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**INDUSTRY AND THE SEXUALLY TRANSMITTED DISEASES
DIAGNOSTICS INITIATIVE:
AN OPPORTUNITY FOR SYNERGISM IN
PRODUCT DEVELOPMENT AND MARKETING**



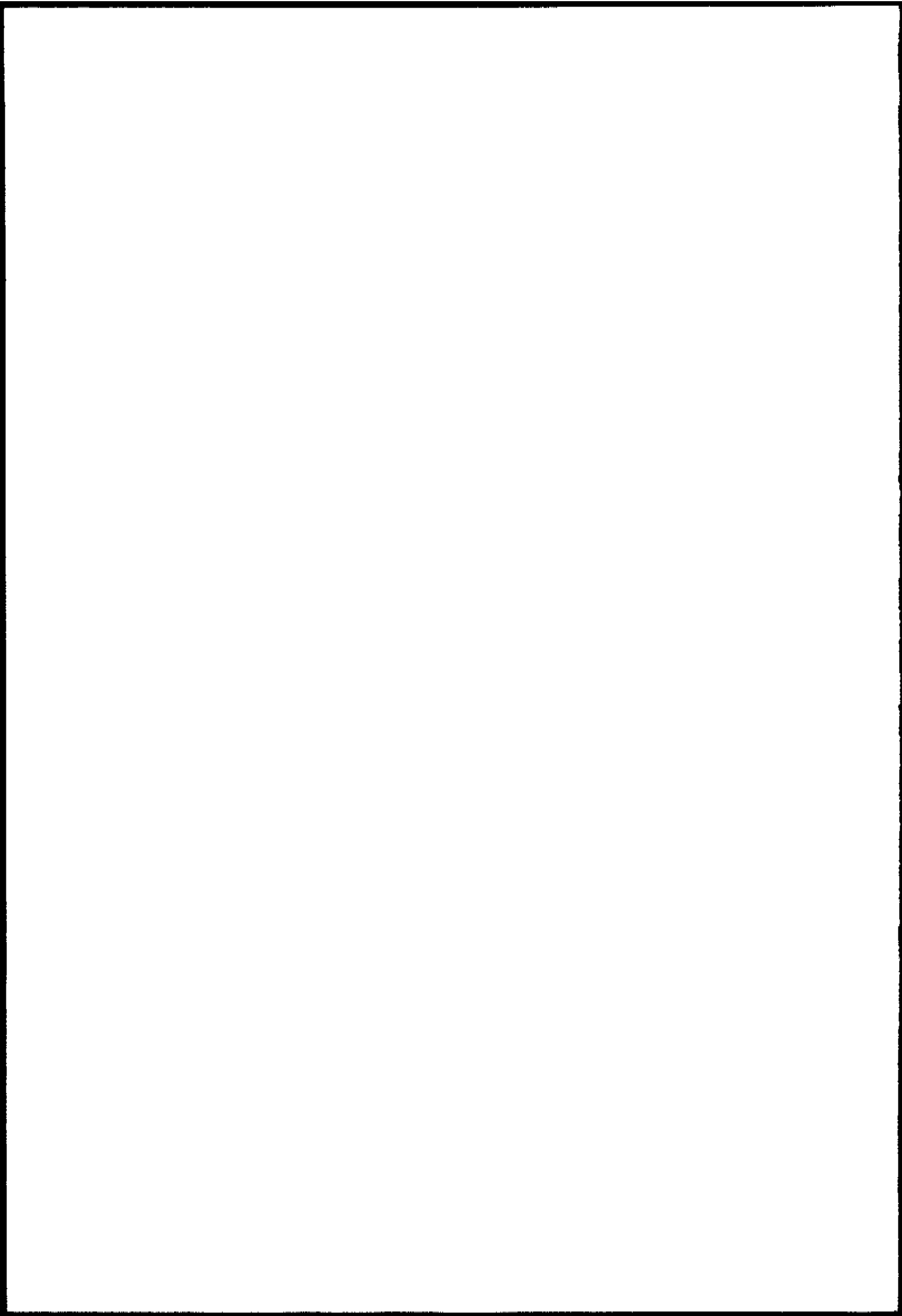
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Global Programme on AIDS
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This document has been developed by the Sexually Transmitted Diseases Diagnostics Initiative (SDI) and LABAT-ANDERSON Incorporated based on needs identified by 31 diagnostics manufacturers who attended the Information Meeting on the Research Priorities of the Sexually Transmitted Diseases Diagnostics Initiative at WHO Headquarters in Geneva, Switzerland on 22-23 September 1994

