

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. folder	Women's Voices '92 (134 pages)	Sep. 1992	Personal Misfile
002. fax	From: Rutgers Center for the American Woman and Politics, To: Missy Darwin (20 pages)	10/7/92	Personal Misfile
003. report	Research Stories (16 pages)	1992	Personal Misfile
004. memo	From: Kim, To: Melanne and Maggie (9 pages)	n.d.	Personal Misfile

COLLECTION:

Clinton Presidential Records
First Lady's Office
Liz Bowyer
OA/Box Number: 3988

FOLDER TITLE:

Women

2014-0483-S

sb504

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
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WOMEN

PHOTOCOPY
PRESERVATION

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WHEN WILL WOMEN GET TO THE TOP?

Not for a long time yet, according to a new FORTUNE CEO poll. But a few pioneers are already there, and a growing crowd of others are doing all the right stuff. ■ by Anne B. Fisher

TALK FOR A WHILE with any woman who has worked her way to the top of a sizable U.S. corporation. You'll get a strong sense that she feels a bit like *Apollo 14* astronaut Alan Shepard when he improvised a six iron out of a piece of lunar equipment and, one-handed in his cumbersome space suit,

whacked a golf ball that flickered eerily across the airless surface of the moon. Exhilarated, isolated, keenly aware of the world's attention ("Houston, can you see me now?"), female high executives are eager to colonize this unaccustomed terrain with more of their own. But like astronauts, they know too much about the rigors of the journey to believe that it can happen by next Wednesday, or even by next year. Says Carol Bartz, 44, recently named chairman and CEO of Autodesk, a leading maker of software for engineers and architects in Sausalito, California: "I think that women in corporate America are still a generation away from real success."

Alas, the top men in corporate America appear to agree. A poll of 201 chief executives of the nation's largest companies, conducted exclusively for FORTUNE by the opinion research firm Clark Mairle & Bartolomeo, reveals that only 16% believe it is "very likely" or "somewhat likely" that they could be succeeded by a female CEO within the next decade. And only 18% think it's "very likely" that even after 20 years a woman would be picked to run their companies.

Why? The CEOs in our survey cite a host of reasons, but the biggest barrier, as a few of them admit, is an irrational one—plain and simple discrimination. Notes John H. Bryan, 56, CEO of Sara Lee: "I'm not sure there's a lot that women can do about it. They're already working hard and are very qualified. It shouldn't be this way, but too many senior managers, and particularly CEOs, tend to want to pass their jobs along to someone who's the image and likeness of themselves." John Nelson, 48, who heads Norwest Colorado, a bank holding compa-

Q How likely is it that your company will have a female CEO ...

	In next 10 years?	In next 20 years?
A Very likely	2%	18%
Somewhat likely	14%	63%
Not very likely	42%	15%
Not likely at all	40%	2%
Not sure/no answer	2%	2%

ny, agrees: "The problem with women advancing has more to do with men than with women. Men have dragged their feet."

Thanks for the honesty, guys, but that's pretty discouraging news. And coming during an election year in which, incredibly, some conservative politicians and leaders of the religious right are openly or implicitly condemning the very notion that women *should* work outside the home, it's enough to make even the most optimistic female executive despair. That would be wrong, however, because better days *are* coming.

True, progress has been painfully slow and there has even been some backsliding. Susan Lowance, director of senior executive programs at MIT's Sloan School of Management, points out that the executive training seminars run by U.S. business schools—an indispensable credential for future CEOs in many companies—are as most as exclusively a male preserve as Behemian Grove. Enrollment in these

REPORTER ASSOCIATE Therese Eiben



IRENE ROSENFELD, 39, executive vice president, Kraft-General Foods: "Do your job brilliantly, and the cream will rise to the top."



CAROL BARTZ, 44, chairman and CEO of California software maker Autodesk: "You have to be willing to step out of the pack and take risks, even jump completely out of your element if that's what it takes."

programs nationwide is just 5% female, after peaking at 8% in the late 1980s. "Companies were trying a little harder, for a while, to develop senior women managers," Lawrence explains. "But the recession scotched that. In tough times, top management prefers to entrust the risks that accompany decision-making at the highest levels to a known quantity—meaning someone like themselves. A man."

Here's more bad news: The Department of Labor's latest report on the limits to promotion of women at 94 major government contractors finds that few are being groomed for senior-level jobs. "The glass ceiling in most companies is a lot lower than we thought it was," says Labor Secretary Lynn Martin. "And too few women are getting the training they need to move up."

Nor have women managers achieved paycheck parity with men. Among all females with full-time jobs, the much publi-

cized wage gap between the sexes keeps shrinking. On average, a woman now earns about 74 cents for every dollar a man brings home, up from 65 cents a decade ago. Those relative gains reflect the fact that women are better educated and hold more highly skilled positions than ever before.

Q How has the number of female executives in your company changed over the past five years?

A	Middle managers		Officers	
	Increased	92%	62%	
	Decreased	0	1%	
	About the same	8%	36%	

What's frustrating is that at the same level of management, the typical woman's pay is lower than her male colleague's—even when she has the exact same qualifications, works just as many years, relocates just as often, provides the main financial support for her family, takes no time off for personal reasons, and wins the same number of promotions to comparable jobs. That discouraging conclusion comes from a new study of 1,029 managers at 20 FORTUNE 500 companies across eight industries. Over five years ending in 1989, women managers' pay increased 54%, their male counterparts' 65%.

Says Linda Stroh, 44, one of the study's co-authors, who teaches in the Institute of Industrial Relations at Loyola University in Chicago: "The disparity probably comes partly from the lingering and often unconscious perception that women are going to leave to have babies. But the women managers we studied were in the work force to stay and had done all the right stuff. It still wasn't enough."

Even so, most of the available data support the notion that, on balance, women in the workplace undeniably are advancing. To a man—and that's what they all are—the CEOs polled by FORTUNE say over the past five years the number of female middle managers at their companies has either increased (92%) or stayed about the same (8%). As for female officers, 62% of chief executives say their number rose as well. Insists Richard Deihl, 64, chairman of H.F. Ahmanson & Co., a big California mortgage lender: "Women are already moving up into higher and higher positions. We should at least see a woman chief operating officer here well before 20 years from now."

Labor Department statistics support this upbeat forecast. Using a broad-gauge definition of "manager" that includes everybody from the head of a fast food restaurant to a CEO, Labor reports that about 41% of U.S. managers were female as of mid-1991, up from 32% in 1983.

FORTUNE's own research suggests that a similar though smaller increase occurred in the number of top female managers. To see if America's business leaders were really walking their talk on this subject, we commissioned Directorship, a research and consulting firm in Westport, Connecticut, to comb the 1986 and 1991 annual reports of the companies whose

bosses had answered our CEO poll. Its task: to tally the number of women who held senior positions in those two base years. We defined "senior" as a job within three levels of management of the chief executive's office. In the case of staff, that would encompass a chief financial officer or his equal, a company comptroller and his counterparts, and finally, say, someone like the head of the accounting staff. Among line officers, the three tiers might stretch from president to a division head.

Of this select group, 4.8% in 1991 turned out to be women. Think that's small? Go back five years, to 1986: Only 2.9% of senior managers were then female. Gazers at the half-empty part of glasses will quickly complain that roughly 5% is still a scant one-tenth the number of female managers we would have if women's presence in the executive suite matched their representation in the rest of the workplace. (Women now account for nearly half all full-time U.S. workers.) An optimist, of course, would applaud a rise of nearly 60% in just five years.

MOST IMPORTANT, evidence abounds that women's second-class citizenship in corporate America is finally about to be upgraded. Sex discrimination is already less of an obstacle in some industries than in others. High-tech and service companies, for example, are generally more inclined to promote women than old-line manufacturers in businesses like steel and autos.

One important agent of change will be demographics. Restructurings and layoffs have produced a surplus of skilled, experienced managers of both sexes. But rock-bottom birth rates in the early and middle 1970s guarantee that later in this decade and well into the next one, not enough boy baby-busters will be there to fill the new managerial jobs that the economy will generate. Any business that wants to stay competitive will have to hire, train, and reward women.

Another demographic factor is the increasing prevalence of two-career marriages. Ellen Galinsky, co-president of a nonprofit New York City research and consulting group, the Families and Work Institute, often conducts focus groups with men in their 20s and 30s. "These men are almost all in dual-career households, and they have a totally different perspective from their fathers' generation," she notes. "They empathize far more with conflicts between family and work responsibilities,

Q How widespread a problem is discrimination against women?

	Middle management	Top executives/officer level
Very widespread.....	6%	20%
Somewhat widespread.....	52%	44%
Not really a problem anymore.....	38%	31%

since they know firsthand what it's like to have no full-time help tending the home fires. They quite often say to me, 'These guys upstairs who are running things just don't understand.' "

Galinsky believes that as the current crop of thirtysomethings ascend to positions of power, companies' cultures are bound to become more flexible—and less insistent

that a valued manager choose, in effect, between a child and a promotion. Jill Elikann Barad, 41, who in July was named president and chief operating officer of Mattel, the \$1.6-billion-a-year toy-maker, shares that faith in generational change. When told the results of FORTUNE's CEO poll, she dismissed as "ridiculous" the notion that women must expect to wait 20 more years to become chief executives. She says: "I don't know how these guys can say that. Maybe they won't be the ones making the decision."

