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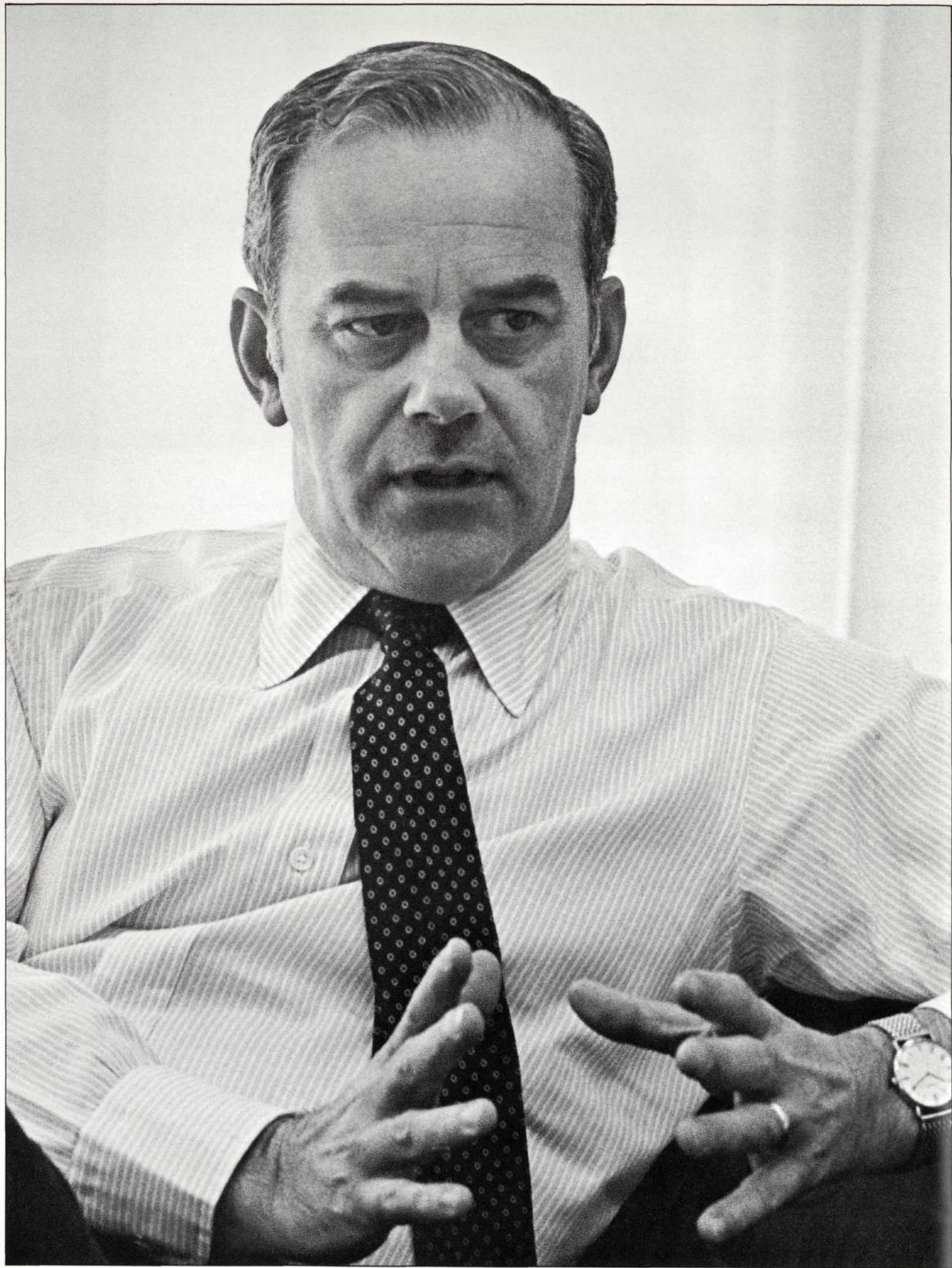


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An interview with Schering-Plough's **Bob Luciano**

V.A.: What do you see ahead for the pharmaceutical industry?

R.P.L.: I anticipate a period of renewed growth after a time in the seventies when the industry experienced a somewhat flatter period than it had been accustomed to. This will result, I think, from the converging effects of several factors. First, you have to remember that the research cycle is not a linear process, unlike a production process where you put in so many widgets, the line moves along at a predetermined rate, you add so much labor and out pops the product.