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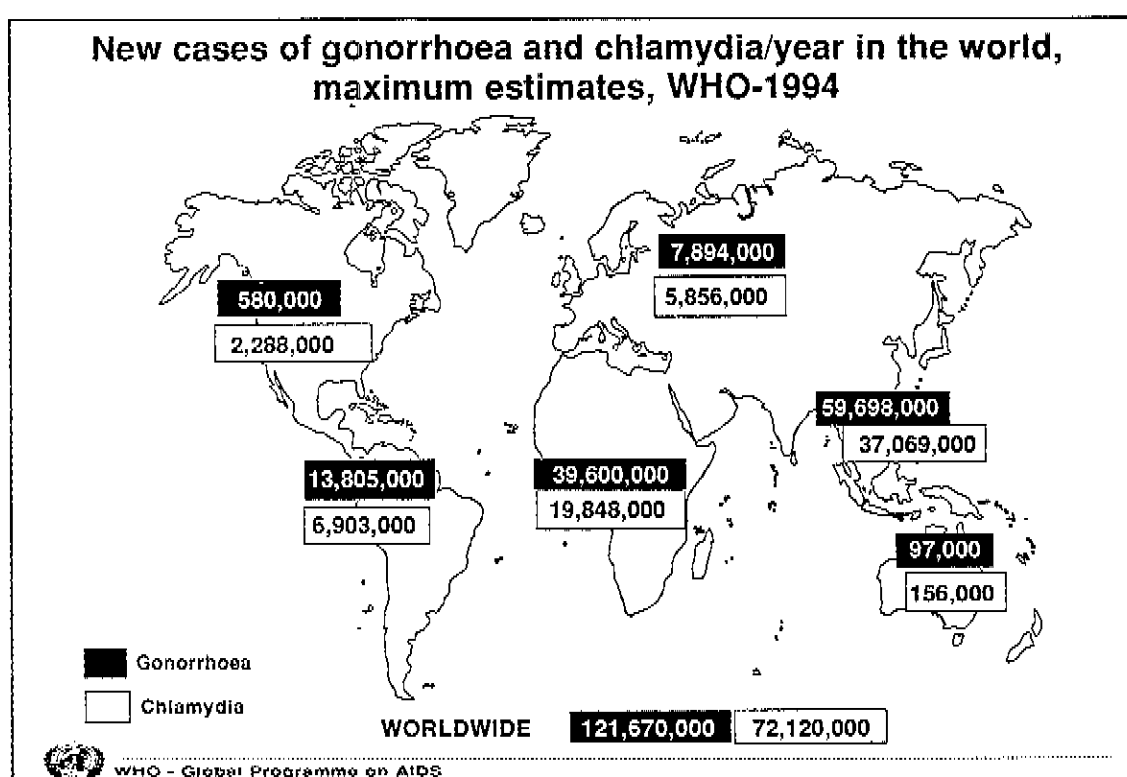
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I. INTRODUCTION

A. MAGNITUDE OF SEXUALLY TRANSMITTED DISEASES WORLDWIDE

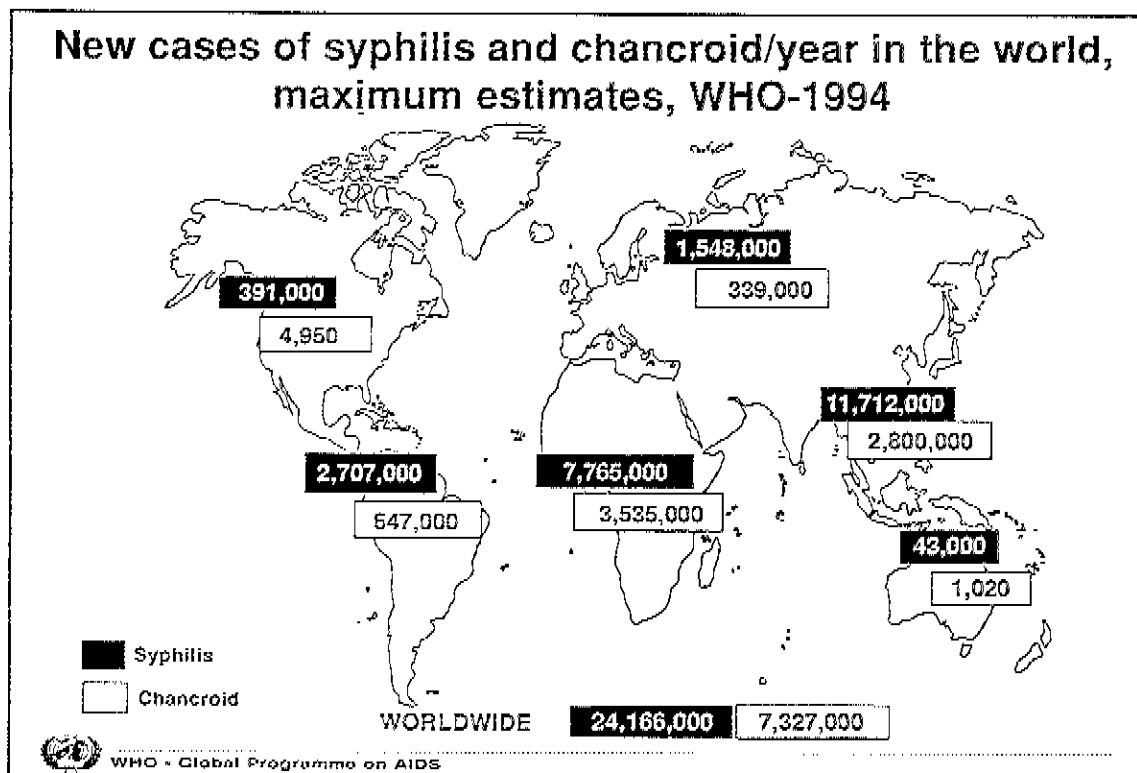
Sexually transmitted diseases (STD) collectively rank second among diseases for which intervention is possible among women 15-44 years of age worldwide; and four curable STD - gonorrhoea, chlamydial infection, syphilis and chancroid - rank among the top 25 causes of healthy days of life lost in sub-Saharan Africa. The global distribution of these four diseases is shown in the following maps which clearly demonstrate the greater importance of STD in developing countries where 209 million (93%) of the estimated 225 million new cases occur each year.