Finally, there's the "pipeline" argument. For at least ten years we've all been hearing that while there aren't yet enough qualified women, as their number and experience increase, more will reach the top. Fully 64% of CEOs in FORTUNE's poll attribute women's absence from the executive suites in large part to lack of experience. "We've always joked that it takes 30 years to be al-

D. J. HULET, 36, regional marketing manager, Pacific Bell: "I'm very candid and speak my mind. Other managers have told me, 'If you did the same things you're doing and you were a guy, you'd be OK.' "



lowed to empty the wastebaskets around here," says Charles A. Corry, 60, chairman of USX Corp. "It took me 21 years and 12 job changes to become a vice president. It's the same for women. It takes time." Robert C. Winters, 60, CEO of Prudential, agrees: "Women should persist, endure, hang in. The wave is really crest high now. Women are making a mark, but they have to keep up the good work."

It's been a wearisome slog, but a light is now glimmering at the end of the pipeline. The Bureau of Labor Statistics reports that there are 6.1 million female managers in the U.S., up from about 3.5 million in 1983. These women, many of whom are in their early 30s to mid-40s, are the first generation to accumulate the same education, experience, and expectations as their male counterparts, and to find strength in their considerable numbers. Says MIT's Susan Lowance: "If many women are ever to reach the top of corporations, it's the ones in that big middle-management group who are going to do it." Labor Secretary Martin expects those middle managers to push hard for recognition. "A lot of us thought our pioneering days were over," she says, "but they aren't."

That's why the smartest companies are devoting ever more time and resources to broadening and developing the talented female middle managers they have already hired. Hardly any of the CEOs polled by *FORTUNE*—only 8%—think women lack the aggressiveness or determination to scale the corporate heights. And just 5% said that women should be more willing than they are to relocate for a promotion, an issue that some studies have suggested is keeping good female managers down. But nearly half insisted that the reason it will take two decades for a female to rise to the top of their companies is that women managers are still too concentrated in fields such as communications and human resources, which rarely if ever lead upward.

"It really isn't a question of what else women should be doing. It's a question of what companies should be doing to ensure that women are getting the opportunities men get," says William Ruckelshaus, 60, chairman of Browning-Ferris Industries. Even in relatively nonsexist industries like retailing, some CEOs think there's much to be done. "We have to step up our commitment to exposing women to different dimensions of the business," says Allen Questrom, 51, chairman of Federated Department Stores. "Management has a clear



KERRI BAUCH-SPARKS, 37, information systems manager at a Monsanto plant in Illinois: "Some men's initial reaction to diversity training is defensive. They think it's going to be a lot of finger pointing."

responsibility to prepare women for broad-based roles."

Toward that end, dozens of corporate colossi, from AT&T to Johnson & Johnson to Xerox, have hired full-time "diversity managers," charged by top management to make the workplace more hospitable to talent of either sex and all colors. In some cases this is pure tinsel and tokenism, but for many companies it's a hard-nosed business strategy. Says Actna Life & Casualty CEO Ronald Compton, 59, who is largely responsible for the fact that roughly half his company's managers are now women: "I'm not doing this out of the goodness of my heart. I'm selfish. I want the very best people I can get. A lot of them happen to be women." No diversity campaign will succeed without that kind of blessing from the top.

Alarmed that turnover among female engineers and salespeople was twice as high as among men, chemical giant Monsanto hired a consultant to do exit interviews with departing women. Most said they'd had better offers from competitors or planned to start their own firms. "There is a glass ceiling at Monsanto," admits vice president of administration Michael Miller. "We're trying to break it." How? Like many another company with a formal diversity program, Monsanto now evaluates—and

pays—its managers partly on the basis of how carefully they identify, train, and promote women.

Accounting behemoth Arthur Andersen recruited Joseph Stokes, a psychology professor at the University of Illinois at Chicago, to help it work out a diversity program. Stokes says that to ensure that women get more of the broad experience required to rise to officer status, companies must stop assuming that men are automatically more willing than women to leap across divisional boundaries for new assignments. "More companies need to ask both women and men what their long-term career goals are, what kinds of jobs would interest them most, whether they'd consider an overseas transfer, and so on," says he. "And then use that laundry list—which is a kind of blueprint of a person's ambitions—and develop everyone accordingly."

BYOND ALLOWING qualified women an equal chance at the same jobs men get, diversity-minded companies are trying to recast their cultures so that old attitudinal hurdles don't trip up women who might otherwise be gold medalists. Nancy Hamlin, president of consulting firm Hamlin Fox in Marblehead, Massachusetts, has



HAZEL O'LEARY, 55, executive vice president, Northern States Power in Minneapolis, is learning how to play golf; "Without losing your personality, it's important to be part of the prevailing corporate culture."

spent 25 years as an adviser on gender issues to General Electric, Hewlett-Packard, Digital Equipment Corp., Fleet Bank, and the U.S. Coast Guard. She says that even in the best-intentioned and most progressive companies, women are usually kept out of the informal channels of information, where important decisions sometimes crystallize. Female managers, for example, are left behind when their male peers go out to lunch, or to a sporting event, or on a good old-fashioned pub crawl. "Men don't do this on purpose," Humlin says. "They just don't think about it."

She and other diversity experts add that, since the Anita Hill-Clarence Thomas debacle, fear and confusion have multiplied. As she says, "Male executives will think, 'Hmmm, wouldn't it be easier, and safer, to take this business trip, or go to that client dinner, with another guy?'" But the most pervasive problem, and perhaps the most intractable one, is that a lifetime of social conditioning has trained many men to think of women as sweethearts, wives, daughters, secretaries—not as equal colleagues. Muses Hamlin: "It's hard to completely re-socialize people."

Hard, but not impossible. Short of waiting for the diehard chauvinists to retire or threatening to fire them if they can't get with the program, what can top management do? Monsanto's diversity effort is

typical. The company holds workshops, run by consultants Pope & Associates, designed to expose and dismantle workers' prejudices. About 5,000 Monsanto employees have attended the six-day sessions, and more are signed up to do so.

Keri Bauch-Sparks, 37, an information systems manager at a Monsanto chemical plant in Sauget, Illinois, has been through this drill twice in the past four years. "Some men's initial reaction to it is defensive. They think it's going to be a lot of finger pointing," she says. "But the idea is to improve communications for everybody. Once people see that, they're generally enthusiastic."

In one exercise, the moderator asks group members to write down every stereotypical notion about women they can think of, and the answers are posted on the walls for discussion. One widespread per-

ception among men, which comes up repeatedly, is that women make lousy candidates for promotion because they always put their personal lives, particularly their children, ahead of work. "When you see this stuff up on flip charts around the room, it gets people thinking," says Bauch-Sparks. "Society has been telling us these things for years, but do we necessarily believe they're true?" Slowly but certainly, perceptions at Monsanto are changing, and that seems to be encouraging ambitious women to stick around. Turnover is down, and a second round of exit interviews this summer unearthed far fewer responses marked by frustration and bitterness.

Rare is the company intent on keeping its best female employees and managers that doesn't have some kind of work-family program—a bit of jargon that encompasses everything from day care centers to programs that counsel employees on how to cope with the problems of elderly parents. All share the same purpose: to bolster employee productivity by eliminating some of the distractions that family life inevitably imposes on single parents and two-income couples.

Since 1971 the number of large U.S. employers that provide some kind of day care assistance has grown from 11 to nearly 4,000. Now many companies are going

Q What should female executives be doing to get to the top? (Choose one or more answers.)

A Develop a broad base of experience	30%
Go into nontraditional positions, such as operations, engineering, manufacturing	14%
Don't change; already doing what they need to do to excel	13%
Make career a higher priority than family life	12%
Be more visible/assertive	12%
Expand network of contacts	9%
It's a matter of time	10%
It's performance, not gender	6%
Get more line (vs. staff) work	6%
Be willing to relocate	5%

much further. Kraft-General Foods offers the 2,000 employees at its headquarters in White Plains, New York, a smorgasbord of work-family benefits, including nearby company-subsidized day care centers, extended parental leaves, and vacation time available by the half-day.

Irene Rosenfeld, 39, is executive vice president in charge of the \$1-billion-a-year beverage division that makes Kool-Aid and Country Time lemonade. She's also the mother of two young daughters, and she calls the work-family program "terrific." These new policies and services are not for women only. Says Rosenfeld: "Women's issues are rapidly becoming work force issues, and companies that best address them will win in the marketplace." Her own division is winning handily, with double-digit earnings increases in each of the past five years.

About one-third of chief executives in FORTUNE's survey say they've noticed that women's careers often stall out for lack of the kind of informal advice and sponsorship men get from one another. Some companies are trying to remedy that with mentoring programs that pair promising women, nominated by their department heads, with senior executives who proffer one-on-one career counseling. San Francisco-based Pacific Bell started its mentoring drive in late 1989, so the second batch of about 35 female protégées are now nearing the end of their two-year program. What exactly does a mentor do? Consider the experience of D. J. Hulet, 36. She started out in sales 15 years ago, moved up steadily, and in 1990 was assigned mentor John Seymour, 48, vice president and general manager of Pacific Bell's Orange-Riverside division.

