OF PATENT PROTECTION AS OF SECONDARY IMPORTANCE TO THEIR OPERATIONS.

11. TO COUNTER THESE PROBABLE LINES OF ARGUMENT, IN ADDITION TO ESTIMATES ON DAMAGES, WE BELIEVE IT USEFUL TO PROVIDE DATA ON THE OPPORTUNITY COSTS ASSOCIATED WITH THE LACK OF PATENT PROTECTION. WHILE ADMITTEDLY DIFFICULT AND INEXACT, PERHAPS OUR BEST CHANCE FOR A GOB RE-EXAMINATION OF ITS POSITION ON THE PATENT ISSUE IS TO CONVINCING THE GOB THAT THE FOREGONE INVESTMENTS, JOBS AND EXPORTS ARE SIZEABLE. WE WOULD ALSO RECOMMEND THE U.S., IN THE CONTEXT OF OUR GLOBAL CONCERNS ABOUT INADEQUATE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS, CHALLENGE THE LACK OF PATENT PROTECTION FOR PHARMACEUTICALS/FINE CHEMICALS IN MULTILATERAL FORA SUCH AS GATT AND WIPO. WHILE ADMITTEDLY A LONG-TERM EFFORT, THIS MULTILATERAL PRESSURE WILL ENCOURAGE OTHER COUNTRIES TO EXAMINE THE GOB'S POLICIES.

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INADEQUATE PROFITS

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USTR FOR JON ROSENBAUM AND CHRISTINA LUND

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

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12. THE GOB HAS STRESSED THAT A REQUEST FOR SPECIAL TREATMENT ON PHARMACEUTICAL PRICES IS OUT OF THE QUESTION. SUCH TREATMENT WOULD VIOLATE THE GENERAL PRICE FREEZE INTRODUCED ON FEBRUARY 28 AS PART OF BRAZIL'S ECONOMIC STABILIZATION PROGRAM. THE PRICE FREEZE WILL NOT, HOWEVER, LAST FOREVER. PRICE ADJUSTMENTS WILL LIKELY BE A KEY PART OF THE MODIFICATIONS TO BE INTRODUCED AFTER THE NOVEMBER 15 ELECTIONS. NEVERTHELESS, WE SHOULD ADDRESS KEY PRICING POLICY ISSUES, AS WELL AS PRESS THE GOB TO PROVIDE

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PRICE RELIEF IN THE SHORT TERM:

-- FINANCE MINISTER FUNARO HAS SAID THAT HE WOULD EXAMINE ALLEVIATING THE INDUSTRY'S PROBLEMS BY REDUCING OR EXEMPTING THE FEDERAL EXCISE TAX (IPI) AND THE FINANCIAL OPERATIONS TAX (IOF). THE GOB HAS GRANTED TAX EXEMPTIONS IN OTHER SECTORS AS A MEANS OF REDRESSING THE COMPLAINTS OF INDUSTRIES CAUGHT WITH LOW PRICES (E.G., THE MAKERS OF GLASS BOTTLES AND VIALS FOR MEDICINES).

-- REDUCED TARIFF LEVELS ON RAW MATERIAL INPUTS WOULD ALSO ALLEVIATE THE SECTOR'S PROBLEMS. IRONICALLY, IOF OR DUTY REDUCTIONS WOULD BENEFIT COMPANIES THAT ARE MOST IMPORT DEPENDENT. (FYI. WITH INCREASED CONSUMER DEMAND, REDUCED FINANCIAL COSTS AND A STRONGER CRUZADO, SOME AMERICAN PHARMACEUTICAL FIRMS ARE MAKING SOME OF THE BEST DOLLAR PROFITS IN YEARS. ON THE OTHER HAND, EUROPEAN MNCS ARE BEING SQUEEZED BY THEIR INCREASINGLY EXPENSIVE NON-DOLLAR DENOMINATED IMPORTS. END FYI.)

-- IN THE MEDIUM-TERM (E.G., AS PART OF CRUZADO PLAN PRICE MODIFICATIONS), WE SHOULD PRESS FOR PHARMACEUTICAL PRICE ADJUSTMENTS TO BE AMONG THE LARGEST AND THE FIRST PRICE CHANGES. THE LEGITIMACY OF THE INDUSTRY'S 28 PERCENT INCREASE SCHEDULED FOR MARCH 1, WHICH WAS CANCELLED BY THE CRUZADO PLAN PRICE FREEZE, IS WIDELY CONCEDED.