Gonorrhoea and chlamydial infections, asymptomatic in 50-80% of women, are the most common infectious causes of pelvic inflammatory disease, ectopic pregnancy and impaired fertility in women. Complications of these two infections in pregnancy include spontaneous abortion, stillbirth, chorioamnionitis, premature rupture of membranes, pre-term delivery and post-partum endometritis. Complications in neonates include gonococcal conjunctivitis, which may lead to blindness; and chlamydial pneumonia which may lead to chronic neonatal respiratory disease.

The young female population in developing countries shares a disproportionate burden of STD and its sequelae. Because young women are an essential component of socioeconomic progression, the successful diagnosis and treatment of sexually transmitted diseases is of great

importance as developing countries utilize healthcare expenditures in an efficient and productive manner to maximize domestic fortitude.



The ulcerative STD, including syphilis and chancroid; and other STD which cause inflammation, such as gonorrhoea and chlamydial infection, facilitate transmission of HIV in both men and women. Early diagnosis and treatment of STD has thus become one of the two WHO-recommended strategies for prevention of sexual transmission of HIV.

**GONORRHOEA, CHLAMYDIAL INFECTION, CHANCROID AND SYPHILIS:
MOST IMPORTANT AND CURABLE STD**

ESTIMATE: 225 MILLION NEW CASES OF THESE FOUR STD ANNUALLY

**TWO-THIRDS OF ALL STD OCCUR IN PERSONS UNDER 25 YEARS:
FEMALES SHARE UNEQUAL BURDEN**

**GONORRHOEA AND CHLAMYDIAL INFECTIONS:
50-80% ASYMPTOMATIC**

**HIV TRANSMISSION IS FACILITATED BY
ULCERATIVE STD AND THOSE WHICH CAUSE INFLAMMATION**

**EARLY STD DIAGNOSIS AND TREATMENT: ONE OF TWO
MAJOR STRATEGIES FOR HIV PREVENTION**

B. The Global Response

Existing diagnostic tests for STD are highly sensitive and specific, but because of lack of equipment and/or their cost, use of diagnostic tests is not possible at first level health facilities in many developing countries. Because effective control of STD requires diagnosis and treatment at the point of first encounter (most often at first level health facilities), with minimal delay between diagnosis and treatment, WHO recommends syndromic management of STD. Syndromic management requires the identification of persons with collections of signs and symptoms of STD — STD syndromes — and the provision of treatment for all the sexually transmitted infections commonly associated with that syndrome in that particular geographic setting. Because the syndromic approach cannot differentiate specific infections within syndromes, over-treatment occurs with relatively expensive drugs. In addition to adding to the financial burden of health care, such over-treatment may contribute to the development of antibiotic resistant strains. Since the majority of gonorrhoeal and chlamydial infection in women are asymptomatic they cannot be diagnosed by a syndromic approach. The majority of these infection will therefore not be treated, resulting in sequelae and continued STD and HIV transmission.

LIMITATIONS TO SYNDROMIC CASE MANAGEMENT:

- INABILITY TO DIFFERENTIATE SPECIFIC INFECTIONS WITHIN SYNDROMES WHICH INEVITABLY RESULTS IN OVER-TREATMENT WITH RELATIVELY EXPENSIVE AND OFTEN INAPPROPRIATE ANTIBIOTICS, AND MAY CONTRIBUTE TO THE DEVELOPMENT OF ANTIBIOTIC-RESISTANT STRAINS; AND
- INABILITY TO IDENTIFY THOSE WHO ARE ASYMPTOMATICALLY INFECTED.

A diagnostic test with the following characteristics would overcome these limitations and permit more cost effective STD management:

DIAGNOSTIC TEST REQUIREMENTS FOR USE AT THE FIRST LEVEL

- REQUIRE MINIMAL OR NO TRAINING FOR USE
- DO NOT REQUIRE LABORATORY EQUIPMENT
- ARE INEXPENSIVE
- ARE STABLE IN ADVERSE CLIMATES WITH LONG SHELF LIFE
- ARE RAPID TO APPLY AND INTERPRET
- REQUIRE CLINICAL SPECIMENS WHICH CAN BE COLLECTED AT THE LEVEL OF FIRST CONTACT

The Sexually Transmitted Diseases Diagnostics Initiative (SDI) has been established in response to the need for laboratory testing to diagnose asymptomatic STD, and to differentiate infections among those with symptoms of STD. It is a voluntary group of agencies, laboratory specialists and public health experts which strives to facilitate implementation of effective control programmes for sexually transmitted diseases in all populations - but most particularly among women and children, who suffer the greatest sequelae - and to decrease the potential for the transmission of the human immunodeficiency virus (HIV). To accomplish this mission, the SDI promotes:

- The development, evaluation and application of STD diagnostic tests for use at first level health facilities in developing countries; and
- The establishment of mechanisms to ensure availability of these tests worldwide.