Perhaps not surprisingly, she and he view her strengths and weaknesses somewhat differently. "I'm very candid, and I speak my mind," says Hulet. "Other managers have told me, 'You know, if you did the same things you're doing and you were a guy, you'd be OK.'" Really? Seymour explains: "Some people here saw her as very bright but too aggressive. In my opinion there's no such thing as too aggressive. But you do have to learn how to approach peo-

ple in a way that doesn't create enemies." Seymour coached her on how to influence people without alienating them, manifestly a valuable skill: Hulet was promoted in mid-1991 to regional marketing manager for Los Angeles.

As more women attain high positions, they are reaching out to guide their younger counterparts—sometimes those still in school. A University of Pennsylvania alumnae group called the Trustees' Council of Penn Women, currently headed by First

is something I didn't have when I was starting out in business," says Duckworth. "It's an 'old-girls' network," in an embryonic stage."

"Women do need to do more networking," declares Autodesk Chairman Carol Bartz. As a stellar senior executive at Sun Microsystems before taking her current job, Bartz met often with groups of women in the company for brown-bag lunches and tried to make herself available to advise anyone who sought her insights. "At some point I realized, 'Hey, these people are looking up to me,' and my first reaction was, 'I don't have time for this,'" she recalls. "But I decided I had to take the responsibility to help pave the way for others—including my daughter, who's 4."

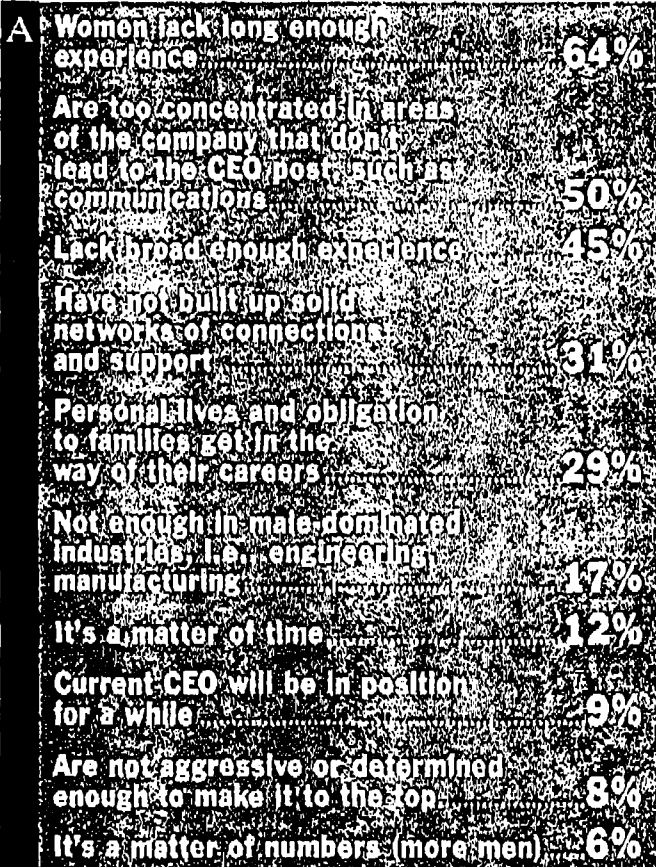
What advice does she give women who aspire to the top job? Like the chief executives in FORTUNE's poll, Bartz believes that women often don't get a wide enough range of experience. "You have to step out of the pack and take risks, even be willing to jump completely out of your element if that's what it takes," she says. It helps, she adds, to start as early as possible. Bartz knows whereof she speaks. Seventeen years ago, while still in her 20s, she quit a comfortable job as a systems analyst at 3M in Atlanta after a marketing executive at headquarters told her the company would never let a woman sell computers.

That fellow is probably kicking himself now. In 1987, with some trepidation, Bartz took over Sun's federal government sales division, an area of the business that was not only entirely alien to her but was populated largely, she says, with "cigar-chomping ex-defense contractors." In just two years under her management, the unit's revenues jumped from \$21 million to \$124 million.

"There's still a lot of folklore out there about what women can and can't do," observes Kraft-General Foods' Irene Rosenfeld. "But don't ever believe you can't do something until you've tried it." In an apt metaphor, given her position, she adds: "Just do your job brilliantly, and sooner or later the cream will rise to the top."

Over and over again, female—and

Q Why is a woman not likely to be a CEO sooner?



Interstate Bancorp senior vice president Pamela Reis, gives female seniors and business school students a list of about 70 distinguished women they can call for career advice or information. The council also runs a "shadowing" program that lets students spend a workday with a woman executive for a close-up peek at the real world. Constance Duckworth, 37, a partner in fixed-income securities at Goldman Sachs in Chicago, spent time this summer with a 21-year-old Wharton finance student. The two plan to stay in touch. "This

male—managers urge women to set career goals and work out a specific plan for achieving them. Hugh McColl Jr., 57, is CEO of NationsBank, the holding company in Charlotte, North Carolina, formed by the recent merger of NCNB and C&S/Sovran. McColl told *Fortune*'s pollsters: "Women have to push harder. They often feel that things will be done fairly, whereas men don't believe that, and in reality it's often not the case. So women must ask their bosses what's needed to get to the next level. They then need to make sure they get those opportunities,

and ask for feedback every step of the way."

But while you're pushing, keep a stiff upper lip. Mary Herbert, 41, vice president and director of quality for international operations at Motorola, has talked extensively with her female colleagues about their careers. "You do have to go to management and say, 'Here's what I think I can do; here's why; let me try it,'" she says. "But from what I've seen, women who have had a chip on their shoulder—who basically said, 'I should get this job because there are no women at this level of the company'—those are the ones

who aren't getting anywhere at all." (See following story.)

The surest way to ascend, of course, is to be so good they can't overlook you. Jill Barad won the No. 2 spot at Mattel largely because as head of the girls' toy division she had overseen a doubling of worldwide sales of Barbie dolls in under four years, to nearly \$1 billion (see box). She dismisses the notion that women are at any special disadvantage in business—at least, not if they're smart, hard working, and imaginative. "One day soon, it isn't going to matter anymore what sex anyone is," she says. "It'll come down to a question of who delivers the goods. Performance is what counts."

Hazel O'Leary, 55, an executive vice president at Northern States Power in Minneapolis, agrees: "Whatever you're asked to do, make sure you do a better job of it than the man next to you." But while you're at it, don't neglect to form friendships. "Without losing your own personality, it's important to be part of the prevailing corporate culture," she says. "At this company, it's golf. I've resisted learning to play golf all my life, but I finally had to admit I was missing something that way." O'Leary has bought a set of clubs and tees up with an instructor on weekends.

THE BEST REASON for believing that more women will be in charge before long is that in a ferociously competitive global economy, no company can afford to waste valuable brainpower simply because it's wearing a skirt. That isn't easy for some folks to accept. "Dealing with change is always painful," notes William Boyle, a Monsanto plant manager who is a big believer in the company's diversity-training programs. "But the days when any U.S. company could stand pat, do things the same old way, and say, 'Gosh, look how good we are'—those days are gone."

Happily for women in corporate America, radical change has a way of favoring the underdog. Says Jane White, author of the forthcoming book *A Few Good Women: Breaking the Barriers to Top Management*: "I think we're living in a fantastic time. The ferment that is happening now will push the barricades down." For that to occur, it's crucial that the brightest and best women not become discouraged. As White puts it, "If you're going to be in the forefront of a revolution, you have to keep taking the flak until it's won." **F**

FIVE MAGIC WORDS: 'GIVE ME A BIGGER CHALLENGE'

■ Ten years ago Jill Barad, then a junior manager in the boys' toys division at Mattel, went to Tom Kalinske, the senior vice president who had hired her, and said, "Okay, I'm ready now. Give me a bigger challenge." His reply: "I was waiting for you to say that." He assigned her to Barbie dolls. In 1988, the year Barad took over that business, sales hovered around \$485 million. The figure has since more than doubled to nearly \$1 billion. Mattel's earnings over that time proved as resilient as Barbie's curls, springing from a \$113 million loss in 1987 to a \$113 million profit last year.

President and chief operating officer since mid-July, Barad never expected to end up the reigning diva of toymodom. Raised in New York City, she graduated from Queens College and, perhaps because her father was television director Lawrence Elikann (*Falcon Crest*, *Knots Landing*), aspired to be an actress. A single day in front of the cameras in a 1973 Dino De Laurentiis film called *Crazy Joe* changed her mind. She moved to California and worked for a cosmetics maker and an ad agency before joining Mattel.

Among her first projects at the company: an icky toy called A Bad Case of Worms. Designed to be slammed against a wall, whence it would slither slimily to the floor, the thing was aptly named—and has since disappeared. "I



Mattel's Jill Barad is the diva of toymodom.

think everyone thought I managed out of that well," says Barad. Ten promotions later, she runs a staff of more than 1,000 worldwide but relies too on the judgment of sons Alexander, 12, and Justin, 9—with now and then a comment from husband Thomas Barad, an independent film producer.

