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Novartis and the United Nations Global Compact Initiative

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Abstract

The United Nations Global Compact Initiative evolved from a challenge posed by Secretary-General Kofi Annan to business communities at the Davos World Economic Forum in January 1999. "I call on you--individually through your firms, and collectively through your business associations--to embrace, support, and enact a set of core values in the areas of human rights, liberal standards, and environmental practices." Since that time, the Global Compact has emerged as a voluntary initiative where corporations are asked to embrace nine principles.

As companies join the Global Compact, an independent outside analyst is invited to assess the incorporation of these principles into their daily operations. The attached case, one of the first, is a study of Novartis AG, a large Swiss pharmaceutical enterprise. The report analyzes the inclusion of the Global Compact as an integral part of a strategy for sustainable corporate development. Based on managerial interviews, the process of initiating a principles-based human rights dimension into managerial behavior is assessed.

Keywords: Novartis, Pharmaceutical Industry, UN Global Compact, Gleevec, Novartis Institute for Tropical Diseases

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The spirit of the Global Compact found fertile ground and has become an integral part of Novartis corporate strategy since the enterprise was formed by the merger of the two large Swiss pharmaceutical companies, Sandoz and Ciba, in 1996. Following a four-year concentration on economic consolidation and performance, Daniel Vasella (Chairman and CEO) signed the Global Compact. Together, productivity-based economic performance and a proactive approach to the expectations of society are envisioned as the key to long-term corporate success in the rapidly integrating global economic, political, and social environment of today's large multinational corporation.

This paper outlines the Novartis strategy and its implementation including the coalescing role of the Global Compact in the drive for sustainable corporate development. Following a review of extending corporate strategy to incorporate social concerns into the economic business model, the process of implementing the strategy will be assessed. In part three, specific examples of this strategic positioning will be outlined.[i]

1. STRATEGIC POSITIONING

1.1 Post Merger Economic Consolidation

Ciba and Sandoz approached the merger into Novartis ("new skills" in Latin) as an operating response to the growing competition, concentration, and institutional buying structure in the globally integrating life science industry. Both companies had roots in Basel dye production during the late 19th century, and had entered the merger after what The Operational Review called, "their best year ever."[ii] External observers, however, were less reassuring as to the past history of the two companies. According to *Forbes*, "Sandoz and Ciba-Geigy were plodding, risk averse and assiduously Swiss firms that often got trounced by faster, fiercer U.S. rivals. The research pipeline was dry, and marketers were slow on the draw."[iii] On the other side, financial analysts embraced enthusiastically the formation of Novartis resulting from the largest industrial merger in history at that time, and forming the world's largest life science company (healthcare, agribusiness, and nutrition) and the second largest pharmaceutical firm.

The post merger period of intense performance-based consolidation included changes in the structure of the firm as well as its management system.

- At the time of the merger Ciba's Dyestuffs, Additives, and Plastics divisions were spun off into a separate company, "Ciba Speciality Chemicals."

- Due to the lack of substantial synergies with other Novartis activities, Agriculture was divested in 2000 and merged with the agricultural division of Astra-Zeneca to form the Syngenta corporation. At that time, the agribusiness operation was the largest in the world. It represented 28 percent of Novartis revenue and 24 percent of operating income.

- In 2000, Novartis shares were listed on the U.S. stock exchange as American Depository Receipts, positioning Novartis as more attractive to U.S. investors.

- Merger personnel redundancies were reduced largely through natural attrition and early retirements. Some employees started their own businesses with financial support from the Novartis Venture Fund. The first year following the merger, the workforce was reduced by 9,199 at which point 62 percent of the anticipated merger cost synergies and the targeted 12 percent workforce reduction were achieved. At the same time, 2,400 new people with needed expertise were hired.

- During the consolidation phase, a third of the 100 most senior managers joined Novartis from other companies. In the United States, of the top 13 executives in 1999, only two remain.

- Performance-based compensation was rigorously applied across the company with total compensation targeting the fiftieth percentile of the compensation offered by a set of comparable competitors. Over 6,000 employees now receive share options as part of their remuneration.

- The pharmaceutical business was split into worldwide strategic business units centered around therapeutic areas and customers with some of its global management headquartered in the United States.

- The Novartis presence in the U.S. market was dramatically increased--the sales force growing from 3,100 to 4,600 in 1999 alone, probably the fastest expansion in pharmaceutical history. Using direct-to-consumer advertising, upgrading sales training, and accepting the risk of comparing their products with the best the industry has to offer in clinical trials and post approval marketing, the *Wall Street Journal* credits Vasella with "...transferring the firm into a bare-knuckled, American-style marketing powerhouse."[iv]

- The process of drug discovery and development was reorganized and revitalized to get drugs to the market more quickly. At the time of the merger, over half of drug sales were from patent-expired products. Development time has been shortened from 12 to about 8 years, with a sharper market-oriented focus.

- The financial performance (See Appendix A) reflects the synergistic value of the merger and the emphasis on managerial performance.

1.2 Strategic Expansion To Include Corporate Citizenship

By 2000, with the consolidation process becoming secure, Vasella believed Novartis had achieved the economic freedom to be more encompassing in its response to societal claims on business enterprises. In July, Novartis signed the United Nations Global Compact following a conversation between Kofi Annan and Daniel Vasella. The Global Compact served an important coalescing role as Novartis moved to a sustainable long-term position in the market. Urs Baerlocher, the senior executive for implementing the policy, describes the role of the Global

Compact, "The Global Compact, its principles and requirement to demonstrate credible action, triggered a discussion within Novartis on the nature of human rights, access to medicines, and the existing Code of Conduct, which led to our Corporate Citizenship Policy as an encompassing view of Novartis responsibility." According to Karin Schmitt (Head, Social Development, Novartis Foundation), "The Global Compact was an opportunity to show the Novartis commitment to human rights values, and the determination to live up to them realizing that we are inviting public scrutiny."