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- -- WE MIGHT ALSO CONSIDER PUTTING FORWARD IDEAS ON HOW A POST-CRUZADO PRICING SYSTEM MIGHT WORK. FOR EXAMPLE, WOULD PHARMACEUTICAL COMPANIES AND THE GOB
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CONSIDER THE PARTIAL DECONTROL OF PRICES FOR MEDICINES DESTINED LARGELY FOR MIDDLE-CLASS CONSUMPTION IN EXCHANGE FOR A COMMITMENT TO PROVIDE ESSENTIAL MEDICINES FOR LOW-INCOME GROUPS AT COST? THIS IDEA WAS EXPLORED BY THE COMPANIES WITH THE GOB SEVERAL YEARS AGO.

- -- A TRANSPARENT AND REVISED PRICING SYSTEM SHOULD BE AT THE TOP OF OUR PRIORITIES. WE NEED TO HAVE A CLEAR COMMITMENT FROM THE GOB THAT THE POST-CRUZADO PRICING MECHANISM WILL BE TRANSPARENT AND THAT ADEQUATE PROFITS ARE NECESSARY TO ENSURE THAT THE BRAZILIAN CONSUMER WILL HAVE ACCESS TO THE NEEDED MEDICINES. INADEQUATE PRICES MEAN INADEQUATE PROFITS, WHICH DAMAGE NCCS EVEN MORE THAN THE MNCS AND, THUS, BRAZIL'S GOAL OF DEVELOPING A STRONG NATIONAL INDUSTRY.

- -- WE SHOULD SEEK COMMENTS ON A NEW PRICING POLICY HAVING AS ITS OBJECTIVE SIMILAR PRICES FOR SIMILAR PRODUCTS. THE PRESENT COST STRUCTURE SUBMISSION PROCESS CREATES DISINCENTIVES FOR IMPROVING PRODUCTIVITY AND RESULTS IN WIDELY VARYING PRICES FOR IDENTICAL (OR VIRTUALLY IDENTICAL) DRUGS. (SEE PARA 2, REF E.)

13. THE GOB MAY ADMIT THAT PRICE DISCRIMINATION WAS FREQUENT IN THE PAST, BUT ARGUE THAT THE SARNEY GOVERNMENT HAS VIRTUALLY ELIMINATED THESE PRACTICES. FAR FROM RENDERING PAST DISCRIMINATION IRRELEVANT, THE CURRENT FREEZE HAS LOCKED IN THE EFFECTS OF PAST DISCRIMINATORY PRICING POLICIES. THEREFORE, IT IS APPROPRIATE TO PRESS THE GOB TO TAKE PAST DISCRIMINATION

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INTO ACCOUNT WHEN PRICES ARE ADJUSTED. IT WOULD ALSO
BE USEFUL TO DOCUMENT THE COSTS OF INADEQUATE PROFITS
IN TERMS OF PRODUCT LINES WITHDRAWN FROM THE MARKET,
COMPANIES THAT HAVE LEFT BRAZIL OVER THE PAST SEVERAL
YEARS, AND LOST JOBS. WE MUST BE ABLE TO DOCUMENT
PRICE DISCRIMINATION AGAINST U.S. MNCs AND TO

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DEMONSTRATE THAT THIS DISCRIMINATION WAS NOT AN ISOLATED OR CASUAL PHENOMENON IN A COMPLEX SYSTEM.

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REGISTRATION PARALYSIS

14. THE REGISTRATION OF NEW MEDICINES, AND EVEN ROUTINE OR MINOR CHANGES, HAS SLOWED CONSIDERABLY SINCE THE BEGINNING OF THE SARNEY ADMINISTRATION. ACCORDING TO DIMED (GOB DRUG REGISTRATION ENTITY ROUGHLY EQUIVALENT TO THE FDA) FIGURES, DURING THE FIRST 9 MONTHS OF 1986, 4 NEW PRODUCTS WERE REGISTERED AND 160 ROUTINE PROCESSES WERE APPROVED. THESE APPROVAL FIGURES PALE WHEN COMPARED TO THE 3,600 OUTSTANDING PROCESSES -- RANGING FROM NEW PRESENTATIONS, NEW STRENGTHS, NEW DOSAGE FORMULAS AND IMPORT/EXPORT REQUESTS -- THAT ARE ON DIMED'S DOCKET. ON TOP OF THIS STAGGERING BACKLOG, DIMED RECEIVES ABOUT 20 NEW APPLICATIONS PER DAY. TO HANDLE THIS WORKLOAD, DIMED HAS ONLY SIX DOCTORS. DIMED'S DIRECTOR, SUELI ROZENFELD, HAS PUBLICLY ADMITTED THAT DIMED NEEDS TO INCREASE ITS STAFF "BY AT LEAST THREE TIMES". DIMED'S DIRECTOR ADMITS THAT THE REGISTRATION PROCESS IS SLOWER THAN IN THE PAST BUT ATTRIBUTES THE SLOWDOWN TO STRICTER REQUIREMENTS ON TECHNICAL DOCUMENTATION. INCREASED STRICTNESS ASIDE, IT IS ALSO TRUE THAT DIMED'S CURRENT ADMINISTRATION BELIEVES THAT THERE ARE TOO MANY PRODUCTS ON THE MARKET TODAY. WE SHOULD PRESS THE GOB TO INCREASE STAFF LEVELS ADEQUATE TO COMPLY WITH ITS MANDATED FUNCTIONS.