Pleasing little customers can yield big money. When Barad signed on with Mattel in 1981, she earned \$38,000 a year. In 1991, as head of operations for North America, she had a pay package that came to \$711,539. Not too shabby a decade. "We all have to get the best people we can get," she says. "And you won't get the best people if they don't feel they'll have a chance to rise." Some of the best people won't ever know the chance is there or not—unless, as Barad did, they ask for it.

"A President's wife who undertakes a specific job in the government faces double jeopardy; she is without real authority, yet she is expected to perform miracles. When she dares to assert leadership, it is resented and resisted and if she does not, officials try to anticipate what she wants done." Eleanor Roosevelt Washington Post 1/20/77

"The capacity for accomplishment is great, but an activist First Lady is assured of not only rewards and heady personal power, but criticism and frustration as well.

If done right, it can be one of the toughest unpaid jobs in the world."

Washington Post 1/20/77

"But she comes into a job description that is pretty firmly set: A first lady is supposed to be the supportive help-mate. She's not supposed to be an outspoken public figure. She's not supposed to have separate, visible employment - although she is supposed to have interests." Kathy Kleeman - Center for the American Women in Politics - Newsweek 1/22/89

"No other woman in our country is automatically elevated to international prominence through marriage as is the First Lady."

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BREAST CANCER:



**The President's Cancer Panel
Special Commission on Breast Cancer**

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute



BREAST CANCER:

A NATIONAL STRATEGY ■ A REPORT TO THE NATION

**The President's Cancer Panel
Special Commission on Breast Cancer**

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

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EXECUTIVE SUMMARY

Overview

Breast cancer is a large and growing public health problem in the United States. During the decade of the 1990s, it is estimated that nearly 2 million women will have been diagnosed with the disease and that 460,000 women will have died of it. Between 1950 and 1989, the incidence of breast cancer increased by 53 percent. The magnitude of this problem and its constant increase over time understandably result in considerable anxiety among all women.

Some improvements in breast cancer detection and treatment have occurred over the past few decades. Yet even these modest improvements are not uniformly applied throughout the population. Most current therapies (surgery, radiation therapy, and chemotherapy) are non-specific in their effects and frequently diminish quality of life. Although women diagnosed with early-stage breast cancer have a 5-year survival rate of 93 percent, there is no period of time after which a woman who has been treated for breast cancer can be assured that it will not recur. At this time, there are no proven methods of preventing breast cancer.

Advances in basic science have raised the realistic hope that more specific methods can be developed to treat or prevent breast cancer.

Breast cancer advocates – women with breast cancer, their families, friends, and supporters – demand that breast cancer become a national priority. There is a widespread sense of urgency that more can and must be done to address the problem of breast cancer in this country. There is growing public demand for even greater levels of funding of a national breast cancer program and an outcry for the development of cure and prevention.

Recommendations

The goals of the President's Cancer Panel Special Commission on Breast Cancer recommended breast cancer program are:

1. To make substantial progress in developing effective methods to cure and to prevent breast cancer, and
2. To make current and future proven methods of early detection, treatment, and prevention universally available.

The National Institutes of Health and other involved federal agencies must receive research funding of no less than \$500 million per year for this program until these goals are achieved.

Specific recommendations made by the commission are outlined below.

Causes and Prevention

- Research into breast cancer causes and prevention must receive high priority.
- Investigator-initiated inquiry should remain the mainstay of research funding.
- Genetic, hormonal, environmental, dietary, and other causes of breast cancer must be identified through basic and epidemiologic research; this knowledge is the foundation needed to develop effective preventive strategies.
- Knowledge gained through research must be translated into clinically effective methods of prevention, early detection, and treatment.

Earlier Detection and Diagnosis

- Early detection should be improved by further refining x-ray mammography, developing newer imaging methods using non-ionizing radiation, and identifying breast cancer biomarkers that can be detected in a blood test.
- Improved access to early detection must include prompt diagnostic work-up and treatment referral for patients in whom breast abnormalities are identified.

Treatment Strategies

- Women must be empowered to be active participants in their decisions about breast cancer screening and, if diagnosed with the disease, about their treatment options.
- Patients, their families, and breast cancer experts want and deserve less invasive, disfiguring, and toxic treatments than surgery, radiation, and chemotherapy.
- High priorities for new and more specific treatments include: therapy directed at hormones and hormone receptors, tumor growth factors or growth factor receptors; inhibitors of angiogenesis and metastasis; immunologic therapy; and gene therapy.
- Methods should be developed to overcome resistance to hormonal and chemotherapeutic agents.
- Diagnostic decisions, treatment options, and recommendations should be provided in an interdisciplinary setting.

Psychosocial Effects

- Current methods of psychosocial support should be available to all breast cancer patients and their families.
- More effective supportive care interventions for breast cancer patients and their families must be developed.

Access

- Current and future methods of early detection, treatment, and prevention should be universally available as soon as their efficacy is demonstrated.
- United States health care delivery system reforms must ensure the removal of financial barriers to access.

- Research is required to understand and remove the non-financial barriers to universal use of effective means of combating breast cancer.

Public Policy

- Federal regulations should limit the proliferation and use of unproven treatments, prognostic markers, prevention methods, and technologies, except within the confines of a well-defined clinical trial.
- Clinical testing of new detection, treatment, and prevention methods should be supported cooperatively by third-party payors, industry, academic centers, and the National Cancer Institute.
- Research costs for clinical trials should be carefully delineated and paid by industry or the National Cancer Institute, while patient care costs should be covered by third-party payors.
- The 1992 Mammography Quality Standards Act should be implemented immediately.
- Federal agencies should coordinate their breast cancer programs through an interagency breast cancer task force.

A Partnership of Breast Cancer Advocates and Breast Cancer Scientists

- This partnership must continue in a way that promotes the shared objective of finding effective prevention and cure of breast cancer.
- Breast cancer advocates should be integrated into decision-making regarding the optimal use of breast cancer research funding.

Information and Empowerment

- Women in the United States should be provided with accurate, up-to-date, and culturally sensitive information about the risks of breast cancer and how it is best detected.
- Women diagnosed with breast cancer should be provided with accurate, up-to-date, and culturally sensitive information about their treatment options.
- The National Cancer Institute should provide leadership in the development and distribution of culturally sensitive breast cancer educational materials and special materials for women with low levels of literacy.
- Women should be empowered both psychologically and financially to take responsibility for their own breast health, including adopting healthy lifestyles, practicing breast self-examination, following recommended guidelines for breast cancer screening, and immediately obtaining diagnostic and treatment services when breast abnormalities are observed.

Past investments in basic science and breast cancer research have brought us to a point where numerous opportunities exist to advance our ability to prevent and treat breast cancer. The enormity of the impact of breast cancer on the mental and physical well-being of women in the United States and their families requires that we as a society devote the resources needed to achieve the most rapid progress possible.

INTRODUCTION

Over the last decade, patients and their families have directed increasing national attention to breast cancer. Their input has stimulated breast cancer research, focusing on the need for prevention and cure. During the 1970s and 1980s, breast cancer incidence rose by 21 percent among women of all ages in the United States, and increased by 49 percent among women 65 and older. Even among women least likely to experience breast cancer—those under 50—incidence rose by 13 percent. National Cancer Institute funding for breast cancer has increased from \$92.7 million in 1991 to \$196.6 million in 1993. In addition, Congress appropriated \$210 million to the Department of Defense in Fiscal Year 1993 for a multi-year breast cancer research program. There is wide public demand for even greater levels of funding of a national breast cancer program and an outcry for effective prevention and cure.

In response to a request from the Vice President of the United States to the Chairman of the President's Cancer Panel, the President's Cancer Panel Special Commission on Breast Cancer was appointed by the Director of the National Cancer Institute in 1992. Its 19 members held 11 meetings over 14 months, hearing testimony from more than 190 scientists, clinicians, patient advocates, and experts in all aspects of breast cancer. This report contains the findings and recommendations of the Commission based on this comprehensive review.

Breast cancer is a large and growing public health problem in the United States. All women are at considerable risk for developing breast cancer during

most of their lives. It is estimated that during the 1990s nearly 2 million women in the United States will be diagnosed with the disease and that 460,000 women will die of it. Between 1950 and 1989, the incidence of breast cancer increased by 53 percent. Expanded use of screening mammography explains part of the recent rise in incidence, but the causes of the long-term increase are largely not known. The increasing magnitude of this problem has understandably resulted in considerable anxiety in the population, particularly among young women and especially regarding future generations of females.

Specific points about breast cancer should be recognized. The incidence of breast cancer rises continuously as women age: At age 30-34, the rate is 27 per 100,000; at 40-44, it is 127 per 100,000; at 50-54, it is 222 per 100,000; at 60-64, it is 343 per 100,000; and at 70-74, it is 434 per 100,000 women. Also, the natural history of the disease is prolonged. The time from the inception of breast cancer to its detection using current methods is estimated to be at least several years. The time following initial diagnosis and treatment to the development of recurrence and death is measured in years. Furthermore, there is no time period beyond which recurrence and death may not occur. If a cure is defined as elimination of any chance of recurrence and metastases, it is not correct at present to describe a "cure" of the disease. Nevertheless, most patients diagnosed with breast cancer live out the remainder of their lives without recurrence. As reported by the National Cancer Institute's Surveillance, Epidemiology, and End Results program, women diagnosed with early-stage

breast cancer have a 5-year survival rate of 93 percent, in contrast to 70 percent and 17 percent for those diagnosed with regional and distant metastases, respectively. Finally, the clinical course of breast cancer varies greatly among patients, suggesting that there is heterogeneity in the factors that affect both the occurrence and the natural history of the disease.