The generality of the Global Compact principles needed to be particularized for the specific Novartis environment as a first step in implementation. The Corporate Citizenship Policy translates these principles to fit Novartis as a global pharmaceutical company. During its year-long preparation, Novartis planners sought the counsel of nongovernmental organizations such as the World Resources Institute, SustainAbility Ltd., and the Stakeholder Forum for Our Common Future (formerly UNED Forum).

Introducing the Policy on Corporate Citizenship in October 2001, Vasella stated:

> "The Policy was developed in response to our commitment to the Global Compact, which was set forth by the Secretary General of the United Nations, Kofi Annan. Across geographies and throughout our organization we will, in all our business, social, and environmental activities, strive to be in line with the principles of the Global Compact. We believe that adhering to values is especially important for large organizations in times of rapid change and globalization, as they provide guiding principles. In our business, we are using innovative new technologies to search for novel lifesaving medical treatments. In some cases, these developments raise ethical challenges which must be carefullyconsidered with the establishment of proper boundaries, but Novartis' ultimate goal is to contribute to helping patients in need.
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> "On a global level, Novartis is committed to sustainable development and its three principles of economic, social, and environmental progress. We want to be a leading corporate citizen, both technologically and economically, and achievement of that goal is closely linked to our ability to contribute to the benefit of people. Our Policy on Corporate Citizenship outlines our pledge, and it is both a strategic business initiative--and the right thing to do."

At Novartis, corporate citizenship is not considered a socially responsive add-on. It is intended to be an integral, necessary component of a successful pharmaceutical company. Novartis is serious about this being a strategic business initiative. Martin Batzer (Head, Pharma Affairs) describes this initiative in terms of a "license to operate." "It is the third concentric circle in a strategy of economic maximization for shareholders; attention to other stakeholders including associates (the Novartis term for employees), customers, and communities; and the third part of continuing attention to the permission of society for the right of the corporation to exist. Integrating these three circles and ensuring that the third (license to operate) feeds back into the other two is the key to sustainable corporate development in the long-term. If you don't have the license to operate, you can forget everything else." And, as noted by Terry Barnett (President and Chief Executive Officer, Novartis Corporation), "Right now, as a pharmaceutical company,

that license seems to be up for renegotiation. At issue is the appropriate role of the pharmaceutical industry in the total healthcare environment." Baerlocher states, "If we want to be truly successful we need to achieve beyond products and services. We also need our stakeholders to recognize that we are a valuable part of society, a good corporate citizen." Johannes Frey (Head, Corporate Affairs) notes, "Often the pursuit of corporate citizenship can have a direct payoff. You follow a risk management approach as we have refined it in our Health, Safety, and Environment Practices of incurring an expense now to minimize great damage down the road. Corporate citizenship is an investment."

2. OPERATIONALIZING A STRATEGY OF CORPORATE CITIZENSHIP

In its Policy on Corporate Citizenship, Novartis commits itself to the broad vision of human rights--the same base as the Global Compact principles. "The Novartis core values are based on the fundamental rights of every individual, such as the protection of privacy, freedom of opinion and expression, freedom of association, nondiscrimination, and the right to be heard. We seek to promote and protect the rights defined in the Universal Declaration of Human Rights of the United Nations within our sphere of influence. We do not tolerate human rights abuses within our own business operations."

2.1 A Focus on Process

This policy goes well beyond the political and civil rights that form the core of what are called the first generation of human rights to include second generation economic, social, and cultural rights. In most business activities, it is the second generation rights that are to be promoted and protected "within our sphere of influence" and the abuses which will not be tolerated "within our own business operation." These second generation rights are far more difficult to specify; society is continually redefining its human rights concerns and acceptable thresholds; while national legislation supports these rights, they have received only modest recognition in the constitutions of modern Western cultures; they can easily become politicized; they can contradict one another; protecting second generation rights can be expensive.

Given the continuing advance of societal expectations for the private sector, and based on a foundation of valuable experience in responding to environmental and social needs, Novartis is focusing on the *process* of achieving corporate citizenship. The process begins with an articulation of one's ultimate vision as quoted above supported by a strategy and a system that incrementally ratchet toward that vision through a steady process of setting, measuring, achieving, testing, and refining standards. The idea is to establish a transparent process relating to those inside as well as outside the firm where objectives can be adapted as learning and measurements are refined. There will be shortfalls as Norman Walker (Head, Human Resources) notes, "I can't say we will meet all of our requirements today. It's a journey we have started with the purpose of seeing that our standards are achieved." In the final analysis, however, as Vasella states, "Don't make commitments you can't keep."

2.2 Valuable Experience

In its implementation efforts, Novartis draws on a valuable history of involvement with civil society in its environmental and social response through its Health, Safety, and Environment (HSE) initiative and the Novartis Foundation for Sustainable Development.

The HSE initiative began in the early technologically driven, production-focused ecological era of the 1980s. Over time, HSE has become a part of line managerial responsibility analyzed annually in the context of local legal requirements, relative impact, competitive performance, and available state of the art technology. Targets are set for each sector, performance measured (116 sites in 2001), externally verified and published in detail. The development of this HSE process over the years has benefited substantially from dialogue with representatives from the other components of civil society.