The SDI, its participating centres, secretariat and network of scientists and public health experts, can assist industry by :

- identifying and classifying the demand side of the market for STD diagnostics in both industrialized and developing countries; and
- helping overcome product development and market penetration constraints.

Industry collaboration with the SDI will facilitate re-evaluation of research and development goals and marketing cost projections for STD diagnostics tests. Combined with an increased level of social responsibility, and enhanced by the importance of STD diagnosis and treatment in AIDS prevention, there is a synergistic environment for SDI, Industry, donors and governments to join forces, maximize resources, and significantly contribute to the control of STD.

SYNERGISM: INDUSTRY BENEFITS FROM COLLABORATION WITH THE SDI

- **VALID MARKET PROJECTIONS**
- **REDUCED RISK IN PRODUCT DEVELOPMENT/MARKET PENETRATION**
- **DEMONSTRATION OF SOCIAL RESPONSIBILITY**

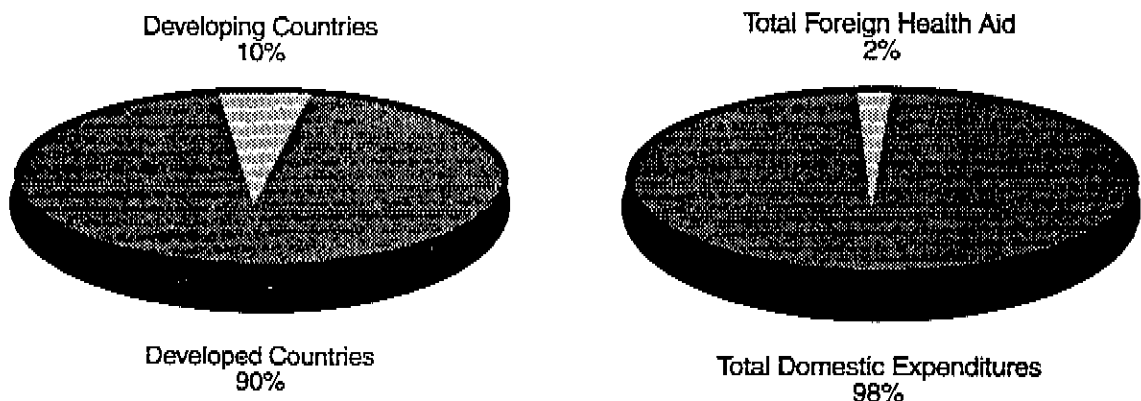
II. MARKET DIMENSIONS FOR STD DIAGNOSTIC TESTS

A. Global Healthcare Spending

In 1990, the global budget for healthcare exceeded 1.7 trillion U.S. dollars or 8% of total world product. Despite representing less than one quarter of the world population, industrialized countries accounted for approximately 90% of this total healthcare expenditure. Even so, developing countries spent a substantial total of \$170 billion on health care in 1990. Of this total disbursement, \$166.7 billion (98%) was funded from national health budgets and only \$3.3 billion (2%) was funded by aid from industrialized countries.

World Health Care Expenditures-1990

**Source of Health Expenditures-1990
(DEVELOPING COUNTRIES)**



Source: World Development Report

Of the global healthcare budget, public spending accounted for \$1.2 trillion dollars (70%) and the private sector accounted for the remaining \$500 billion (30%) of total global health expenditures in 1990. The portion of healthcare financed by public funding varies from country to country. For example, in 1990 the public sector in the United Kingdom was responsible for 85% of all healthcare expenditures whereas in India, only 20% of healthcare was purchased by the public sector.

HEALTH CARE EXPENDITURES

GLOBAL HEALTHCARE EXPENDITURE IN 1990 \$1.7 TRILLION

- THROUGH PUBLIC SECTOR \$1.2 TRILLION

- THROUGH PRIVATE SECTOR \$500 BILLION

- IN DEVELOPING COUNTRIES \$170 BILLION

- DEVELOPING COUNTRY FOREIGN AID \$3.3 BILLION

Source: World Development Report

B. Quantitative Indicators of Demand: Country Scenarios

Sixteen countries, with diverse and viable markets for diagnostics tests, were selected by SDI and country scenarios were developed on which to base global estimates of STD diagnostic test needs. Healthcare spending per capita among these sixteen countries is shown in the table below, based on information contained in the 1993 World Development Report. The seven industrialized countries spent an average of \$1,500 per person while the nine developing countries spent an average of \$41 per capita on well over 3 billion people. Total healthcare expenditures varied greatly among countries. The highest spending per capita was in the United States at \$2,763 while the lowest was in Indonesia, estimated at only \$12.