Breast cancer is now believed to result from a series of alterations (mutations) in the genes of the breast cells. Some such genetic changes may be inherited, but most are not. These alterations can result in an increased likelihood of additional genetic changes (genomic instability), uncontrolled cell growth (proliferation), invasion into adjacent tissues, and spread to other sites in the body (metastases). The causes of these genetic alterations are largely unknown. Ovarian hormones (estrogen and progesterone) clearly play an important role in the development of breast cancer. It appears likely that influences beginning very early in life and continuing throughout adulthood are important. At this time, there are no proven methods of preventing breast cancer.

Some improvements in breast cancer diagnosis and treatment have occurred over the past few decades. A major advance has been achieved through screening with mammography and clinical breast examination. Screening mammography can detect many cancers before they are clinically evident and can lead to a breast cancer mortality reduction of about 25 percent. However, the mortality benefit from mammography has been unequivocally demonstrated only in women aged 50–69. Possibly due to limitations in study design and implementation, the data for women aged 40–49 are inconclusive, and there is a paucity of information regarding the

effectiveness of screening women aged 70 and older, despite their high risk.

Breast-conserving treatment (consisting of excision of the cancer—commonly referred to as “lumpectomy” combined with breast irradiation) results in survival rates equivalent to those following mastectomy and provides important quality-of-life gains for many patients. In addition, new surgical techniques facilitate breast reconstruction in patients treated with mastectomy. Drug treatment, such as chemotherapy and Tamoxifen, given at the time of local therapy can decrease breast cancer mortality. While these improvements are important, the survival benefit of about 26 percent is relatively modest given the magnitude of the problem, and is achieved at a substantial cost in toxicity. Most current therapies (surgery, radiation therapy, and chemotherapy) are toxic to normal tissues and organs and thus frequently impact negatively on quality-of-life. Moreover, although the last decade has brought refinements in the available treatment modalities, no major treatment advances have been introduced, and the mortality rate has remained constant.

Even these modest improvements are not uniformly provided for all women. For many women, optimal early detection, diagnosis, and treatment measures are unavailable for financial reasons—they are unable to pay and have inadequate or no health insurance. These women represent a large and growing percentage of the population. Access is a particular problem for women who are low-income, minority, young, old, and living in rural areas. The inequities of this situation have become painfully manifest. Even well-insured women with adequate resources often do not receive the best of care, indicating the presence of significant non-financial barriers to optimal health services delivery.

The past decade has seen a major increase in understanding of the basic biological processes underlying both normal cell division and growth and the biology and genetics of cancer. This knowledge is beginning to be applied to breast cancer. Many excellent investigators have been supported in a broad spectrum of breast cancer research by the National Cancer Institute, the American Cancer Society, and other federal agencies and private organizations. This and other basic biomedical and cancer research have increased our understanding of many aspects of breast cancer and led to some promising new approaches for patients. However, more detailed information is needed about the biology and action of hormones on the normal breast, the genetic changes that lead to breast cancer, biologic factors that cause these genetic changes, and the means by which breast cancer cells grow and spread. It is reasonable to hope that this information will lead to new, more specific methods of earlier detection and diagnosis, treatment, and prevention.

In Fiscal Year 1993, the Department of Defense received an appropriation of

\$210 million to spend over 2 years on a breast cancer research program. The Commission notes the effort being made by the Army to ensure that this money is well spent, including an Institute of Medicine study commissioned by the Department of Defense to recommend funding priorities. The Institute of Medicine advised that most of the money be spent on investigator-initiated research projects, with some funds allocated to training, recruitment, and infrastructure enhancement.

There is a widespread sense of urgency that more can and should be done to address the problem of breast cancer in this country. This report provides our findings and recommendations. The Commission concludes that more and sustained resources are required to address breast cancer problems effectively. Specific areas and approaches that we believe are most likely to result in meaningful progress are emphasized. Our recommendation for support of breast cancer research at a level of no less than \$500 million per year is congruent with the funding level recommended in the Fiscal Year 1995 NCI bypass budget.

BREAST CANCER ETIOLOGY AND PREVENTION

Findings

- The ultimate goal of breast cancer research is prevention. To develop effective prevention strategies, basic and epidemiologic research must first identify risk factors that can be modified. Prevention studies can then determine the most useful approaches to reducing breast cancer risk by modifying such factors. Prevention trials can evaluate the relative effectiveness of modifying several risk factors and determine the impact of changing single risk factors.
- Today, the most promising areas of research for understanding breast cancer causes and developing optimal prevention methods include: genetics, hormones, diet, physical activity, environmental risk factors, premalignant and tumor markers, and, for secondary prevention, understanding the metastatic process.

Genetics and Tumor Markers

- There is both molecular and epidemiologic evidence that genetic changes are involved in the development of breast cancer, as has been observed for all cancers. Mutations in normal genes, loss of tumor suppressor genes, and altered expression of cellular proto-oncogenes may all be involved in converting a normal breast cell to a malignant one. Additional genetic changes altering expression of proteins on the tumor cell surface can increase or decrease tumor aggressiveness or metastasis. Knowledge of these genes and the proteins they encode potentially may be used to facilitate early detection and diagnosis and to identify high-risk women for prevention trials.

Hormones

- Being a woman is the major risk factor for breast cancer. Women develop breast cancer not only because they have breasts, but also because they have ovaries. Sex hormones, particularly the steroids made by the ovaries, have a central role in breast cancer. They increase the circulating level of two key ovarian hormones—estradiol and progesterone—and modify the levels of other hormones and locally acting growth factors. These changes alter the hormonal environment in the breast, increasing breast cancer risk.
- Other proxy indicators of hormonal activity support the concept that an altered hormonal environment is a major influence on breast cancer risk. Early age at menarche, late age at menopause, obesity in postmenopausal women, nulliparity, and older age at first full-term pregnancy are each associated with increases in risk.
- The effects of steroid hormone contraceptives and hormone replacement therapy have been studied extensively, but the findings have not been totally consistent. However, with each of these hormonal treatments, some elevation in breast cancer risks are noted for specific subgroups of women or in relation to particular characteristics of the hormonal regimen.

Diet

- Five-fold international differences in breast cancer incidence rates and major changes in rates among migrating populations indicate that non-heritable factors play a major role in disease development. Correlations between dietary factors and

breast cancer incidence rates internationally, as well as animal studies, suggest that nutritional factors strongly influence development of breast cancer. At this time, no dietary change has been proven to reduce breast cancer risk in humans.

□ Alcohol: A modest positive association between alcohol consumption and breast cancer risk has been shown in many case-control and cohort studies.

□ Vitamin A and precursors (carotenoids): Animal studies show reduced mammary carcinogenesis from high doses of vitamin A and related synthetic compounds; human case-control and cohort studies suggest a modest protective effect of pre-formed vitamin A and carotenoids.

□ Total energy intake: In animal models, restricting total energy intake profoundly and consistently reduces mammary carcinogenesis. Human epidemiologic data are consistent with an important effect of childhood and adolescent energy balance (caloric intake and energy expenditure) as rates of breast cancer are associated with height.

□ Plant constituents: In several studies, women with higher vegetable intake experienced lower rates of breast cancer. Epidemiologic evidence does not generally support a major role for dietary fiber in breast cancer prevention, although this was suggested in some laboratory studies.

□ Dietary fat: In some animal models, high-fat diets increase mammary tumors; polyunsaturated fats appear to have the strongest influence. Some human case-control studies show an association between fat intake and breast cancer risk, but little or no association has been shown in all recent, large, prospective studies, which are less subject to

methodologic biases. Protective effects of very low fat intake or alterations in dietary fat early in life cannot be excluded by available data.

□ Vitamin D: Women in latitudes with low sunlight exposure, and presumably lower vitamin D levels, appear to have higher breast cancer incidence rates, but more direct evidence for a protective effect of vitamin D is lacking.

□ Little is known about the influence of dietary factors on breast cancer prognosis.

Physical Activity

- A few studies have suggested that breast cancer risk is lower among female athletes and among women who have engaged in moderate physical activity.

Environment

- There have been few studies of environmental or occupational exposures as etiologic agents for breast cancer. Most conducted to date were severely flawed methodologically or based on small samples. Research on the effects of exposures to environmental and occupational agents must include assessment of known breast cancer risk factors.
- For none of the 30 known human chemical carcinogens is the human breast the primary site for the initiation of cancer. Exposure to high doses of ionizing radiation, such as that experienced by female atomic bomb survivors in Japan and women who had multiple fluoroscopic examinations for tuberculosis, is known to increase the risk of female breast cancer. Whether non-ionizing radiation from electromagnetic fields increases breast cancer risk is currently being studied.