The HSE experience has helped Novartis find a balance between precaution and innovation in applying the "precautionary approach." This approach, more than any other clause of the Global Compact, has created hesitancy among firms in the United States. The Global Compact is not specific in its seventh principle, asking firms to: "Support a precautionary approach to environmental challenges." The principle is defined in the United Nations Rio Declaration: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." In applying the approach to human health as well as the environment, Novartis makes a distinction between prevention and precaution. Prevention applies when there is a scientifically known cause and effect. Prevention is an issue of cost. Precaution applies when there is scientific uncertainty. As Kaspar Eigenmann (Head, Corporate Health, Safety, and Environment) points out: "When the activity could lead to grave consequences, even if there is no full scientific proof, one should take reasonable measures. The principle makes common sense. It's the application that creates controversy--how is the reasonable likelihood or the application of reasonable measures to be determined?" The Novartis position states: "We take a precautionary approach in the innovation and development of new products and technologies. To this end, we follow a step-by-step approach, we engage in scientific peer review, and we consider benefits and risks of innovation in a scientific and transparent manner," a position initially "challenged" by the U.S. legal staff. Alternatively, as Julie Kane (Vice President, Novartis Corporation) notes, "Lawyers are nervous, but their role is to advise about the risk so management can make the right decision."

The Novartis Foundation for Sustainable Development concentrates on sustainable development in the poor regions of the world. With the philosophy that "only autonomous development can constitute sustainable development," social development projects are undertaken in partnership with local nongovernmental organizations (NGOs): work with AIDS orphans in Northern Tanzania and South and East Africa, conflict management and the empowerment of women in Palestine, community development in Brazil and Sri Lanka, as well as leprosy cure and rehabilitation in partnership with the World Health Organization (WHO), National Health authorities, and NGOs. Other activities include a social research and publication program, and stakeholder dialogue and networking. Stakeholder dialogue is directed to "increase internal awareness of societal perceptions of development issues," to "increase external awareness of business realities," and to "keep in touch with societal expectations" through conferences, symposia, workshops, and membership in social committees and boards.

The twenty years of experience with each of these initiatives has helped Novartis recognize the value of access to the information and worldviews of civil society. There are many guiding

principles about how best to undertake the dialogue between management and representatives from other segments of civil society. Two experiences as reflected in the interviews have been helpful in shaping Novartis policy. Kaspar Eigenmann describes an interaction that began in the late 1980s. At a casual dinner following a formal meeting on chemicals policy, a small group of participants from Ciba-Geigy and The Ecological Scientific Institutes in Vienna and Freiburg i.B. concluded that dialogue would be more productive than confrontation. They initiated a series of small informal meetings often with neutral experts. Initially, neither side told their colleagues about these discussions, since both assumed their colleagues would judge this kind of interaction inappropriate. Over time, each side learned to appreciate the other's logic. Some discussion topics led to joint research and scientific publication, some only to more talk. In all, around five projects emerged from this contact. The periodic meetings continue with new younger people coming into the process. A stakeholder experience related by Klaus Leisinger (Executive Director, Novartis Foundation) involved the importance of including the decision makers in the process. In a joint corporate/NGO attempt to assess the consequences of Green Gene Technology, senior corporate and NGO management assigned the dialogic task to staff specialists. In an effective dialogue over three years, the participants learned from each other in what Leisinger describes as a "discursive learning curve." They reached consensus on a series of recommendations, a consensus to which neither corporate nor NGO senior management would agree, since they had not participated in the learning curve and could not be convinced.

Based on these kinds of experiences, the Novartis stakeholder policy states: "We provide relevant information and actively listen to stakeholders. In assessing controversial products, processes and technology, we seek dialogue with all stakeholders." This policy extends the business model of listening to the market to the sustainable corporate model of listening to the signals from civil society. As Andreas Seiter (Head, Stakeholder Relations) explains, "It's important that we tell them, but even more important that they tell us. When there is a developing issue which influences our future business strategy, we should be part of that debate, listening first before we make our point." The idea is to extract issues as they begin to form, long before they reach the media threshold, at which point the perceptions are set. If initiated early, discussions are interesting for both sides, particularly when there is scientific evidence to share. This window of discussion opportunity can last for up to six years.

2.3 From Concept to Action

While the idea of corporate citizenship is defined by headquarters as a component of long-term corporate sustainability, managers at the local levels, where the policy takes effect, face a plethora of immediate concerns and pressures toward short-term performance targets. Dieter Wissler (Head, Corporate Communication) describes the challenge. "The deeper you go into the organization, the greater the pressure on short-term results, and the less a person thinks about corporate social responsibility. For local managers, corporate citizenship can be seen as a dictate from headquarters that drains energy from their operating focus." Complicating the distinction between headquarters and the field at Novartis are differences in the European and American views about the role of the Global Compact principles in corporate sustainability. What is clear in the European perception is not as clear in the U.S. environment.

Norman Walker sees corporate citizenship as a more difficult task than implementing the HSE Policy. "It poses a deep challenge to a company and the way it operates, it is much more about

our collective behavior. This demands a specific attitude throughout the organization." Erwin Schillinger (Head, International Coordination) makes a similar comparison to the Novartis Code of Conduct, initiated on a global basis two years before the Global Compact. "The Global Compact added a whole new dimension. While the Code addresses individual rights and responsibilities, the Global Compact is an obligation of the company with the necessity of bringing managerial decisions in line with its provisions."

A senior management Steering Committee was formed with the charge of making corporate citizenship an integral part of line management, including the information system, performance measurement, and incentives. A campaign of awareness was initiated throughout the organization. Following a series of corporate announcements, the Corporate Citizenship Policy was one-fourth of the program at the annual retreat of the top Novartis executives at Interlaken in February 2002, as well as sectoral and regional management meetings. Discussions were initiated through the Novartis Intranet. According to Walker, "You need to allow people to understand why you are pursuing these changes. This is best accomplished by engaging people face-to-face in a young company like Novartis. The enthusiasm for corporate citizenship as a strategic initiative has been a pleasant surprise. We found that the purpose of the company is very important to our people, far more than just coming to the office day after day. This is something they can relate to." Alternatively, "While our people in the United States are proud to have their company endorse the Principles, they are very much focused on the realities of the marketplace. They are somewhat detached from the Principles and do not see their relevance as a U.S. issue" (Barnett).