15. THE GOB IS LIKELY TO ARGUE THAT REGISTRATION OF NEW PRODUCTS TAKES NO LONGER IN BRAZIL THAN IN THE U.S. THE CHARGE THAT NCCS GET FASTER TREATMENT AT DIMED THAN MNCS CAN BE COUNTERED BY THE ARGUMENT THAT IT IS THE MNCS WHICH INTRODUCE NEW TO MARKET

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PRODUCTS WHICH MUST UNDERGO A CLOSER SCRUTINY THAN
SIMPLE VARIATIONS ON KNOWN FORMULAS.

16. EMBASSY ONCE AGAIN REQUESTS WASHINGTON AGENCIES'
COMMENTS ON WHETHER AND, IF SO, HOW THE FDA MIGHT
COOPERATE WITH DIMED TO ASSIST IN IMPROVING EFFICIENCY
AND TRANSPARENCY IN THE REGISTRATION PROCESS (REF C).
A COOPERATIVE APPROACH TO DIMED'S PROBLEMS COULD TURN
THIS PART OF THE CONSULTATIVE PROCESS IN A POSITIVE
DIRECTION.

GOB PROGRAMS, PLANS AND THE ROLE OF FOREIGN INVESTMENT
IN THE PHARMACEUTICALS/FINE CHEMICALS SECTOR

17. THE GOB'S INTENTIONS IN THE PHARMACEUTICAL/FINE
CHEMICAL SECTOR REMAIN UNDEFINED. WHILE IT IS CLEAR
THAT THE CONCEPT OF MARKET RESERVE IS SUPPORTED AT
THE WORKING LEVEL IN SEVERAL KEY MINISTRIES, AND IN
SOME SEGMENTS OF CONGRESS, WE DO NOT BELIEVE THE GOB
WILL OPENLY ADOPT A MARKET RESERVE POLICY. IT IS
CLEAR THAT MNCS CAN EXPECT LESS THAN NATIONAL
TREATMENT FROM THE GOB IF THEIR EXPANSION PLANS
CONFLICT WITH PLANS OF NATIONAL GROUPS. THE
EXPERIENCES OF RHODIA AND CORNING ARE ILLUSTRATIVE
OF HOW THE GOB CAN USE SEEMINGLY NEUTRAL PROGRAMS,
SUCH AS PORTARIA IV, TO BENEFIT NCCS. WE MUST MAKE
IT CLEAR TO THE GOB THAT NOT ADOPTING MARKET RESERVE
FOR THE PHARMACEUTICAL/FINE CHEMICALS SECTOR IS NOT
ENOUGH. FURTHER RESTRICTIONS AND A CONSOLIDATION
OF NON-NATIONAL TREATMENT WOULD BE SUITABLE GROUNDS

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 TO SECSTATE WASHDC IMMEDIATE 0798
 INFO USDOC WASHDC IMMEDIATE
 AMCONSUL RIO DE JANEIRO
 AMCONSUL SAO PAULO
 AMCONSUL PORTO ALEGRE POUCH
 AMCONSUL RECIFE POUCH
 AMCONSUL SALVADOR DA BAHIA POUCH

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USTR FOR JON ROSENBAUM AND CHRISTINA LUND

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

- 4300/IEP/WH/DAS/ANN HUGHES

E.O. 12356: DECL: OADR
 TAGS: ETRD, EINV, PREL
 SUBJECT: PHARMACEUTICAL CONSULTATIONS: SOME THOUGHTS

TO JUDGE THE BRAZILIAN POLICIES AS UNFAIR, WARRANTING
 A STIFF REACTION FROM THE USG. WE CAN EXPECT THAT
 THE GOB WILL PRESS MNCS TO PRODUCE MORE RAW PRODUCTS
 IN BRAZIL.