Recommendations

Etiology

Genetics and Tumor Markers

- Evaluate the role of proto-oncogenes in normal breast tissue growth, differentiation, and reproduction.
- Identify genetic changes during the transformation from normal mammary tissue to premalignant to frankly malignant tissue.
- Evaluate the specific effects of point mutations or deletions of specific oncogenes, tumor suppressor genes, or chromosomal segments associated with breast cancer.
- Identify intermediate or premalignant events or markers of events that occur in the interval from the start of breast abnormalities to the detection of breast cancer. This will lead to earlier diagnosis, higher cure rates, and the development of rational preventive measures.
- Study new marker technologies for the identification of premalignant changes that could be targets for preventive interventions. As such technologies become available, they should be evaluated in multi-investigator or multi-institutional cooperative clinical research groups, which should establish quality control guidelines and design and conduct peer-reviewed clinical trials with adequate power to validate the sensitivity and specificity of new markers and tests.
- Enact federal regulations to limit the widespread sale and clinical use of markers of modifiable premalignant changes (when they become available) that are still experimental, and for which firm quality control guidelines and usefulness have not been established.

Hormones

- Study epithelial cell proliferation and hormonal control of the normal breast during the adolescent and adult menstrual cycle, during pregnancy and lactation, during systemic contraceptive use, and during hormone replacement therapy.
- Identify the genes in the normal breast and in breast cancers that are specifically regulated by endogenous hormones and growth factors, and by hormones in contraceptives and hormone replacement therapy.
- Conduct human research on “low-dose” hormonal contraceptive regimens, and compare the effects of estrogenic versus progestational components of systemic contraceptives on breast tissues.

Diet

- Study basic mechanisms of the preventive role of retinol and carotenoids.
- Define the dose-response relationships and the relative contributions of various forms of dietary vitamin A.
- Elucidate the mechanisms whereby energy restriction reduces mammary carcinogenesis.
- Investigate the relationship between specific types and amounts of dietary fat and protein and breast cancer incidence. Such studies should include a wider range of dietary intakes and examine diets beginning in childhood.
- Expand laboratory, clinical, and epidemiologic research on non-nutritive protective factors in vegetables and fruits, including screening the food supply for potential preventive agents.

- Study mechanisms by which moderate alcohol intake could increase the risk of breast cancer, with one focus being the relationship of alcohol consumption to hormone levels.
- Evaluate the interaction between dietary factors and markers of genetic predisposition as the latter become available.
- Investigate the possible relationship between vitamin D status and breast cancer risk.
- Conduct observational studies and clinical trials on the effect of dietary factors on breast cancer prognosis.

Environment

- Investigate the molecular nature of the carcinogenic process in breast epithelium to understand mechanisms by which environmental chemicals might influence mammary carcinogenesis.
- Conduct animal studies on mechanisms of species differences in susceptibility to chemically induced mammary cancers to increase understanding of human diversity in susceptibility.
- Study occupational exposures to chemical and other carcinogens and breast cancer risk in the context of other known risk factors.
- Investigate exposures to natural and synthetic estrogenic chemicals in the environment and their effects on breast cancer risk, particularly during prenatal, prepubertal, and pubertal periods. Such exposures must be evaluated in the framework of known breast cancer risk factors.
- Develop methodologies needed to study environmental risk factors: molecular

markers of exposure and susceptibility, improved methods of assessing dose-response relationships, and mechanisms of enzymatic transformations of precursor molecules to active carcinogens in humans.

- Determine the variable effects of individual and multiple etiologic factors on breast cancer risk by age at exposure.
- Continue studies of Japanese atomic bomb survivors, particularly women exposed *in utero* and during adolescence; evaluate the effects of hormonal, dietary, and genetic factors on susceptibility to breast cancer due to radiation exposure.

Prevention

- Develop approaches to modulate or eliminate the expression of specific oncogene products or abnormal genetic segments in premalignant breast tissue.
- Investigate hormonal chemoprevention intensively through basic, epidemiologic, and clinical studies. Research should focus on the development of pure antiestrogens and antiprogestins, the elucidation of hormonal regimens that mimic the protective effects of early pregnancy, work with retinoids and other vitamins, non-steroidal hormones and hormonal antagonists as systemic contraceptives, and non-hormonal contraceptive methods.
- Conduct observational studies and clinical trials on the effects of modifying multiple risk factors—for example, diet, physical activity, and hormones.
- Complete the Tamoxifen trial to determine whether it can prevent breast cancer among high-risk women.

SCREENING AND EARLY DETECTION AND THE DEVELOPMENT OF NEW TECHNOLOGIES FOR DETECTION AND DIAGNOSIS

Findings

- While prevention is the ultimate goal, earlier detection increases the likelihood of reducing mortality and should have a high research priority.
- Mammography in conjunction with breast physical examination has been shown to reduce mortality from breast cancer in women ages 50–69. Data regarding the benefit from mammography screening in women ages 40–49 are inconclusive, possibly due to limitations in study design or implementation.
- The technology of film-screen mammography has improved greatly over the past decade, but its sensitivity and specificity are still not adequate to detect all breast cancers at an early stage, especially in premenopausal women.
- Screening mammography is underutilized, especially by women aged 60 and older, who are most at risk. Racial and ethnic minorities and low-income women are also less likely to get mammograms.
- Failure of health care providers to recommend mammography is a major cause of poor utilization.
- The Mammography Quality Standards Act, designed to ensure high-quality mammography facilities across the country, was passed in 1992, but has not yet been implemented. The Food and Drug Administration is responsible for implementing this law, but instead is expending its efforts modifying it.
- Ultrasonography has limited use for breast cancer detection. Newer imaging

modalities such as positron emission tomography and magnetic resonance imaging are still under development and should be used only in the context of well-designed studies.

Recommendations

Practice and Outreach

- Immediately implement the Mammography Quality Standards Act to ensure that all women receive mammography of acceptable quality, and remove overlapping and conflicting standards. Current multiple certifications required at federal and state levels and from private organizations impose an excessive burden on mammography facilities, waste tax dollars, and increase costs.
- Promote utilization of screening mammography and clinical breast examination for groups of women who are currently being screened at disproportionately low rates (e.g., older women, rural women, women of lower socioeconomic status, and specific racial and ethnic populations, especially African American, Native American, Latino, and Asian women). This will require gathering additional information on barriers to screening and the information needs of these groups, and using existing information to develop effective educational materials and programs. Special attention should be given to conveying the message that increasing age is the major risk factor for developing breast cancer. These efforts should recognize the diversity of needs among and within specific groups and the necessity to develop materials, services, and interventions that address these specific needs.

- Educate and encourage physicians to recommend screening mammography actively.
- Provide screening and appropriate follow-up services for women, regardless of financial status or extent of insurance coverage.
- Help women assure their own breast health by providing financial and psychological support, enabling them to take responsibility for following recommended breast cancer screening guidelines and practicing breast self-examination.

Screening Research

- Conduct further studies to determine the mortality benefit of screening in women ages 40–49 and in women ages 70 and older, the optimal periodicity of screening in relation to age, and the relative utility of mammography and clinical breast examination. Investigators should first assess whether case-control studies could answer some of these questions as a less costly and more rapid approach than randomized controlled trials. Such studies should use state-of-the-art mammography and must be well designed and well executed. Consideration should be given to providing support for the ongoing trial in the United Kingdom to resolve questions related to screening women in their 40s.

- Develop a system designed to provide information about the practice of breast cancer screening in the United States.
- Assess the effects of co-morbid medical illnesses on breast cancer screening outcomes in women in different age groups.
- Determine the full range of breast cancer screening roles that nurses and physician extenders can play.

New Technologies Research

- Develop better technologies for detection and diagnosis. Such technology should detect breast cancer at its earliest stages, be highly sensitive and specific, non-invasive, and effective for women of all ages.
- Study the feasibility of earlier detection using computer-assisted mammography interpretation and techniques using digitization of mammographic images. Continue research into improving ultrasonography.
- Determine the comparative efficacy of stereotactic fine-needle and core biopsy and ultrasound-guided fine-needle and core biopsy with the goal of reducing the need for excisional biopsy.

IMPROVING THE OUTCOME FOR BREAST CANCER PATIENTS: TREATMENT AND QUALITY-OF-LIFE EFFECTS

Findings

- Despite some recent improvements in treatment, many thousands of women diagnosed with breast cancer die of the disease. No currently available treatment can be defined as curative.
- Since current treatments result in modest improvements in survival, assessing the effects of treatment on quality of life is important to inform patients adequately about treatment options. Quality-of-life issues include functional status, psychological well-being, social (work and home) functioning, sexuality and fertility, and spiritual well-being. Quality of life is influenced by personal factors (e.g., developmental stage and social support), clinical factors (e.g., stage of disease and type of treatment), and demographic factors (e.g., ethnicity and geographic location). The effects of treatment on long-term quality of life are not adequately known at this time.
- Adjustment to breast cancer is an ongoing process. While some patients do well following diagnosis and treatment, many experience adjustment difficulties in succeeding years. Fear is an overriding issue for women who have had a diagnosis of breast cancer.
- Treatment recommendations are best made in a clinical setting that includes experts in the various disciplines. Patients should be empowered to participate actively in making treatment decisions.