The next step was specific guidelines. In structuring the guidelines, the Steering Committee prepared an inventory of policy commitments which relate to the underlying themes of the corporate citizenship strategy, how it unfolds into specific concerns to be addressed, and to their related policy commitments. Further preparation involved the analysis of a wide range of United Nations documents and various codes of business conduct. The Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Cultural, and Social Rights provided the broad framework. More specific guidance on qualitative and quantitative standards was drawn from the International Labor Organization conventions, recommendations, and declaration as well as other specific principles such as the United Nations Code of Conduct for Law Enforcement Officials, the U.N. Human Rights Sub-Commission Draft on Universal Human Rights Guidance for Companies, and the OECD Guidelines for Multinational Enterprises. Consideration extended, for example, all the way to the possibility of credit schemes for microentrepreneurs in the supply chain. Checklists for core indicators of minimum requirements and best practices were prepared. In the end, however, there were surprisingly few specific standards in these documents.

Four guidelines were issued in June 2002 with a fifth in formulation. In preparation for a year, these guidelines were debated internally at all levels of the organization and circulated externally for comment. Each addresses responsibilities, principles and standards, the management process, and the reporting criterion unique to the specific guideline.

Guideline #1: Management of Corporate Citizenship. This initial guideline regulates the scope and applicability for those that follow. It sets the structure for the "active management of

corporate citizenship." The broad reach of the document addresses priority conflicts that might arise between corporate citizenship and short-term operating objectives that need to be arbitrated;
a safe complaint procedure for employees who report corporate citizenship deficiencies; application of the principles to Novartis partners; reporting and audit procedures as well as the possibility of commissioning external auditors.

Guideline #2: Fair Working Conditions. This guideline is directed to human resources, including the related aspects of human rights. The creation of a reporting system is an important component of this guideline. Before the Global Compact, working conditions were considered to be a local responsibility. Early resistance to reporting was reminiscent of the early days of the HSE--Why do we have to do this? What's it really for?

The third Global Compact principle was discussed at length in the preparation of this guideline. It asks world business "to uphold freedom of association and effective recognition of the right to collective bargaining." Jeff Benjamin (Vice President and Deputy General Counsel, Novartis Corporation) states, "Our existing policy is union neutral. Our companies make sui generis decisions." While the language of the principle itself is not inflammatory, nor risky, legal staffs and managers of many companies, particularly in the United States, are concerned that the United Nations will interpret and measure the principle in ways that put pressure on firms to be pro union.

The guideline clause on freedom of association recognizes the employee's right to choose whether to join a trade union or employee association, but establishes criteria for these associations in terms of democratic principles, the existence of written statutes, a history of legal compliance, and that they be free and independent associations not committed to violence. Additional criteria may be established by local Novartis companies. As in other Novartis policies, dialogue is included: "Each Country Service Officer shall establish a communication process that ensures a free exchange of opinion [with associates] and a constructive dialogue."

The guideline on wages goes well beyond the Global Compact: "In each market, full-time wages must be set at or above a level that covers the market price of a basket of goods and services representing the subsistence level for an average worker in the town or region in question." Dependent children are included in this "living wage."

Guideline #3: Business Ethics – Bribes, Gifts, and Entertainment. This guideline covers a topic not explicitly included as a principle in the Global Compact, drawing on the provisions of the Novartis Code of Conduct. Governmental corruption, bribery, and marketing practices, along with access to medicines was identified by Novartis top management at the introduction of the Corporate Citizenship policy in Interlaken as the most important issues facing the industry.[v] Batzer sees marketing practices as the toughest part in all of the guidelines, "How does one find the balance between competing in what has become a very aggressive market set against the exposure to the damage of what are viewed as unethical practices, with guidelines that hold across cultures and legal regimes?" The Code of Conduct states, "No employee shall make any payment, or kickback, or offer improper financial advantage to an official of a government or a government-controlled entity for the purpose of obtaining business or other services, as set out in

the OECD Convention on Combating Bribery of Foreign Public Officials." A true challenge, Christian Seiwald (Sector Head, Generics) said, "Corruption is a problem that all companies have to confront. Solutions can only be home grown." There are undoubtedly cases out there, the task of Novartis is to change that behavior.

Here, especially, senior management must convince everyone in the company of the seriousness of bribery. Johannes Frey notes, "What headquarters would regard as a corrupting action can make sense to a local associate focusing on a specific business transaction in a lenient community who does not internalize the great risk to the company in an environment where the company needs to prove every day that it lives by its statements."

This guideline defines and prohibits bribing of government officials directly or through intermediaries. It addresses the distinctions between, and provides guidance for, facilitating payments, gifts and entertainment, charitable donations and cultural contributions, political donations and contributions, and acceptable payments. Local managers must explicitly report on their large transactions and consult with the relevant Corporate Citizenship Officer for any payments over $US 100. Acts of private bribery are particularly difficult to assess due to the complex of codes, regulations, and contractual provisions that apply.

Guideline #4: Human Rights and Engagement in Society. Focusing on the human rights issues that become the responsibility of Novartis, this guideline covers stakeholder engagement and government relations. The policy recognizes that many human rights issues occur when local background institutions or governments are uninterested or not sufficiently empowered to protect human rights, and that Novartis has varying degrees of power to intervene. The guideline directs a policy of governmental engagement. "Relationships with governments and other public authorities need to be actively managed." But, "As a rule, local Novartis companies should be reluctant to get involved with political parties and take sides in election campaigns." Advocacy stances are acceptable if managed with care. Aware of the increasing importance of the cultural, economic, and social dimensions of human rights, an amended version of this guideline will be issued in early 2003.

Johannes Frey believes this will be the most difficult guideline to implement. The margin of judgment is great, as can be the cost of making a mistake. Managers must let governments and NGOs (groups with whom they tend to be uncomfortable) into their decisions with the attendant loss of control.