Research is a demanding, creative process, although it does have a natural rhythm, a cyclical pattern. The process also depends to a certain extent on accumulating a reservoir of knowledge which can be exploited. Right now, for instance, a whole new base of knowledge in biology is emerging. Perhaps for the first time, the function of cell receptor sites is being defined and understood. Concurrently, we are also building a whole new discipline focusing on the "tools" to exploit this new biological knowledge, such as the recombinant DNA technology that has only become commercial within the last year or two.

We are learning at an accelerating rate, and so we're coming to a point in the history of this industry where we are going to have quantum increases in the type and number of products coming to market. If you look at most forecasts, the consensus is that the industry is going to grow from the 1980-81 level of \$75 to \$80 billion worldwide to a \$145 to \$150 billion level by the end of the decade, 1990. This represents a real growth rate of about 6 percent, which is better than we experienced in the 70s. In the 1970s, the real growth rate—depending again on whom you talk to—was probably 4½ to 5 percent. So I think we are coming to a pretty healthy period for the industry from the standpoint both of new products and sales and profits.

In this special *DH&S Reports* interview with Morristown partner-in-chief Vic Albrecht, Schering-Plough Corporation President and Chief Executive Officer Robert P. Luciano explores the current state of the drug industry and new drug development, the outlook for the future, and, most especially, Schering-Plough's role as an international marketer of pharmaceutical and consumer products.

Mr. Luciano, an attorney, held high-ranking positions with several leading pharmaceutical companies before joining Schering-Plough as senior vice president for administration in 1978. He was named president and chief operating officer in October 1980, and has held the post of president and chief executive officer since February of this year.



Schering-Plough Corporation: *a profile in brief*

Schering-Plough Corporation, by its own definition, is "a research-based pharmaceutical company whose worldwide business is enhanced by leading brand-name consumer products." Based in Kenilworth, N.J., the Fortune 200 corporation has some 27,000 employees and operates manufacturing facilities in more than forty countries. Sales in 1981 exceeded \$1.8 billion.

Following recent fundamental advances in the recombinant DNA and immunological sciences, Schering-Plough carefully evaluated the commercial potential of these new technological approaches and moved decisively to capitalize on them.

Schering-Plough has already established itself as a leader in the highly promising and exciting area of research focusing on genetically produced interferon, a substance that holds great promise as both an anti-cancer and antiviral agent.

In the field of immunological sciences, the company has targeted three specific areas on which most of its efforts will concentrate during the next five to ten years. These are:

Immunomodulation, where the goal is to identify and produce entities that are specific suppressors or inducers of the body's immune response. This research may provide new knowledge for the treatment of diseases ranging from rheumatoid arthritis and multiple

sclerosis to cancer.

Allergy, where a key objective is to identify and produce substances that will prevent an allergic response by the body rather than merely block the effects of histamine after that substance has already been released in the body.

Infectious diseases, where the effort is directed toward identifying and producing substances that will stimulate the production of an antibody that is the human body's main defense against a broad spectrum of infectious diseases.

Schering-Plough's well-known consumer products include Maybelline eye, lip, face and nail cosmetics; the Coppertone line of sun-protection lotions and Solarcaine sunburn medications; Scholl foot-care products; Correctol laxatives; Duration nasal spray; Di-Gel tablets; Sardo bath products; and Paas Easter activity toys. In mid-October, Maybelline will enter the fragrance market and has scheduled a \$3.5 million advertising campaign to launch Daydreams, a medium-priced fragrance developed by Maybelline's research laboratories in cooperation with top fragrance houses.

Other divisions of Schering-Plough include animal-health products; vision-care products, such as the hard and soft contact lenses marketed under the Wesley-Jessen brand; DAP home products; and Plough Broadcasting, which operates six AM and six FM radio stations. □

V.A.: With this kind of potential for achievements in medical science and your company's record as a major innovator in the pharmaceutical industry, what is Schering-Plough's plan to enhance its future and improve its position as a world leader in the health and personal-care fields?

R.P.L.: We view ourselves first and foremost as an ethical, research-based pharmaceutical company. If that is our principal or core business, that's what our strategy for growth has to revolve around—and it does revolve principally around research. We have increased significantly the financial resources devoted to our research programs. These expenditures have been growing at a compound growth rate of about 20 percent a year for the last two to three years. They will probably grow about 20 to 21 percent this year, and I would look for a compound growth rate over the next five years in the range of 15 to 18 percent annually.