Health Care Spending Per Capita

| | Per Capita Spending | Total Spending (\$mm) |
|--------------|---------------------|-----------------------|
| Thailand | \$158 | \$4,061 |
| India | \$21 | \$17,000 |
| Indonesia | \$12 | \$2,148 |
| Zimbabwe | \$42 | \$416 |
| South Africa | \$158 | \$5,671 |
| Brazil | \$132 | \$19,871 |
| Honduras | \$26 | \$134 |
| Argentina | \$138 | \$4,441 |
| Mexico | \$59 | \$7,648 |
| U.S.A. | \$2,763 | \$690,667 |
| Canada | \$1,945 | \$51,594 |
| U.K. | \$1,039 | \$59,623 |
| France | \$1,869 | \$105,467 |
| Germany | \$1,511 | \$120,072 |
| Japan | \$1,538 | \$189,930 |
| Australia | \$1,331 | \$22,736 |

Source: World Development Report

STD diagnostic test needs in each of these sixteen countries were estimated for use in 1) differentiating symptomatic gonococcal and chlamydial infections, and symptomatic syphilis and chancroid infections; and 2) case finding by screening of women attending antenatal clinics for gonorrhoea, chlamydial infection and syphilis. Estimates for differentiating symptomatic infections were based on the incidence of symptomatic disease, and estimates for case finding based on the birth rate and health facility utilization rates in each country. The total test needs in these sixteen countries for one year is approximately 124 million as shown in the tables below, with approximately 20 million (16%) tests needed in the seven industrialized countries compared to 104 million (84%) needed in the nine developing countries.

STD Test Demand by Selected Country

| | Chlamydia & Gonorrhoea (000) | Syphilis & Chancroid (000) |
|--------------|------------------------------|----------------------------|
| Thailand | 2,007 | 1,417 |
| India | 41,257 | 29,991 |
| Indonesia | 4,250 | 3,935 |
| Zimbabwe | 504 | 424 |
| South Africa | 1,900 | 1,474 |
| Brazil | 5,807 | 4,273 |
| Honduras | 206 | 181 |
| Argentina | 1,136 | 610 |
| Mexico | 2,222 | 1,932 |
| U.S.A. | 5,101 | 4,752 |
| Canada | 516 | 435 |
| U.K. | 982 | 874 |
| France | 882 | 839 |
| Germany | 1,069 | 1,014 |
| Japan | 1,713 | 1,516 |
| Australia | 358 | 323 |
| Total | 69,910 | 63,990 |

Source: SDI

By projecting¹ test needs for the sixteen highlighted countries to the world population of 5.267 billion inhabitants, it is estimated that at least **326 million STD tests** would be needed throughout the world **during the current year** for differentiating symptomatic gonorrhoea and chlamydial infection, syphilis and chancroid; and for screening women attending antenatal clinics for gonorrhoea, chlamydial infection and syphilis.

Of this global need, 5% or 16 million tests would be required by industrialized countries and the remaining 95% or 310 million tests, representing significant market potential, and the majority of need, would be required by developing countries.

| MARKET DIMENSIONS: STD DIAGNOSTIC TEST NEEDS | | |
|--|----------------------|--|
| ■ 326 MILLION STD TESTS NEEDED WORLDWIDE ANNUALLY FOR: | | |
| GONORRHOEA | CHLAMYDIAL INFECTION | |
| SYPHILIS | CHANCROID | |
| ■ 16 MILLION TESTS NEEDED BY DEVELOPED COUNTRIES | | |
| ■ 310 MILLION TESTS NEEDED BY DEVELOPING COUNTRIES | | |
| ■ DEVELOPING COUNTRIES REPRESENT THE LARGEST POTENTIAL FOR THE MARKETING OF STD DIAGNOSTIC TESTS | | |

The table below illustrates demand by private and public sector in the sixteen selected countries. Extrapolated to the 326 million STD tests needed worldwide by both industrialized and developing countries, approximately 212 million tests could potentially be provided

¹ total tests needed = (total test requirements in 16 selected countries) divided by (percentage of world population these 16 countries represent)

through the private sector compared to the remaining 114 million tests through the public sector.