Guideline #5 will concentrate on third party relationships. The Novartis policy states, "We give priority to business partners, suppliers, and contractors who share our societal and environmental values, and we support their efforts to promote these values through their business activities." The questions to be addressed in translating the policy to guidelines as outlined by Kaspar Eigenmann include, "How do we assess those who share our values; how is giving preference different from imposing specific standards; how does one balance how far to press one's values on third parties and what legal liabilities are created; how does responsibility differ for subcontractors using Novartis technology, for suppliers where Novartis takes most of their output, or where national legal environments are weak?" On a practical basis, where should initial efforts be concentrated--on the largest subcontractors in the most difficult countries?

The guidelines are in a continuing process of review and revision as experience is gained and measures refined. Standards will be clarified as general principles are linked with concrete business activities.

2.4 Establishing Credibility

Implementing a long-term corporate citizenship strategy is a matter not only of actions but also of being perceived as doing a good job by internal and external stakeholders as well as by the broader society. As an integral component of sustainable corporate development, corporate citizenship becomes a matter of pride for members of the Novartis organization, generates positive reputational effects among external stakeholders, and ensures continuation of the license to operate from the broader society. Following the HSE and Foundation experience, it is intended that NGOs will have input into the process, measurements, and targets, as well as certification of the results.

The active management of corporate citizenship means making it an integral part of Novartis line management and, to the extent possible, with third parties. Each of the guidelines concludes with a section on "reporting criteria and measurement." The internal process of auditing compliance will follow the procedures of the financial and HSE audits. Specific responsibilities have been created throughout the organization and assigned as collateral duties. Novartis has concluded that making the compliance auditing responsibility a collateral duty at numerous levels throughout the organization is more effective in creating organizational change than fewer specialized personnel. Most of these collateral duties are currently assigned to the human relations and legal staffs although Eigenmann would like to include more line managers. With an initial emphasis on managerial processes and auditors serving in a consulting role, the auditing function will increasingly include performance as measures are refined and targets set--following the HSE experience. Understanding transparency as a necessary precondition for credibility, these assessments will be a component of the Novartis annual report following a process to be initiated in 2002. At that time, the HSE data and verification which have been published in a separate Operational Review since 1996 will be included in that document.

External monitoring is yet to be resolved. It is accepted in principle and included in the guidelines but not yet operationalized. As Leisinger notes, "Independent external verification plays an important role for the credibility of a company's compliance effort--indeed, it is a precondition.... The search for consensus should therefore not focus on the question 'Yes or No' but on the 'How.'" As with all external monitoring systems there are questions of appropriate expertise, the process and its cost, the protection of proprietary information, the external monitor's attitudes and organizational culture as well as their own credibility, and the public disclosure process and detail. An unusual problem with NGOs as monitors outlined by Peter Tobler (Compliance Officer) is the breadth of the Policy set against the typically more narrow focus of the individual NGO. An ideal external monitor is one with credibility who is willing to participate with Novartis as they both jointly work to improve a transparent process. As successful as the HSE external auditing process has become, it is still a public verification of technical data collected and reported by Novartis.

3. EXAMPLES OF IMPLEMENTATION

Three examples of applying the principles of the Global Compact and Corporate Citizenship reflect where Novartis finds itself in the process at this time. Two projects reflect the issue of access to medicine unique to the pharmaceutical industry. The third example is common across industries, particularly those relying on subcontracted production in developing countries.

3.1 Responsibility for Access to Drugs

It is estimated that over one-third of the world's population lacks access to essential health services, including drugs. Limitation on access to treatment is a multifaceted issue involving the absence of medical services, unreliable health and supply systems, lack of sustainable financing, irrational selection and use of drugs, as well as the availability and price of drugs.

Society is evolving to the conclusion that medical care is a human right, and that the pharmaceutical industry has a unique responsibility to help sick people gain access to life saving medicines. This is an extension of the Global Compact first Principle which asks world business to "support and respect the protection of internationally proclaimed human rights within their sphere of influence." In outlining the specific requirements associated with that principle, the U.N. directs business responsibility to an extension of the workplace ensuring the "rights to basic health, education, and housing (in areas where these are not provided)." The pharmaceutical access to medicine programs reach well beyond the workplace and local communities to a broader "sphere of influence" embracing patients far beyond the traditional stakeholder boundaries. This is a reflection of Dr. Vasella's early experience in medical practice as well as that of other physicians in Novartis and the industry. It also recognizes the view expressed by Vasella, "Unless the pharmaceutical industry achieves its objectives of being an accepted and valued player in society, we will be at a disadvantage in every new law and regulation that comes up."

Pharmaceutical companies are responding. For developing countries, they are networking with civil society, governmental agencies, and components of the United Nations. Novartis, for example, is part of the Global Alliance to Eliminate Leprosy. The firm donates a multi-drug therapy which can cure the disease in six months or a year (depending on the disease form). The drug has been available free of charge since 1995, and Novartis is committed to continue until leprosy has been eliminated. Through the Novartis Foundation for Sustainable Development, in conjunction with governmental agencies, private foundations, the WHO, and the World Bank, the inadequacies of local health infrastructure as well as the fear and prejudice associated with leprosy are gradually being overcome. Another partnership with the WHO is for the treatment of malaria. In conjunction with the Chinese Academy of Military and Medical Science, Novartis discovered and developed the most potent anti-malarial for non-complicated *Plasmodium falciparum*. In this agreement, Novartis is providing the drug at cost. For Novartis employees and their nuclear families in developing countries, the firm is involved in the diagnosis, treatment, and care of HIV/AIDS, TB, and malaria. When not available through other sources, Novartis pays for the cost of assuring this coverage.