In addition to putting more dollars to work, we have concentrated the research program on several major areas. If you have a nonfocused program, no matter how much money you pour in, you will dilute your efforts and waste those valuable funds. The paths you can pursue are so varied and so many that, even with a fairly substantial budget, and ours will be about \$130 million this year, you have to concentrate your activities. So we streamlined the program from eight or nine areas that the company was working in several years ago to four basic areas of concentration; namely anti-infectives, cardiovasculars, anti-inflammatories and allergies. And we defined it even further by selecting specific targets in those four areas toward which we intend to direct our activities. The newly developing technology that I mentioned earlier lends itself very nicely to the accomplishment of results in our target areas. For example, we are fairly heavily involved in the recombinant DNA field, as you know, first through our investment in Biogen, an international organization of genetic scientists, and second through our development of an in-house R&D capability and manufacturing capacity.

As part of our research realignment, we also decided to actively pursue our interest in the field of immunology, which was growing at a very rapid rate. The tools used in recombinant DNA technology can also be applied to the field of immunology, and, conversely, some of the tools developed to be used in immunology complement the skills used in the recombinant DNA area. So

for us it involved an increased financial commitment to coincide with our redirected strategic thrust. We have also restructured our personnel and improved things tremendously through a number of changes in key managerial slots. And last, but not least, we put in management systems that enable us to track a program financially as well as in terms of objectives, to have finite cutoff points so that a program doesn't go on forever just because it was started. We are using new management tools for the periodic measurement of accomplishments against predetermined goals, and we know where we are going and how we are going to get there. To sum up, intensified and targeted research is our principal strategy for the company. In the final analysis, research is the essential core of our business.

V.A.: How does the recent acquisition of DNAX (a biotechnology research firm concentrating on immunology and genetic engineering) fit into Schering-Plough's overall research strategy?

R.P.L.: As part of our program to establish a capability in immunology, we set up several task forces to study both the scientific feasibility of various areas in which developments were most likely to take place in the 1980s and to assess the commercial attractiveness of those areas. The task force that looked at immunology identified a program which we thought was quite interesting, and we were setting out to pursue it by constructing a laboratory in France and building an immunology infrastructure from the ground up. Some of the skills necessary had to be recruited from outside the company. By pure coincidence, I received a phone call about a possible joint venture with the DNAX people on a specific project.

When our people began talking to the DNAX group, they developed a growing appreciation for the caliber of scientific talent that had been assembled at DNAX within the one year of its existence. That particularly talented body of people represented a really valuable asset, one that, if we were to build at all, could only be assembled over a period of years and perhaps couldn't be built at all within an internal industrial setting like ours. It really required a quasi-university environment.

One thing led to another as we described our program to them and they described their capabilities and interests to us. Each group became impressed by the other, and we concluded that Schering-Plough could expedite our in-house building process and perhaps gain two or more years in developing an immunology infrastructure of a quality that perhaps we might never have achieved. So DNAX enabled us to do earlier what we had already decided to do. They adopted our program, and adopted it wholeheartedly, I might add. So for us, it was a shortcut in a race which I think is going to go to the swiftest.

V.A.: In view of the presently clouded picture regarding patents in biotechnology, how does Schering-Plough view the issue of patent protection?

R.P.L.: Schering-Plough and most pharmaceutical companies, most research-based companies, have a large investment in the development of technology. We have a policy of respecting patents in any field in which we're active, as do our competitors. This policy is one that, because of self-interest, will not be abandoned lightly by anybody. The record will demonstrate that our patent position, for example in the interferons, which was the first of our recombinant projects, is based on what we have been able to research and produce better than anyone. I have never been prepared to concede that valid, enforceable patents would not issue through this technology. I remember when I first started talking about this in January or February of 1980, I got a lot of questions from the security analysts regarding patentability. I took the position then, and I take it now, that valid patent protection will issue. That has been justified in part by the patent position in the case of the General Electric research scientist who developed an organism that eats oil slicks.

The fundamental question of the patentability of the living organism was addressed by the Supreme Court, and it was found to be patentable. That case

did not dispose of all the issues, but I think it indicates that we're moving in the right direction. The issuance to Stanford University of some of the basic process patents is another indication that we're moving in the right direction. Logically, there should be valid patent protection in the field. I think the record indicates that, in the case of the interferons at least, Schering-Plough is going to achieve a superior position.