STD Test Demand by Private & Public Sector in Selected Countries

| | Chlamydia & Gonorrhoea | | Syphilis & Chancroid (000) | |
|--------------|------------------------|---------------|----------------------------|---------------|
| | Public | Private | Public | Private |
| Thailand | 442 | 1565 | 312 | 1106 |
| India | 8939 | 32318 | 6498 | 23493 |
| Indonesia | 1488 | 2763 | 1377 | 2558 |
| Zimbabwe | 260 | 244 | 219 | 205 |
| South Africa | 1026 | 314 | 842 | 632 |
| Brazil | 3871 | 1936 | 2849 | 1427 |
| Honduras | 133 | 78 | 117 | 64 |
| Argentina | 676 | 460 | 363 | 247 |
| Mexico | 1111 | 1111 | 966 | 966 |
| U.S.A. | 2267 | 2834 | 2112 | 5640 |
| Canada | 331 | 135 | 322 | 113 |
| U.K. | 837 | 145 | 745 | 129 |
| France | 654 | 228 | 622 | 217 |
| Germany | 775 | 294 | 735 | 279 |
| Japan | 1285 | 428 | 1137 | 379 |
| Australia | 251 | 107 | 227 | 96 |
| Total | 24,456 | 45,454 | 19,442 | 34,548 |

Source: SDI

C. Economic Efficiency of Increased STD Testing

Simple, rapid and inexpensive diagnostic tests for gonorrhoea, chlamydial infection, syphilis and chancroid would permit rationalization of the use of antibiotics, resulting in an increase in **appropriate prescribing** and a decrease in cost per treatment. As a result of this cost saving, greater quantities of pharmaceuticals could be procured either for treating STD or for treating other diseases such as diarrhoea, respiratory infections and AIDS associated infections such as tuberculosis.

Rapid simple diagnostic tests for gonorrhoea, chlamydial infection and syphilis would permit **screening of asymptomatic populations** at risk of STD, thus facilitating case finding and treatment. The preceding section indicates the magnitude of one population which could be targeted for screening: women attending antenatal clinics. Finding and treating asymptomatic infections among these women will decrease STD transmission, thus decreasing antibiotic needs for STD, with additional cost savings that can be applied to treatment of other diseases.

The **absolute expenditure on health care** in both industrialized and developing country markets is set by economic conditions and social and political policy, with allocation of financial resources fungible among competing needs and desires. None-the-less, the end result of use of STD diagnostic tests meeting the SDI objectives would be an increase in comprehensive disease management efficiencies in all countries where the test was made available. This increase in efficiency could be expected to encourage greater expenditures on other diseases as STD syndromic management and case finding become more effective and affordable. The increase in sales of tests and drugs for STD syndromic management and case finding will thus provide positive economic and social returns in developing and industrialized countries.

International bilateral donors to developing countries and the World Bank have identified early diagnosis and treatment of STD as a major funding priority in order to prevent STD sequelae and decrease the rate of HIV transmission. As a result they are currently financing the purchase of **antibiotics to treat STD** in over 25 developing countries through bilateral arrangements. Were an easy-to-perform STD diagnostic test available it would be financed by these donors and the World Bank as a means of increasing "value for money".

III. PRODUCT DEVELOPMENT/MARKET PENETRATION ISSUES

COUNTRIES WITH THE GREATEST NEED FOR STD DIAGNOSTIC TESTING SPEND LESS PER CAPITA ON HEALTH CARE, ANALYSIS OF THESE COUNTRIES IN VIEW OF TEST NEEDS AND BENEFITS FROM COLLABORATION WITH SDI CAN PROVIDE AN OPTIMISTIC MARKETING PERSPECTIVE.

A. POSSIBLE CONSTRAINTS TO PRODUCT DEVELOPMENT AND MARKET PENETRATION

Industry may not perceive a potentially profitable private sector market for a simple and rapid STD diagnostics test specifically designed for developing country use. This is suggested by the somewhat limited research and development for such tests at present. Some of the issues which could discourage private sector development activities are discussed below. Collaboration between Industry and the SDI can reduce and even eliminate some of these constraints.

Product Development Issues:

| | |
|--------------------------------------|--|
| Funding for research and development | Development of products which are considered high risk, that is, products which may not have the potential for high economic return because there is not a large industrialized country market, may not receive budget support or even small amounts of seed funding for an additional scientist, technician, or equipment and reagents which could demonstrate feasibility. |
| Reference Specimen Access | Company access to specimen panels which have been standardized in reference laboratories and are geographically representative may be costly and/or not possible, adding considerably to research and development costs. |
| Research Site Access | Company access to developing country sites with high incidence and prevalence of STD, ensuring less costly validation studies and field testing with a result of decreasing time and cost to market entry, may likewise be costly and/or limited. |
| Liability Concerns | Product liability concerns, in view of the high sensitivity and specificity of existing tests for the diagnosis of STD (eg culture and/or Polymerase/Ligase Chain Reaction technologies), result in the need for high cost liability coverage, thus increasing research and development/production costs. |

| | |
|--|--|
| Regulatory Requirement | Cumbersome regulatory requirements, demanding long and expensive validation studies, and the costly approval process which results may be a primary deterrent to the decision to develop new products. |
| Patent Protection/ Proprietary Rights | Technology considered necessary for rapid and simple tests which is still on patent or considered proprietary, and for which development costs have not yet been recouped, may restrict its availability to companies interested in using this technology for development of new products. |