Some pharmaceuticals are directly involved in finding treatments for diseases where there is no viable commercial market, thus posing a challenge to the wealth maximizing business model. Merck, for example, developed Mectizan to treat onchocerciasis (river blindness), a disease

which had devastated the populations of rich tropical river valleys for centuries. Novartis is in the process of creating an Institute for Tropical Diseases in Singapore, which will concentrate on the discovery of treatments for these kinds of diseases.

The new research approach of searching for molecular targeting therapies is expensive, thus driving treatment costs beyond the reach of many patients. Here, broad patient assistance programs, such as the Novartis graduated assistance approach to its new drug, Gleevec, are coming into use.

3.1.1 Research on Tropical Diseases: Example #1

The Novartis Institute for Tropical Diseases has recently been established in collaboration with the Singapore Economic Development Board. The purpose of this research institute is to discover treatments for diseases of poverty, beginning with tuberculosis and dengue fever. At the present time, less than 10 percent of the total pharmaceutical spending on research is directed toward tropical diseases which comprise 90 percent of the world's health problems.

The Global Compact was an important stimulus in the decision to emphasize drug discovery for tropical diseases. Paul Herrling (Head, Research) noted, "Within Novartis, the Global Compact stimulated the discussion of access to medicines which led to the idea of a tropical disease laboratory and to Singapore." On a broader basis, the kind of awareness reflected in the Global Compact has brought shareholders from resistance, to acceptance, and now to preference for these kinds of contributions. "Feedback at shareholder meetings about the Singapore project has been very positive."

Singapore is one of many collaborative efforts of Novartis.[vi] As a non-commercial effort, however, the open nature of its research environment will be unique. Indeed, the intent of the Institute is to become a center for developing-country scientists, including a major training component. Its initial focus on tuberculosis (a bacterial disease) and dengue fever (a viral infection from parasites) will be extended to other tropical diseases. Its contribution will be in drug discovery, seeking other partners for the development of these drugs.

More important than the financial commitment of $US 122 million is access to the Novartis laboratory management skills and experience in drug discovery. Beyond that, Novartis will be contributing specific compounds that may have potential for the treatment of tropical diseases. "In the drug discovery process, it repeatedly occurs during searches for a specific therapeutic profile that medicines are found to have additional beneficial effects in other diseases. One could imagine that while searching for drugs against the hepatitic C virus, something useful for dengue fever might be found, and vice versa. This occurs because evolution uses similar biological mechanisms in different contexts" (Herrling). Thus, a mechanism is being implemented to redirect compounds or small molecules that show potential for the treatment of tropical diseases from the Novartis commercial discovery laboratories to the Institute. At the time of the interview, Herrling had two of these compounds on his desk for evaluation. One compound in particular, while ineffective against cancer, had been identified as a possible treatment for parasitic tropical infections, given the nature of the compound and its history.

3.1.2 Ensuring Access to a Viable Commercial Drug: Example #2

The second example involves an economically viable commercial drug. A breakthrough in drug discovery, this treatment has demonstrated unprecedented efficacy in treating a relatively small population of cancer patients. While it is expensive, Gleevec holds a virtual "efficacy and tolerability" monopoly in treating specific forms of leukemia and rare gastrointestinal tumors. The Novartis position is that all appropriate patients should not be denied access to the drug because of financial reasons. As such, the company has initiated patient support programs globally.

Gleevec is a young drug with stunning early success in treating chronic myelogenous leukemia (CML), a disease with a mortality rate near 25,000 yearly across the world.[vii] Paul Herrling describes Gleevec as "a new class of drugs based on understanding the pathway which leads from the gene to the disease and targeting the therapy to that specific abnormality." The results of the first clinical trials, begun in mid-1998 and initially reported in December 1999,[viii] "took the oncology-hematology community by storm." Of the 31 patients in this Phase I trial, all experi-enced a significant decrease in the number of cancerous white blood cells (symptomatic of the disease) while a third experienced very significant reduction or disappearance of cancer cells with the diseased chromosome. Based on these early results, Novartis, in rapid fashion, began industrial-scale production in February 1999 (a complex process taking eight to nine months and requiring a dozen steps) and initiated its Phase II clinical trials. Application for approval by the United States Food and Drug Administration was completed in March 2001, just 32 months after the first human trials. This compares to the typical drug development time of six years. As David Epstein (President, Novartis Oncology) described the process, "We believe this is the fastest from first dose in man to filing." Approval (a process that can take anywhere from 12 to 18 months normally) was granted in 72 days. The product was at the wholesalers within 24 hours of approval. It is currently approved in most countries for treating certain forms of CML and now certain forms of gastrointestinal stromal tumors (GIST).

Thanks to the internet, the news of Gleevec has spread rapidly across the world. At a worldwide price of between $2,000 and $2,500 per month, most patients would not be able to pay for the drug without insurance or reimbursement through their country's healthcare system. Novartis management firmly believes a drug with such a dramatic potential should be available to all appropriate patients with CML. At the same time, as a breakthrough drug, Gleevec must provide a profit in order to support additional investment not only in further study of it, but also for further research in oncology and other therapeutic areas. The Novartis solution is to make Gleevec available worldwide through special assistance programs.

A specific program was devised for the United States since the healthcare system is not a federally subsidized one as is the case in most other industrialized countries. This is a graduated program with patient assistance offered at various levels based on income, assets, and household size--from receiving the drug free of charge if assets are below a certain amount and income less than $44,300 a year to paying a graduated portion of the total cost. Assistance extends beyond five times the poverty level in some instances. (Most donation programs are limited to less than two times the poverty level.) The operation of this system in the United States is managed by a third party--Documedics--with specific expertise in reimbursement programs in oncology. In the United States, Gleevec is covered by virtually all private insurance policies, although it is not

covered by Medicare since Medicare only covers injectables or physician administered drugs and Gleevec is an oral therapy. Patients contact the Gleevec Reimbursement Hotline to see if they are eligible. This is the program managed by Documedics, which then assesses the patient's income, assets, and household status based on the information provided by the patients, assists in the search for alternative reimbursement sources and, if necessary, initiates the Patient Assistance Program. Gleevec is then shipped directly to the patient. The Gleevec Program is precedent-setting in the United States market. Many pharmaceutical companies, including Novartis, have made drugs available to those who could not afford them, but no one else to date has published a graduated support system based on a patient's ability to pay. This program works due to the dependability of medical diagnosis, the assistance of the physician's office staff and the Novartis sales force, access to Documedics, and the breadth and uniformity of private healthcare coverage.