V.A.: Realistically, when can we expect to see new pharmaceuticals emerging from Schering-Plough's research in biotechnology?

R.P.L.: When we first announced our collaboration with Biogen in the development of leucocyte interferon, we set a timetable of having a product on the market in 1984-85. That was a very ambitious target because, if you look at studies of the development of a pharmaceutical product, the normal time from inception to marketing is about ten or ten-and-a-half years. In early 1980, we were projecting four to five years, so I think you can appreciate that this was a very, very aggressive time schedule. We slipped behind at several points, but we made up time at others, and we're right on schedule now. I think we're likely to see an interferon product on the market in 1984. With respect to products from some of our other biotechnology investments, such as DNAX, we recognize that this project is a long-term investment. Our time-frame, therefore, is to have a marketable product in five to ten years. I think we'll see products being tested in the clinics in three to five years, and I think we'll see products on the market in five to ten years. As an optimist, I'd say less than ten years, but that remains to be seen.

V.A.: With respect to the restraining effects of government regulatory activities on pharmaceutical research, has the current administration fulfilled its promise to remove unnecessary barriers to new drug discovery?

R.P.L.: The present administration, particularly with the appointment of Dr. Arthur Hayes as Commissioner of the Food and Drug Administration, took a giant step forward in regulatory matters. Dr. Hayes is a competent, realistic administrator. I think the process of easing the regulatory pathways is going to be a longer one, however, than the administration anticipated and the industry hoped for when this administration came to office. But some steps already have been taken in that direction. The antibiotic certification program has essentially been abolished, and, quite recently, Secretary of Health and Human Services Richard Schweiker announced a complete reorganization of the new drug application process, which embodies within it a number of features long sought by the industry. For example, in the past, even with good, valid clinical data from European sources, we had to duplicate the work. The FDA would approve drugs only on the basis of U.S. experience, U.S. tests, regardless of the validity of overseas testing.

That began to change two or three years ago, and this year the agency did approve an indication for a new product solely on the basis of foreign, in this case Norwegian, data. It's now official FDA policy to accept foreign data if the studies have been conducted properly. That's a giant step forward. That is going to save a lot of needless duplication. The mechanical process of reviewing a new drug application has taken between two to three years—and that's just to review an application once it has been filed. The process has been one of reviewing it seriatim—you review your whole section in chemistry, I review my section of biology, somebody else review his... one after the other. The new process espouses a concept that we've been after for a long time, concurrent review, which is a logical process.

Also, there was no effective appeal from a reviewer's determination on a scientific point within your application. If he didn't agree with your conclusion and wanted more data, you went out and got more data because there was no other way of approaching the problem, no workable appeal mechanism within the system. The new proposal, I understand, is going to provide a mechanism for appeal to a board of FDA scientists and outside independent scientific experts who will review the subject of any disputed scientific material and make a determination as to who is right or wrong. This is sorely needed. There are

**Robert Luciano
on drug research...**

'the need for a clear strategy, a clear focus'

"New drug development requires a very heavy investment in research. Schering-Plough spends about \$130 million a year, and we're by no means the biggest spenders. The time required to develop a new drug may easily be ten years, so you have to invest a lot of money year after year after year. In the past, these outlays were made on faith, as if to say: 'We had a drug before and we'll certainly have one again.' And maybe, if you went from year to

year, just on the basis of sheer volume, it eventually did happen.

"But I think we'll see a winnowing of companies in the 80s, because the research process is becoming more expensive, and the return on investment—if you want to look at it purely in those terms—becomes more and more difficult to justify unless you have a certain 'critical mass'.

Although it finally seems to be changing, government policy has

made the drug development and testing process more expensive and more involved. And this is while, at the same time, the government talked about wanting to increase competition. After ten, fifteen, even twenty years of policy that's been highly restrictive, the government has produced the opposite effect—and only those companies with a clear strategy, a clear focus and sound resources and talent are really going to make it."



lots of steps which could shorten the process. Take a very mundane example: new drug applications literally require truckloads of data because we are required to supply every single clinical form, and there may be three or four thousand patients. Every time they visit a doctor, there's another form filled out. We've supplied every piece of paper that's required. We've argued for years that we should be able to provide summaries of the data and have the other material available should the reviewer want to see it. The summaries would be akin to the material we now provide in scientific publications—detailed summaries of some fifty to 200 pages. That has not been acceptable in the past. Everybody wanted the raw data so they could start from day one and build up their own analysis. Under the new proposals, the raw data will be available but summaries will be acceptable. There should be appropriate penalties for anyone providing a summary which does not accurately reflect the data in the package; that's only fair and reasonable. But the summaries will make things a lot easier for everyone. So, yes, the administration is moving in the direction of reform, but just announcing those steps is only the first part. Implementing them, changing the basic structure, is going to take a long time. There are no shortcuts. But the goal of this program is to reduce the timeframe for review by six months. This doesn't sound like a lot, but it is, and it would be a big step forward.