Marketing Issues

| | |
|---|---|
| Import Taxation | High import tariffs in developing countries may discourage marketing, the potential for profit, and therefore research and development on products targeted to the healthcare needs of those countries. |
| Access to Market Data/ Other Knowledge | Limited access to market research data and/or legal and regulatory requirements in developing countries may interfere with rational priority setting of research and development activities for developing countries. |
| Marketing, Distribution, and Healthcare Systems | Weak infrastructure of logistics, distribution and delivery systems in developing countries may negatively influence marketing potential and thus discourage development of new products aimed at markets in these countries. Similarly, the lack of company distribution networks in developing countries may negatively influence marketing potential decisions and priority setting for research and development of developing country products. |
| Pricing Constraints | Healthcare reform has placed enormous pressures on healthcare providers and products in industrialized countries resulting in cost containment and price controls that decrease incentives for research and development of products for both industrialized and developing countries. |

B. SDI Commitment and Input

The SDI is committed to facilitating product development and marketing by addressing the issues outlined above to ensure reduced risk for development of STD diagnostic tests for developing country markets, and marketing in the least possible time and with the highest possible financial and economic returns. SDI contributions towards product development and marketing are as follows:

AREAS OF SDI INPUT

Product Development

| | |
|---|---|
| Geographically representative specimen panels | SDI is constituting fully characterized, paired laboratory specimens for use in research and development, and validation studies. Panels include vaginal washing/cervical exudate/urine; and serum/genital ulcer washing, and are being obtained from sites in Asia, Latin America and Africa. Panels will be made available to industry upon request. |
| Validation studies | Validation studies of newly developed diagnostic tests are facilitated by SDI through WHO Collaborating Centres for STD located in developing and industrialized countries throughout the world, and through other associated laboratory networks. |
| Field Trials | Field testing of newly developed diagnostic tests is supported technically and financially by SDI at developing country sites where STD prevalence is high, thus decreasing the time to availability of results. SDI, through WHO, facilitates regulatory agency access to these sites in order to ensure that data from these sites is of the quality required for licensing. |
| Working Groups | SDI will establish <i>ad hoc</i> working groups on topics of interest to companies such as regulation and liability, with the goal of resolving current or potential obstacles to rapid market entry. |
| Advisory Groups | In addition to its scientific Steering Committee - made up of ten world experts in laboratory diagnosis, clinical medicine and public health - which provides confidential advice on research and development issues, the SDI is setting up a business advisory board which will provide confidential advice to companies seeking guidance on issues such as marketing and technology transfer. |
| <i>Ad hoc</i> Fora | SDI supports, on an <i>ad hoc</i> basis, special fora required to review topics such as currently available technologies and to facilitate cross licensing and other industry interaction between or among interested companies. |
| Regular SDI Meetings | SDI ensures regular interchange, on general issues related to technology and business, through annual industry meetings. |
| Small Grants Programme | SDI provides funding of up to US\$ 75,000 per year to industry and/or academic research groups on a competitive basis. Letters of intent are reviewed regularly by the SDI scientific review committee which requests full proposals based on the content of the letters of intent which are then technically reviewed and funded by the SDI Steering Committee. |

Marketing

| | |
|-------------------------------|--|
| Needs estimates | SDI, through WHO, provides comprehensive country- or region-specific market information for STD diagnostic tests in any format requested. |
| Advocacy | SDI, through WHO, advocates for the use of simple STD diagnostic tests for rapid diagnosis and treatment of STD as a means of decreasing STD-associated morbidity and preventing transmission of HIV through policy recommendations and prototype training materials made available to all WHO member countries. |
| Reduction of import barriers | SDI, through WHO, regularly provides policy guidance to developing countries on importation of essential drugs and medical products to discourage tax barriers and other import restrictions which interfere with their availability. |
| Bulk procurement/distribution | SDI, through WHO, purchases essential medical products in bulk and provides them to developing countries through its worldwide distribution system, thus ensuring market penetration in countries with limited private or government sector procurement and distribution. |
| Justification of SDI need | SDI, through WHO, justifies the use of STD diagnostic tests meeting SDI criteria to financial donors to developing countries and the World Bank, thus ensuring their purchase and use in bilateral agreements for HIV prevention and STD control. |

C. Industry Commitment and Input

Private Industry has been and continues to be the leader in healthcare diagnostic and pharmaceutical research and development. The Industry is rich with the scientific and technical competence needed to develop new technologies, laboratory tests and procedures, and innovative test applications. Diagnostics Industry marketing experts are astute in the areas of marketing research, market segmentation, product pricing and distribution.

Industry also has an outstanding record regarding public sector collaboration to achieve common goals. Many of these public-private sector partnerships have resulted in the discovery of diagnostic tests and/or pharmaceuticals which have eradicated disease and increased quality of life. An example of one such joint Industry/WHO collaboration is the Onchocerciasis Control Programme in sub-Saharan Africa which has made ivermectin available at no cost to infected populations since 1974.