A different kind of program is operational outside the United States--the Glivec international Patient Assistance Program (GIPAP). This is not an additional reimbursement program but rather a donation program that follows specific criteria. Outside the United States, the nature of the healthcare systems and the quality of infrastructures varies dramatically. In many countries, the government healthcare system subsidizes pharmaceuticals. However, a large number of countries do not have health insurance--private or government. For these countries, Novartis has initiated the GIPAP Program. Through GIPAP, Glivec is made available in countries where it is approved for treating certain forms of CML and GIST. Qualified patients are those who are properly diagnosed, not insured, not reimbursed, and have no other financial recourse (unable to pay privately).

In order to ensure that appropriate patients are considered for this drug therapy, applications for GIPAP assistance must be initiated by physicians on behalf of their patients. The physician must be involved in all stages of the treatment (diagnosis, prescription, and follow-through). This regulation is in accordance with the World Health Organization (WHO), who provides global guidance on essential drugs and medicines, and works with individual countries on implementation of national drug policies.

The Max Foundation, an international nonprofit organization dedicated to people with leukemia and other blood-related diseases, administers GIPAP (applications are available via the Internet, www.themaxfoundation.org). Most communication with the Max Foundation is through the Internet. The creativity of this approach is the reliance on the physician and the use of the Internet as the systemic vehicle. Together, these minimize the distributional infra-structure.

Thus, both Gleevec, as a young drug, and its distribution systems are works in progress.

3.2 Ensuring the Rights of Workers: Example #3

An early step in implementing the Global Compact was a baseline survey undertaken by the Steering Committee to assess issues relative to compliance with the principles and to identify areas of sensitivity to human rights abuses where Novartis operations could be vulnerable. Of particular concern were third-party activities.

While Novartis has no legal liability for the stakeholders of subcontracting firms, it was

determined that this is a component of the human rights policy as indicated in the Global Compact and since the well being of subcontractor stakeholders is affected by the activities of Novartis. This is particularly true when the stakeholders do not have adequate local background institutions to represent their interests. In Western Europe and the United States, society has decided that these third-party stakeholders are the responsibility of the multinational, a view which can conflict with those of the developing world.

This third example arose from the baseline vulnerability assessment based on the Global Compact Principle six: "to uphold the elimination of discrimination in respect of employment and occupation." In addition, the second Principle asks world business "to make sure they are not complicit in human rights abuses." The initial vulnerability questionnaire identified two examples. To the surprise of management, one was in Basel where a janitorial contracting firm was paying less than the community standard. Another example was the existence of pregnancy testing at a subcontracting production facility in a developing country free trade zone. The management of the plant was pregnancy testing job applicants during a preemployment physical without the applicant's knowledge, and denying employment to pregnant women. Before the Global Compact emphasis on human rights, pregnancy testing had never surfaced as a part of Novartis' anti-discrimination policy.

As with most human rights issues, there were a number of complicating factors: The production facility was owned and managed by the local government, as was the whole free trade zone; undisclosed pregnancy testing was not against the law; it was the policy across the free trade zone where a condition of employment was that the worker be unmarried and not pregnant. The senior plant management believed they were making an important contribution to the applicant by providing a physical examination--perhaps the first in her life. It was argued, since most of these applicants were migrant workers from distant, remote villages, they should know about their pregnancy in time to return home for the birth and for the nurturing environment of the extended family--an environment that could not be replicated at the plant site. The management of the plant and that of the free trade zone were convinced their policy was the best for the applicant, for the free trade zone, and for their society.

The counter argument, based on the dignity of the applicant, was that pregnancy is such a central and unique component of a woman's identity, even though others may treat the issue with great respect, the woman herself should decide whether to reveal her pregnancy and determine what would be best for herself and her child.

Pregnancy testing can be viewed both as a form of sex discrimination and a violation of a woman's right to privacy. While sex discrimination is prohibited by ILO convention, it does not explicitly address pregnancy testing. The United Nations Human Rights Committee has called on States to include the right to privacy in their legal codes, although few have.

Denying employment on the basis of pregnancy can, in many countries, pit local practice against global hypernorms. Is this an area where global society should, and has the right, to overrule local practice? Local Novartis management argued that pregnancy testing was an accepted practice in the country as directly represented by the government-owned facility and management of the zone, insisting that a change would jeopardize the relationship with the plant

that had demonstrated acceptable overall standards for labor practices over an extended period of time and was a model plant for its environment (as confirmed by an on-site monitoring visit). Beyond the pregnancy testing issue, insisting on a change of policy could have a negative effect across a broad range of other interactions between Novartis and the government.

This issue found its way to the Novartis Executive Committee, consisting of the top eight executives in the company. The Committee with Vasella, as chairman, judged that the practice was, indeed, discriminatory and would be immediately stopped. The current policy is that pregnancy testing is offered cost-free as part of the application physical, but is not a condition of employment.

4. PRESENT STATUS

In a pharmaceutical company, long-term performance depends upon the success of research and development as well as the marketing of useful and safe pharmaceutical products, plus the managerial acumen to achieve the financial results needed to sustain that research and development. For Novartis, the spirit of the Global Compact becomes a strategic component of sustainable corporate development as it is interwoven with the business model and cuts across the economic, social, and environmental aspects of decision making. These principles, particularized in the Corporate Citizenship Policy, help the firm meet the expectations of society so critical for its long-term development. Implementation depends upon the ability to continually refine the process of measuring, setting, and achieving targets for the human rights dimension of Novartis and third-party operations within an overall vision; the capability of line management to integrate corporate citizenship into the economic business model, and to settle tensions between competing objectives as they arise; the credibility of the process as perceived by internal and external stakeholders as well as the broader society.