18. THE GOB WILL ATTEMPT TO BE AS EVASIVE AS
 POSSIBLE ABOUT FUTURE PLANS. THE GOB MAY ARGUE THAT
 THE MNC SHARE OF THIS MARKET HAS INCREASED OVER TIME
 AND THAT THIS IS EVIDENCE THAT THE MNCS HAVE LEARNED
 HOW TO ADJUST TO THE BRAZILIAN REALITY. IT IS

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IMPORTANT TO POINT OUT HOW THE UNCERTAINTY IN THE SECTOR, AND OTHER SECTORS, IMPAIRS NEEDED INVESTMENT AND TECHNOLOGY FLOWS.

19. THE INDUSTRIAL DEVELOPMENT COUNCIL (CDI), WHICH MUST APPROVE EXPANSIONS AND NEW INVESTMENTS IN THE PHARMACEUTICAL/FINE CHEMICALS AREA, MUST BE MADE ADMINISTRATIVELY RESPONSIBLE. CRITERIA FOR DECISION-MAKING MUST BE WRITTEN DOWN, FIXED DEADLINES FOR DECISIONS ARE NECESSARY AND A CLEAR AND EFFECTIVE APPEALS PROCEDURE IS NEEDED.

 KEEPING THE PRESSURE ON

20. THE NOVEMBER 20 CONSULTATIONS ARE NOT LIKELY TO PRODUCE SUBSTANTIVE MOVEMENT ON THE ISSUES. HOWEVER, THE MEETING IS AN IMPORTANT FIRST STEP IN A LARGER AND LONGER PROCESS. OUR IMMEDIATE GOALS SHOULD INCLUDE:

- -- SETTING ANOTHER MEETING TO OBTAIN GOB RESPONSES TO OUR UNANSWERED QUESTIONS. WE COULD FOCUS THE GOB RESPONSE BY TABLING A NON-PAPER DETAILING U.S. CONCERNS AT THE CONCLUSION OF THE CONSULTATIONS.

- -- OBTAINING AN AGREED MINUTE.

21. OVER THE LONGER RUN, THE NOVEMBER 20 CONSULTATIONS MAY ENCOURAGE OTHER GOVERNMENTS TO TAKE A MORE ACTIVE ROLE IN PRESSING THE GOB TO CLARIFY ITS POLICIES IN

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THIS AREA. AT THE OCTOBER WEST GERMAN-BRAZILIAN BILATERAL CONSULTATIONS, THE FRG GOVERNMENT AND GERMAN BUSINESSMEN RAISED PHARMACEUTICAL/FINE CHEMICALS ISSUES AT GREAT LENGTH (SEPTEL). THESE CONSULTATIONS HIGHLIGHTED THE FACT THAT PHARMACEUTICAL/FINE CHEMICALS ISSUES ARE NOT SOLELY AN AMERICAN CONCERN. WE INTEND, THROUGH BRIEFINGS ON THE RESULTS OF OUR CONSULTATIONS, TO ENCOURAGE OTHER MAJOR INVESTORS

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(I.E., U.K., HOLLAND, SWITZERLAND AND FRANCE) TO MAKE THEIR CONCERNS KNOWN TO THE GOB.

22. ADDITIONALLY, AS PART OF A LONGER TERM PROCESS, WE RECOMMEND THAT EFFORTS BEGIN IMMEDIATELY IN THE GATT TO CHALLENGE BRAZIL'S LAW OF SIMILARS (REF D). IF THE LAW OF SIMILARS IS ALLOWED TO STAND UNCHALLENGED, WE WILL REMAIN ON THE DEFENSIVE IN COMBATTING FURTHER RESTRICTIONS, NOT ONLY IN THE PHARMACEUTICAL/FINE CHEMICALS SECTORS, BUT IN OTHER SECTORS WHICH DRAW SIGNIFICANT INVESTMENTS FROM POWERFUL NATIONAL ECONOMIC GROUPS. ALSO, WE SHOULD UNDERTAKE TO STRENGTHEN THE SCOPE AND LENGTH OF PATENT PROTECTION IN WIPO AND GATT. SHLAUDEMAM

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