V.A.: In the light of an apparent worldwide recession, what is the outlook for the international segment of Schering-Plough's operations?

R.P.L.: International operations are one of our bright spots. Schering-Plough is a fairly well-balanced company, with almost half our sales coming from overseas. There are recessionary problems in many of the countries we deal with now, and, of course, the problems of hyperinflationary economies in Argentina and Brazil. But, with the global scope of our business, problems in one place are usually offset someplace else. And we haven't fully exploited the opportunities available to us overseas, particularly on the consumer side of our business, which has not been as fully developed overseas as our pharmaceutical business. So the opportunities for growth overseas, in spite of current, essentially cyclical economic problems, are enormous.

V.A.: Like many international companies, Schering-Plough's earnings have been severely impacted by the stronger U.S. dollar. What steps have you taken to minimize the effects of currency fluctuations on Schering-Plough's profits?

R.P.L.: We've done a number of things. We adopted FASB 52 in 1982, which, while not perfect from Schering-Plough's perspective, does represent an improvement. I say not perfect from Schering-Plough's perspective because, as you know, the new rule still treats hyperinflationary economies much as the old FASB 8 did, and a large portion of our investment in South America happens to reside in two hyperinflationary economies, Argentina and Brazil. Moreover, the new rule, unlike the old, requires the recognition of gains and losses on currency which still flow through the profit-and-loss statement. So while our exposure has been moderated, it certainly hasn't been dramatically affected by FASB 52. Therefore, we've engaged in many of the transactions that companies in this situation resort to—typical hedges, some currency swaps, forward contracts and balancing our exposure abroad by having loans in local currencies. But it's very, very difficult to significantly impact a number of our exposures because, while hedges are available, the economics at any particular time may dictate that you not take certain steps. That is to say, the cost of the transaction may be greater than the potential currency loss. So while we've moderated our losses, we've still experienced a fair degree of problems from the fluctuation of currency, particularly with the continued strengthening of the U.S. dollar.

V.A.: In recent years Schering-Plough has engaged in a number of acquisitions. Do you envision any major acquisitions or other significant moves to expand business opportunities over the near term?

R.P.L.: We have a formal acquisition program and we've been relatively active. We've made 12 acquisitions of various sizes, from a sales volume of \$10 million up to sales of \$300 million, since January 1978. We will continue to look for a company that fits our philosophy of doing business, and one which will enable us to achieve more easily our goals and objectives. But we're not going to purchase a company just for the sake of growing in size or because it

seems fashionable. However, based on our past track record, which I think has been good, if we uncover a good fit for us through our efforts, we'll pursue it.

V.A.: What do you consider to be Schering-Plough's major strengths?

R.P.L.: There are several. One is balance. We are balanced between international and domestic operations fifty-fifty. We are also balanced between consumer and pharmaceutical operations roughly in the same ratio. So we do have balance. A cyclical downturn or geographical problem in one segment may be offset by the other. We also have a very strong balance sheet, which enables us to pursue our objectives without undue concern. In both segments of the business, consumer and pharmaceutical, we have achieved a degree of marketing expertise which I think is as good or better than just about anyone's. The record of both those groups demonstrates that. And we've achieved, in both segments of the business, a reputation for quality which enables us to develop new products that are readily accepted by the consuming public and by the physician. In addition, we've completed a restructuring of our management and a recruitment of several key executives that gives us a management team to exploit those strengths in the 1980s. I think those essentially represent our key strengths.

V.A.: In building a management team, what qualities do you look for in key personnel?

R.P.L.: First of all, you've got to have someone who has a high degree of intelligence and knowledge about the business segments you're asking him to devote his skills and talent to. That means someone who can think strategically, looking beyond day-to-day problems; someone who can map out a plan, a direction in which you want to take the business and then stick to and implement that plan consistently and creatively. By creatively, I mean not being wed to practices that we've grown up with just because we have grown up with them. I mean being willing to explore new ideas, to fail in some new ideas, to try different approaches when one does fail.