Novartis is midstride in bringing its strategy of long-term corporate sustainability to fruition. Top management has operationalized the principles of the global Compact as evidenced by the above examples reflecting the uniqueness of the pharmaceutical discovery and distribution of drugs, and as a multinational subcontracting its production to third parties. These outcomes are measurable in terms of drugs discovered, patients served, and rights protected. Still, these are senior management initiatives. The goal of integrating Corporate Citizenship into the mindset of the operating manager remains a work in process. The question is whether the process of implementation and compliance is up to the challenge. It promises to be a more daunting task than either the Health, Safety, and Environment success or the Code of Conduct.

The vision is clear as is the determination of senior management. The publication of guidelines in June 2002 initiated the system of standards and accountability, a system that appears capable of evolving toward fulfilling the vision. Credibility is an open question. Internal credibility will grow with the implementation process. Based on experience, Novartis management is convinced their policy of early, open dialogue with external stakeholders will lead to better decisions and to credibility. Verification will be part of the social as well as the environmental process. Formal, external monitoring has yet to be introduced. This is a continuing process. As Vasella notes, "The policy incorporates our aspirations--recognizing that we still have some areas where we do not yet live up to the policy."

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Appendix A

Novartis AG
Performance Data

	1996	1997	1998	1999	2000	2001
Financial Performance [a]						
Revenues (CHF billion)	20.0	23.1	23.2	25.2	29.1	32.0
Research and Development (CHF billion)	3.1	3.7	3.2	3.5	4.0	4.2
Overall Operating Margins[b]	18.8%	21.8%	24.8%	25.1%	23.1%	22.7%
Pharmaceutical Operating Margins	24.6%[c]	27.9%[c]	31.0%	30.6%	29.8%	28.1%
Industry[d]	30.2%	28.5%	29.1%	36.3%	27.9%	24.1%
Return on Equity[e]	16.7%	20.7%	20.7%	19.4%	17.6%	17.8%
Industry[d]	27.3%	24.5%	32.8%	29.2%	30.2%	23.4%
Business Sectors [a]						
Pharmaceuticals	58.0%	61.0%	62.5%[b]	60.6%	62.3%	63.0%
Generics	6.0%	6.3%	6.6%	7.2%	6.8%	7.6%
Consumer Health	26.0%[d]	22.7%[d]	20.5%	22.1%	22.4%	20.8%
CIBA Vision	6.0%	6.1%	6.5%	6.4%	4.8%	5.6%
Animal Health	4.0%	3.9%	3.9%	3.7%	3.7%	3.0%
Financial Market Assessment						
Price/Earnings Ratios						
Novartis Hi	na	34.0	31.0	31.5	26.3	28.6
Novartis Lo	na	19.6	22.4	21.0	17.5	19.9
Industry[d] Hi	27.4	44.8	50.9	42.9	39.4	na
Industry[d] Lo	19.8	28.3	32.8	30.3	24.3	na
Market/Book Ratios						
Novartis	3.8	6.6	6.4	4.4	6.1	4.3
Industry[d]	7.0	15.5	22.6	16.2	18.1	na

Footnotes

a. Agriculture is not included because it was divested in 2000.
b. Operating Income/Sales.
c. Healthcare operating margins
d. Standard & Poor's Analysts' Handbook.
e. Novartis financial leverage is substantially below the average for the industry. For Novartis, Debt/Total Assets averaged 5.8% from 1996-2000, compared to an industry average of 9.5%.

ENDNOTES:

i. For an extensive, nuanced report on the implementation of the Global Compact Initiative within the changing multinational pharmaceutical environment, see Klaus Leisinger, "Towards Globalization With a Human Face: Implementation of the UN Global Compact Initiative at Novartis" (http://www.foundation.novartis.com/novartis_un_global_compact_globalization.htm).
An executive with Novartis and at a predecessor firm since 1974, Leisinger is President and Executive Director of the Novartis Foundation for Sustainable Development. He is a member of the Steering Committee charged with implementing the Global Compact at Novartis and is closely associated with the process.

ii. *Only One Company*, *Novartis Operational Review 1996*, (Basel, Switzerland: Novartis), 1996.

iii. Robert Langreth, "Reviving Novartis," *Forbes Magazine*, Vol. 167, February 5, 2001, pp. 90-96.

iv. Gardiner Harris and Vanessa Fuhrmans, "Its Rivals in a Funk, Novartis Finds A Technique to Thrive: Swiss Drug Maker Embraces Bare-Knuckled Marketing," *The Wall Street Journal (online)*, August 23, 2002.

(wysiwyg://4/http://online.wsj.com/publi...e_print/0,,SB103006648654413035,00.htm)

v. Ursula Wynhoven, "Case Study of How Novartis International AG Has Begun the Process of Delivering on Its Commitment to the Global Compact," July 2002. (Unpublished case study.)

vi. Of the over US$ 2 billion budgeted annually for research and development, about one-third is allocated to collaboration with other research centers. This share, in the upper range for pharmaceutical companies, is deemed necessary in order to keep the 300 scientists at Novartis in close contact with the many drug discovery networks of interest to the firm. The importance of discovery networks is underscored in the 38-year history of the Novartis drug Gleevec summarized in the next section.

vii. The official name of the drug is Gleevec in the United States and Glivec in the rest of the world. Before April 2001, it was referred to as STI571, a term still in use.

viii. B.J. Druker, Presentation at the 41st Annual Meeting of the American Society of Hematology, December 3-7, 1999, New Orleans

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