Recommendations

Treatment

- Exploit advances in molecular biology to find a cure for breast cancer. In particular, new and more specific therapeutic strategies should be developed, including: therapy directed at tumor growth factors or growth factor receptors; inhibitors of angiogenesis and metastases; gene therapy; and immunologic therapy, including vaccines. Innovative research should be encouraged.
- Identify cell surface factors associated with the ability of tumors to invade and metastasize; develop strategies to modulate the expression of such factors. Explain the predilection of metastatic cells to home to some but not other target organs.
- Improve current treatment strategies to make them more effective—identify mechanisms of resistance to hormonal and chemotherapy, develop ways to avoid or overcome resistance, evaluate dose intensification of chemotherapy in primary and metastatic breast cancer, evaluate pre-operative chemotherapy effectiveness, and optimize the long-term results of breast-conserving treatment and breast reconstructive surgery.
- Determine prognostic and predictive factors (or markers) for systemic therapy in order to select patients who are likely to benefit. However, it is necessary to regulate the clinical use of breast cancer markers that are still experimental. Markers should be made available outside the confines of a clinical trial only

when they have been adequately validated and when firm quality control guidelines for their use have been established.

- Continue drug development research to discover new, more active agents.
- Ensure adequate funding for clinical investigations of new treatments and provide positive inducements for physicians and patients to participate in studies of promising new approaches. In particular, continue support of single institution pilot studies and of cooperative group randomized clinical trials.
- Define the natural history of ductal carcinoma *in situ* and other proliferative breast lesions, including factors strongly associated with progression to invasive breast cancer.

Quality-of-Life

- Evaluate the frequency, severity, and persistence of adverse physical changes caused by treatment and develop strategies to deal with these changes. In particular, evaluate treatment effects on fertility in premenopausal patients, and on sexual function in women of all ages. Strategies to treat menopausal symptoms and arm edema, as well as improved breast implants or other methods of reconstruction, must be developed.
- Include quality-of-life measures in clinical trials of new treatment and prevention regimens and approaches.
- Develop guidelines for psychosocial evaluation and support over time of women diagnosed with breast cancer and those at risk for the disease; develop and test effective interventions to improve psychosocial adjustment. Specifically, studies should involve patients of all ages, women at high risk for developing breast cancer, and patients with recurrent disease. Research also should include the effects of diagnosis and treatment on patients' families and social functioning.
- Develop better strategies for supportive care of end-stage breast cancer patients and ensure availability of these services to patients and their families.
- Conduct clinical trials to provide information on the effects on survival and quality of survival of systemic hormonal contraceptives, pregnancy, and hormone replacement therapy at menopause in breast cancer survivors, including women in whom treatment of premenopausal breast cancer induced premature menopause.

INFRASTRUCTURE, EDUCATION, AND TRAINING

Findings

- Breast cancer research requires resources such as repositories, registries, and specialized research centers which must operate for many years. It is difficult to obtain stable, long-term funding to establish and maintain such resources outside an hypothesis-driven research proposal.
- Advances in understanding the biology and genetics of breast cancer are not likely to be immediately applicable to improved prevention and treatment methods. A new generation of trained, basic, translational and clinical investigators is needed to ensure that the knowledge gained from basic research leads to human benefit, specifically the prevention and cure of breast cancer.
- It is essential to ensure that clinical studies of prevention, detection, diagnosis, and treatment include women of diverse ethnic and sociocultural backgrounds. Culturally acceptable study design and recruitment of women from varied ethnic and racial groups are facilitated by the participation of investigators sensitive to sociocultural issues and who also come from diverse backgrounds.

Recommendations

- The preponderance of research funding should be directed to investigator-initiated inquiry. A major emphasis should be placed on supporting innovative and imaginative research.
- Expand or create specialized research resources: breast cancer SPOREs

(Specialized Programs of Research Excellence), the National Cancer Institute's Surveillance, Epidemiology, and End Results program, and other high-quality cancer registries capable of providing data to monitor long-term trends in breast cancer, relevant animal models and cell lines, and repositories for biological specimens.

- Develop an information-sharing network for breast cancer researchers.
- Fund training grants specifically targeted to the next generation of investigators in all aspects of breast cancer research.
- Train investigators in translational research and in clinical trials to facilitate the development of improved prevention, detection, and treatment strategies.
- Emphasize during research training the role of ethnic and sociocultural diversity in risk of breast cancer, as well as the need to develop acceptable and sensitive strategies for research on prevention, early detection, diagnosis, and treatment for diverse population groups.
- Train future clinical investigators in both translational and clinical trials research. These investigators need broad training in the biology, genetics, and clinical manifestations of breast cancer, and in epidemiology and biostatistics.
- Utilize tumor boards in institutions that treat breast cancer to ensure optimal care through proper and timely input from various cancer specialists and to help train young physicians.

- Ensure that oncologists (medical, surgical, radiation, and nursing) receive interdisciplinary training to improve the quality of breast cancer care.
- Train clinicians of diverse ethnic heritage in breast cancer care.
- Promote continuing education programs for all professional and technical personnel dealing with breast cancer patients to ensure that advances in care are translated to practice.
- Ensure that medical school, residency, and fellowship training programs and training for advanced nursing practice include education on the need for regular breast examinations, including mammography and clinical breast examination, and on the performance of a thorough clinical examination of the breast.
- Encourage health care providers to educate patients about breast cancer, including treatment and rehabilitation options.



PUBLIC COMMUNICATION

Findings

- Information appropriate for and appealing to the mass media and information necessary for public education differs substantially. A fundamental principle of communicating with the public about breast cancer issues is to distinguish between information that is newsworthy and that which is needed for educational purposes. News media professionals generally consider it their responsibility to report news accurately, but not to serve as public educators. Therefore, channels other than the media are required for education.
- There is a discrepancy between the media attention given to breast cancer and its importance as a public health problem. While the media do give some attention to breast cancer, more resources could be expended by the media to present breast cancer-related issues to the public. For example, newspapers, television stations, and radio stations send reporters to international conferences on AIDS, but are very unlikely to send anyone to scientific meetings concerned with breast cancer. To some extent, this discrepancy is attributable to advocacy groups. It is clear that news media respond to activism. The more assertive breast cancer advocacy groups are, the more attention breast cancer will receive from the press.

- A significant segment of the U.S. population has a low level of literacy. It is essential to present educational materials and media messages in diverse formats so that all target audiences are reached. In some situations, it may be best to present both news and education via audio and visual channels (radio and television).

Recommendations

- Support a national work group on low literacy and cancer information and education.
- Make publicly funded public information and educational materials understandable to individuals at all literacy levels.
- Encourage breast cancer scientists, clinicians, and advocates to collaborate to determine the most effective methods for presenting clear messages to the public which neither understate nor overstate specific issues or overall progress in breast cancer research and care.
- Emphasize coordination of public information efforts between components of the National Institutes of Health and with other federal agencies, such as the Centers for Disease Control and Prevention.
- Work with news media to promote accurate, responsible, and adequate coverage of breast cancer issues.

PATIENT ADVOCACY

Findings

- Breast cancer is a public health problem involving multiple constituencies. It must be a high priority for all concerned with the health of women. Improving breast cancer research, prevention, detection, and treatment is a shared responsibility of consumers, health care providers, biotechnology and pharmaceutical industries, health educators and researchers, public health agencies, legislators, third-party payors, the National Cancer Institute, and other government agencies.
- Over the past decade, patients and their families have promoted breast cancer as a national priority and have focused attention on the need for a cure and for prevention.
- Service, patient support, and advocacy organizations exist for women, including underserved and minority women, at local, state, regional, and national levels. These organizations are valuable resources for many women and are influential in shaping public policy. Voluntary organizations fund and operate breast cancer screening programs, often targeted to underserved and minority women, and provide outreach and support to women during and following treatment for breast cancer. Some fund breast cancer research. Patient organizations provide psychosocial support; advocate for individual patients within the health care system and with payors; urge specific research emphases; and work at local, state, and national levels for policies and legislation on many breast cancer issues. Unfortunately, many minority and low-income women do not feel that most existing organizations represent them,

although there are some exceptions. Improved communication between patient advocacy groups and voluntary and government organizations would be beneficial to all.

- Breast cancer advocates want more participation in decision-making concerned with research and the optimal use of breast cancer research funding.

Recommendations

- Encourage patient advocates and voluntary organizations to work cooperatively to achieve legislation that provides funding, research, treatment, education, and support for women with breast cancer.
- Support voluntary and advocacy organizations' work to ensure access to care for all women and fund community-based programs to bring breast cancer information, education, and interventions to affected groups where they live and work.
- Ensure that health care reform implementation in each state reflects breast cancer issues specific to that population and geographic area.
- Educate physicians about the medical and psychosocial aspects of breast cancer and women's needs for screening, diagnosis, treatment, and continuing care. Physicians must include the woman as a partner in arriving at a diagnosis and choosing the most suitable care.
- Integrate breast cancer advocates into decision-making regarding the optimal use of breast cancer research funding.

- Encourage efforts by patient advocate organizations and other voluntary and educational groups to ensure that women are fully informed and educated about their own breast health, including adopting healthy lifestyles, practicing monthly breast self-examination, following recommended guidelines for early detection, and obtaining immediate diagnostic and treatment services when an abnormality is observed.