The qualities I look for in a manager include flexibility and, most important, a willingness and a confidence in his or her own ability to make decisions. Too many people avoid decisions and let events take their own course. I'd rather have somebody who's making decisions actively, even if he's making them occasionally differently than I would. I'd rather have him actively managing the business than taking a passive approach. And last but not least, you have to look for compatibility. No matter how intelligent, how competent a manager is, if he doesn't fit in with the rest of the team, if he doesn't contribute outside of his own area, if he's a narrow specialist with little interest in the business as a whole—then you're going to miss some of that interplay that serves as a check and balance on other people and is so vital in any dynamic, progressive organization.

V.A.: How do consumer products fit into the overall operation of Schering-Plough?

R.P.L.: One of the strengths of the company, as I noted, is that we are balanced between pharmaceuticals and consumer products. Our consumer operations are based fundamentally on well known and respected brand-name franchises that allow us to ride out occasional weaknesses that may develop in the general marketplace. For example, in our Maybelline cosmetic business—one of our stars—we've grown consistently in the last several years at a faster rate than the cosmetics industry as a whole. The paramount reason is that we continually provide a high-quality product at moderate prices. This is largely attributable to our successful mass-merchandising approach that is supported fully by strong and innovative advertising campaigns. Even in a recessionary economy, a woman is more likely to switch to a more moderately priced quality product than give up cosmetics. We provide that lower-priced quality product, we fill that niche.

The management group in our Maybelline operation is typical of our other consumer operations—it's an aggressive management that's looking for niches to fill in the marketplace. They found an opening for a moderately priced fragrance and, at the end of this year, we're introducing a new fragrance, a daring move at this particular time. But I think we've planned it out well, and I think we'll succeed with the plan.

The rest of the organization has also been searching out niches. We dominated the sun-care market, with a 46 percent share last year. We've taken a market which used to be thought of as essentially suntan oil and we've segmented it. We came out with Tropical Blend lotion which went after the youth market. We developed a series of products for the winter markets, such as skiing. Recently, we came out with a product called For Faces Only, which was formulated specifically in response to consumer's needs from the standpoint of scent, nongreasy properties and moisturizing properties. And so we've continued to grow in a market that had been relatively stagnant, one in which we dominate by segmentation and niching. Our people have done an exceptionally good job.

On the proprietary drug side of the business, we benefit from demographics. As the population grows older, as medical care becomes more expensive, people turn more to self-medication, and we have a number of products which address themselves to these needs and wants. The consumer products side of our business complements very well the pharmaceutical side—it's been a very good fit for us.

V.A.: In laying out a roadmap for the restoration of American industrial leadership, what do you see as some of the basic problems?

R.P.L.: Americans tend to look for quick fixes. Whether the question is productivity or the Japanese, we always look for the quick solution to the problem. Right now the fashion is to emulate the Japanese because they are seen as doing everything so well. If you really think about what the Japanese do, if you study them carefully, you find that their attitudes and methods are tied closely to a culture that's been developing for several thousand years in one direction—a direction which is different from our own, not necessarily worse, not necessarily better, but different. Some of the things they do make sense, and we should adopt them. The quality-circle idea—which, incidentally, originated in the United States—has been utilized extremely well by the Japanese. The quality-circle idea is a good one and we have adopted this approach at Schering-Plough.

But to emulate everything the Japanese do is neither desirable nor necessary. One of the things we should emulate—and it's not necessarily a Japanese trait because I first became familiar with it while working for a European company—is a longer-term view of business operations than Americans customarily take. American management is driven by quarterly reports, from one quarter to the next. That can be unhealthy because the result may lack a coherent, long-term strategy. We must adopt a long-term strategy, know what we want to be, have an idea of how we're going to get there and then pursue that goal. We have to be willing to live with the short-term ups and downs involved in pursuing that strategy. Of course, we can't totally ignore the present—not if we want to survive. But the principal emphasis should be on the evolution of a consistent, coherent, intelligent strategy. That's what we're doing, for example, with our research program. As I said earlier, we've increased our research expenditures between 20 and 22 percent annually for the last few years. Last year, even with profits down, we did not depart from that strategy. We know what we want to be, we know how to get there, we have an intelligent plan and we're going to pursue it consistently. That doesn't mean we will ignore year-to-year earnings—but they're not going to be the driving force. □