AREAS OF SDI INPUT

- GEOGRAPHICALLY REPRESENTATIVE SPECIMEN PANELS
- SUPPORT FOR VALIDATION STUDIES
- SUPPORT FOR FIELD TRIALS
- SDI WORKING GROUPS ON LIABILITY AND REGULATION
- FACILITATED CROSS-LICENSING
- TECHNICAL/BUSINESS EXCHANGE
- SMALL GRANTS FOR RESEARCH AND DEVELOPMENT
- ADVOCACY FOR APPROPRIATE PRODUCT IMPORT/LICENSING
- MARKET INFORMATION
- PROCUREMENT AND DISTRIBUTION
- POLICY/TECHNICAL GUIDANCE ON PRODUCT USE
- ADVOCACY FOR PURCHASE/USE OF PRODUCTS

The worldwide movement to decrease overall healthcare spending has had dramatic effects on the private sector. This has produced increased efficiencies through the down-sizing of staff sizes, facilities and pricing schemes. The loss of product exclusivity from patent expirations, reduction in profit margins and increased competition significantly affects "business-as-usual." Private sector healthcare industries are now actively involved in company and product acquisitions, co-marketing efforts, cross-licensing agreements and other innovative business relationships.

It is this current worldwide economic and healthcare environment which presents an excellent opportunity for effective and productive collaboration between Industry and the SDI to accelerate the development of a rapid, simple, effective and inexpensive diagnostic test for STD. The following table lists some of the areas in which Industry could collaborate with SDI.

AREAS OF INDUSTRY INPUT

| | |
|-----------------------|--|
| Technical information | Industry can share or exchange technical and scientific information confidentially with the SDI, or share through cross-licensing or other mechanisms with other companies collaborating with SDI. |
| Marketing information | Industry can share or exchange marketing research data such as market demographics, marketing problems/opportunities, STD incidence/prevalence estimates and estimated market potential information confidentially with SDI. |

| | |
|--------------------------|---|
| Packaging information | Industry can share or exchange product packaging design and composition information which might be unique for storage and distribution to developing countries through cross-licensing or other mechanisms with other companies collaborating with SDI. |
| Meeting attendance | Industry can ensure attendance of interested company scientists or business representatives at SDI meetings and/or working groups. |
| Financial support | Industry can Contribute financially or otherwise to the SDI and/or its activities. |
| Research and Development | Industry can reassess its research and development priorities in light information obtained from the SDI and become a collaborating partner in the SDI |

AREAS OF INDUSTRY INPUT

- INFORMATION SHARING/EXCHANGE: TECHNICAL/MARKET/OTHER
- PARTICIPATION IN SDI MEETINGS
- PROVISION OF SUPPORT TO SDI ACTIVITIES
- REASSESSMENT OF RESEARCH AND DEVELOPMENT PRIORITIES

IV. Synergies and Commercialization

Industry collaborative mechanisms with SDI can take many forms, three of which are described below. Alone, or in combination, they offer synergy and rapid commercialization of new products:

A. Single Company Relationship for Product Development/Commercialization

Industry can work independently with SDI on research and development and/or commercialization of new products. In this type of mechanism, a company may require, for example, additional market data before making the decision to commit significant resources to the development of a test fitting SDI criteria; seed funding for research and development; access to elements such as specimen panels, laboratories for validation study and/or field trail sties; and/or assistance in ensuring purchase and distribution of new tests. To accomplish this, collaborative agreements are set up between the company and WHO, between the company and a WHO Collaborating Centre on STD, or between the company and an SDI Participating Centre in clear and concise memoranda of understanding.

B. Single Company Relationship for Provision of Financial and/or Technical Support

Industry can agree with the importance of the SDI, and desire to stay closely linked to the newest developments in research and development, but may not perceive the development of a diagnostic test meeting SDI criteria as a business priority. In this instance a company can participate in SDI technical and business meetings and/or support the SDI financially with appropriate tax benefits. A company's support to SDI could be translated into equity in an SDI Participating Centre which may produce significant financial returns upon development and the bringing to market of a new diagnostic test.

C. Multiple-Firm Joint Ventures and Consortia

Industry with only part of the technology required or insufficient funds to follow an independent course of research and development, but which wishes to be involved in these activities, can join with others on the development and commercialization of a test. SDI would in this instance facilitate the formation of an appropriate mechanism (consortium, joint venture or other mechanism) and would provide advice on legal issues such as board and stockholder structuring, liability and product licensing.

COLLABORATION STRUCTURES

SINGLE COMPANY RELATIONSHIP FOR PRODUCT DEVELOPMENT/COMMERCIALIZATION

SINGLE COMPANY RELATIONSHIP FOR FINANCIAL AND/OR TECHNICAL SUPPORT

MULTIPLE-FIRM JOINT VENTURES AND CONSORTIA

Both financial and non-financial benefits will be derived from the synergy brought about by collaborative efforts. Industry will:

- Earn goodwill by demonstrating commitment to social and humanitarian initiatives
- Translate participation with WHO as meaning a company willing to support healthcare needs at lower per capita profit to patients of low income, thus in part justifying higher mark up and prices in industrialized countries.
- Indirectly or directly gain the endorsement of SDI/WHO and other participating worldwide health-promoting organizations
- Sell large volumes of product through an uncomplicated system thus avoiding the cost and logistical constraints of selling, distributing, educating practitioners and patients in many different developing countries.
- Increase bottom line profits, even at lower selling prices, from new products and markets at high volumes.