Findings

National and State Legislation

- Recent breast cancer research funding increases have provided a large infusion of support for this area of biomedical investigation and raised the priority level of breast cancer within biomedical research. However, increased National Cancer Institute support for research on breast and other specific cancers without the addition of sufficient funds has required redirection of resources from other areas of cancer research. A sustained level of increased funding should include additions to the budget to strengthen breast cancer research specifically, and cancer research generally.
- In addition to federal legislation pertaining to aspects of breast cancer detection and treatment, states have enacted laws to provide quality assurance for mammography, ensure that treatment options are presented to women diagnosed with breast cancer, mandate payment for some off-label uses of chemotherapeutic drugs, and improve access to mammography by requiring insurance companies and Medicaid programs to cover breast cancer screening.
- Impending health care reform is projected to improve access to breast cancer screening, education, treatment, and supportive care. The main principles expected to govern these reforms include security in health care coverage, eliminating exclusions for pre-existing conditions; provider of quality of care and accountability; cost controls; and comprehensiveness of care.

Payment Policies

- Payment policy for all aspects of breast cancer care has a major health, psychosocial, and economic impact on women. Current problems in payment for breast cancer care include inadequate insurance coverage of screening mammography and breast clinical exam; no reimbursement for preventive interventions; limited or no payment for routine care associated with clinical trials; no reimbursement for drugs that have been approved by the Food and Drug Administration for cancers other than breast cancer, but not for breast cancer (off-label use); lack of reimbursement for physical and psychological rehabilitative services; lack of coverage for prostheses, wigs, transportation, or other indirect treatment or rehabilitation costs; and no reimbursement for reconstructive surgery following mastectomy.
- The ability to purchase health insurance, enroll in a group policy, or obtain publicly funded care is critical for access to care. Exclusion of pre-existing conditions leaves women previously diagnosed with breast cancer without coverage in the event of a recurrence. Women who have been diagnosed with breast cancer cannot change jobs because future treatment for breast cancer would be excluded from coverage. Women with no coverage or inadequate insurance often experience delays in diagnosis and treatment.
- Affordability of care and of health insurance is an important issue. In small companies, breast cancer patients may be discriminated against and feel guilty if the costs of their care lead to a large insurance premium increase for their co-

workers. Increased premiums and patients' out-of-pocket costs for breast cancer care can affect family resources and cause the breast cancer survivor to feel guilty.

- There is a very specific problem with regard to reimbursement for mammography. While the current guidelines of the National Cancer Institute, the American Cancer Society, and other professional organizations recommend annual mammograms for women 50 and older, Medicare provides reimbursement every other year for women 65 and older and does not provide any coverage for breast clinical examination.

Recommendations

National Legislation

- New funds should be appropriated to support the President's Cancer Panel Special Commission on Breast Cancer's recommended program at a level no less than \$500 million per year until breast cancer prevention and cure are achieved. This research effort should be under the leadership of the National Cancer Institute.

State Legislation

- Support state legislation to provide quality assurance for mammography and insurance coverage for screening, diagnostic tests, treatment, and patient care costs of clinical trials.

Payment Policies

- Decisions about health care coverage in this country should involve all members of

our society and take into consideration the society as a whole, government responsibilities, and the concerns of business.

- Increase access to affordable health care coverage by:
 - eliminating pre-existing condition clauses;
 - providing a universal health care package regardless of financial status or job or career changes; and
 - utilizing and adequately reimbursing primary care physicians and other providers such as nurse-practitioners and physician assistants.
- Provide comprehensive coverage for reasonable costs of screening and diagnostic tests, treatment, rehabilitation, and psychosocial services by:
 - consensus development of practice guidelines; and
 - covering treatment known to be effective and listed in the three compendia (*AMA Drug Evaluations*, *United States Pharmacopeia*, *Hospital Formulary*) whether or not FDA-approved specifically for breast cancer.
- Encourage and support breast cancer clinical research by:
 - providing coverage of standard health care costs incurred in peer-reviewed clinical trials;
 - providing coverage of interventions not yet proven to have medical benefit only in the peer-reviewed clinical trial setting; and
 - providing incentives to industry and the private sector to support treatment costs of clinical trials.

SPECIAL ISSUES FOR MINORITY AND UNDERSERVED WOMEN

Findings

- Minority and underserved women are heterogeneous, encompassing diverse ethnic groups (e.g., Native Americans, African Americans, Latinas, and Asian Americans); rural women; women with low literacy; women with inadequate health care, health insurance, or financial resources; women with disabilities from other illnesses or injuries; and women 65 and older, who often do not receive breast cancer screening or obtain state-of-the-art treatment.
- Diversity must be a key word in breast cancer research, prevention, diagnosis, treatment, and supportive and continuing care. No subgroup of women is homogeneous: white women in the United States are considered as a single, homogeneous entity, yet they have diverse demographic, socioeconomic, and ethnic backgrounds which influence their risk of breast cancer and their potential for access to the full range of appropriate care from prevention and early detection to rehabilitation. Similarly, other ethnic groups, such as Latino, African American, and Asian women are treated as if they all were similar. Diversity within these groups in culture, tradition, language, education, and other factors associated with breast cancer risk and access to optimal care must be considered in developing culturally sensitive programs.
- Access to breast cancer education, early detection, treatment, and rehabilitation is often restricted among women having one or more of the characteristics described above. Breast cancer research rarely includes women from many of

these populations and fails to encompass their issues in developing strategies for optimal care.

Recommendations

- Where scientifically appropriate, structure clinical trials to reflect the racial and ethnic population diversity.
- Build partnerships with underserved communities to encourage their involvement and self-advocacy in health care. Hospitals, clinics, health departments, and other providers should be encouraged to assist the underserved in navigating the health care system. Such strategies will increase early detection and reduce costly use of emergency rooms.
- Precede design of outreach and research projects in minority populations with consultation and interaction with community leaders where the project will take place. Provide adequate funding for long-term efforts.
- Conduct behavioral/social research on culturally sensitive approaches to current and future primary prevention strategies and ways to increase access to and utilization of early detection techniques and state-of-the-art treatment.
- Reduce geographic barriers to optimal education, early detection, treatment, and rehabilitation, particularly in rural areas.
- Investigate the psychosocial impact of breast cancer on women and their families and differences related to diversity by ethnicity, urban/suburban/rural residence, and socioeconomic status.

- Conduct studies to determine risk factor prevalence across diverse ethnic, socioeconomic, and cultural (e.g., urban/suburban/rural) populations.
- Make available breast cancer incidence and mortality data for all major ethnic groups: African American, Latino, Native American, Chinese, Japanese, Native Hawaiian, etc. The U.S. Census Bureau should provide intercensal population estimates for these groups. The National Cancer Institute's Surveillance, Epidemiology, and End Results program should provide the incidence data, while the mortality information should be provided by the National Center for Health Statistics.
- Target public information and media channels for providing breast cancer education to specific ethnic communities by: focusing on their media outlets, emphasizing radio advertisements and print media, and developing diverse programming that takes into account differences within an ethnic group in acculturation, literacy, language, and traditional cultural practices and beliefs.
- Remove linguistic and cultural barriers to screening, treatment, and rehabilitation.

APPENDIX A: PRESIDENT'S CANCER PANEL SPECIAL COMMISSION ON BREAST CANCER MEMBERSHIP ROSTER

Chairman

Nancy G. Brinker

Founding Chairman
Susan G. Komen Breast Cancer Foundation
Dallas, Texas

Dorit D. Adler, M.D., M.P.H.

Associate Professor of Radiology
Associate Director
Division of Breast Imaging
University of Michigan Medical Center

Karen H. Antman, M.D.

Chief, Division of Medical Oncology
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Zora K. Brown

Founder and Chairman
Cancer Awareness Program Services
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Mary-Claire King, Ph.D.

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Sherry L. Lansing

Chairman and CEO
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Nutrition Department
Harvard School of Public Health

Executive Secretary

Iris J. Schneider

Assistant Director for Program Operations
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National Cancer Institute

APPENDIX B: MEETINGS OF THE PRESIDENT'S CANCER PANEL SPECIAL COMMISSION ON BREAST CANCER

May 28, 1992

Overview of Breast Cancer Research

July 8, 1992

Issues in Basic Research

September 23, 1992

Radiation and Toxic Exposures as
Risk Factors

Dietary Influences on Risk and
Implications for Prevention

October 23, 1992

Patient Advocacy and Voluntary
Organizations

November 12, 1992

Hormonal Factors

January 11-12 1993

Treatment, Rehabilitation, and Quality
of Life

February 23, 1993

New Product Development for
Breast Cancer Prevention, Treatment,
Detection, and Diagnosis

March 18-19, 1993

Screening and Early Detection

Development of New Technologies for
Detection and Diagnosis

April 29, 1993

Possible Environmental Influences on
Breast Cancer

Health Care Delivery and the Role of
the Payors

June 25, 1993

Information Dissemination and the
Role of the Media

July 21, 1993

Public Policy and Legislation

Copies of meeting agendas, transcripts,
and meeting summaries available by
writing to:

President's Cancer Panel Special Commission on Breast Cancer

Attention: Nora Winfrey
National Cancer Institute
Building 31, Room 4A34
Bethesda, MD 20892

APPENDIX C: PRESIDENT'S CANCER PANEL MEMBERS

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Nancy G. Brinker

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1993 to 1996

NATIONAL
CANCER
INSTITUTE

October 1993