REGULATION

A FRAGMENTED FUTURE

Institute for the Future
Business Issues Series

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AUTHORS:	Maureen Davis, Ashley Manning, and Greg Schmid
ART DIRECTOR:	Jean Hagan
EDITOR:	Maureen Davis
COVER DESIGN:	Karin Lubeck
GRAPHIC DESIGNER:	Robin Bogott

What Are Business Issues?

Business issues are focused, cross-cutting themes that will be of central importance for business in the next five to ten years. They are areas in the business landscape that are susceptible to a major change or shift in the future. Topics for the Business Issues Series are drawn from the key drivers presented in our annual *Ten-Year Forecast*. By exploring topics such as the future of globalization, regulation, and demographics, these reports will help companies think through the consequences of these changes for their investing, organizing, creating, communicating, and marketing efforts.

About the Institute for the Future

Located in the heart of Silicon Valley, the IFTF is a not-for-profit research organization with over 30 years of experience in long-term data-based forecasting. IFTF identifies future trends and key discontinuities that will transform the marketplace. We provide key foresights and guide our members in drawing insights as input to their strategy, as well as possible action steps. Through the exploration of possible futures, we help companies, government agencies, and private foundations make better decisions in today's uncertain world.

Table of Contents

List of Figures and Tables

INTRODUCTION

The old notions of business regulation in the United States are fading fast. While any change in regulation is gradual and painstaking, we are entering a period where there will be less ideology, fewer "natural" coalition partners, and a more delicate balancing of diverse positions mainly around the largely conflicting goals of protecting consumers while ensuring they have as much choice as possible. Look for regulation over the next decade to be more pragmatic in nature with diverse coalitions of advocates and opponents. Outcomes will depend more on careful balancing of positions than on ideology. We are headed toward an era of fragmented regulation.

HISTORY: FROM PRINCIPLES TO FRAGMENTATION

Beginning with the 18th century debates around the Peter Zenger freedom of the press case and the Stamp Tax during the colonial years preceding the American Revolution, regulation of business has been an important part of U.S. economic history. But it was only during the Progressive Era in the early 20th century that American political life defined the regulatory needs of an urban, manufacturing country that relied on large corporations as the dominate force in economic life. It was in this crucible that the principles of contemporary regulatory policy were defined and established. The principles that emerged as the building blocks of today's regulatory world are rooted in the following six beliefs.

- Accurate and widely disseminated information is at the core of effective regulation.
- Regulatory authority should be divided—legislative, administrative, and judicial functions are separated; regulatory agencies have independent, professional staffs; options for self-regulation are welcomed; and the public can participate through the courts.
- Consumers sometimes need protection from risks beyond their control.
- Some services are so essential that consumers need guaranteed access.
- Consumers should have the widest possible set of options available.
- Regulators must be able to take into account the unique characteristics of market situations.

Over the decades, the basic principles came under threats and challenges from the grand shifts of 20th century history—the two World Wars taught the value of industry-government cooperation, the Great Depression of the 1930s increased the perceived range of risks for individuals, new technologies blurred some of the boundaries between carefully regulated industries, and a new spirit of globalization redefined market size and scope.

PRINCIPLES UNFOLDING

For many decades during the 20th century, there were clear ideological divides around regulatory issues. On one side were those who stressed the basic rights of private property and the efficiencies promised by the economies of scale in large-scale enterprises. On the other, there were others who were sensitive to the risks for individuals who did not have the resources to counterbalance the increasing economic power of large corporations. Debates over the basic principles took place in specific historical circumstances where the pendulum swung back and forth in response to contemporary needs. But a careful look at regulatory history in three bellwether areas of business regulation—antitrust, the FDA, and telecommunications—show that wide acceptance of a balance of the six principles are now standard. Contemporary regulatory efforts in these and many other areas of business regulation are not driven by ideology but by the particular effects of regulation on a wide variety of different groups involved.

FORECAST FOR REGULATION IN THE NEXT DECADE

Over the next decade, look for business regulation to be driven by the application of a set of basic principles—some of them in clear conflict with each other. Increasingly, diverse coalitions of various affected parties will band together on regulatory matters. On one side there might be businesses who must change the way they operate, consumer groups who are threatened by change or see increased risk in change, suppliers comfortable with the existing patterns of exchange, workers in affected industries, and a diverse lot of shareholders who have made decisions about their long-term savings and investments. On the other side, might be newer industries who feel they are unfairly excluded from the market, advocates of new technologies or products who want to enter new markets, consumers who want a broader choice of products and services, and workers who want more flexibility in the workplace. Increasingly we expect to see less regulatory debate around the general notion that more or less regulation is good and more debate around the concerns raised by the peculiar coalitions that form around specific issues.

Overall, regulatory debates, decisions, and impacts will be fragmented in the future. There are several kinds issues that are most likely to generate such activities. Specifically, there will be vociferous debates around deeply divisive issues of principle, for example, the market power of large corporations; access to life-saving drugs; and availability of the key channels of information and communications.

This report, *Regulation: A Fragmented Future*, begins in Chapter 1, with a look at the six basic principles that underlie business regulation. The following three chapters review key regulatory decisions in three areas that are at the cutting edge of resolving some of the current regulatory dilemmas and best reflect how future dilemmas will be resolved. We examine the historical underpinnings of the cornerstone of corporate regulation—antitrust and the rules that define fair business competition—in Chapter 2. Regulation and fostering innovation in the critical areas of food and drugs is explored in Chapter 3. And, the issues of access and consumer benefits found in the critical flows of information are tackled in a look at telecommunications regulation in Chapter 4. To broaden our thinking on regulation, Chapter 5, looks across a broad range of contemporary regulatory

issues exemplified in the areas of energy deregulation, privacy, financial services, corporate oversight, and intellectual property.

We use the insights garnered from these regulatory areas to understand how the six principles have evolved and will contribute to future adaptations and changes in regulation in the next ten years. In Chapter 6, we use them to build a forecast of regulation over the next decade and identify the most important implications for business.

Chapter 1

PRINCIPLES OF BUSINESS REGULATION

Business regulation has been driven over the last century by the need to balance business freedom and consumer safety. Over time, dramatic changes in social and economic imperatives have been integrated into this balancing act. What has emerged is a set of basic principles for business regulation. The successive introduction of each principle reflected either a fundamental societal force or a specific crisis produced by business performance at the time. We are now at a stage where these principles are well established in the regulatory framework, with wide popular acceptance.

In the future, any major shift will have to break this subtle balancing of the principles. Fundamental challenges to an established principle will bring together odd and temporary coalitions of advocates. The formation of these quilt-like coalitions means that it is very hard to see business regulation as a simple conflict between large corporations and the public. Instead, over the next decade, we will see a much more fragmented view of regulatory change in the business arena, ruled less by ideology and with greater discord between winners and losers after each round of change.

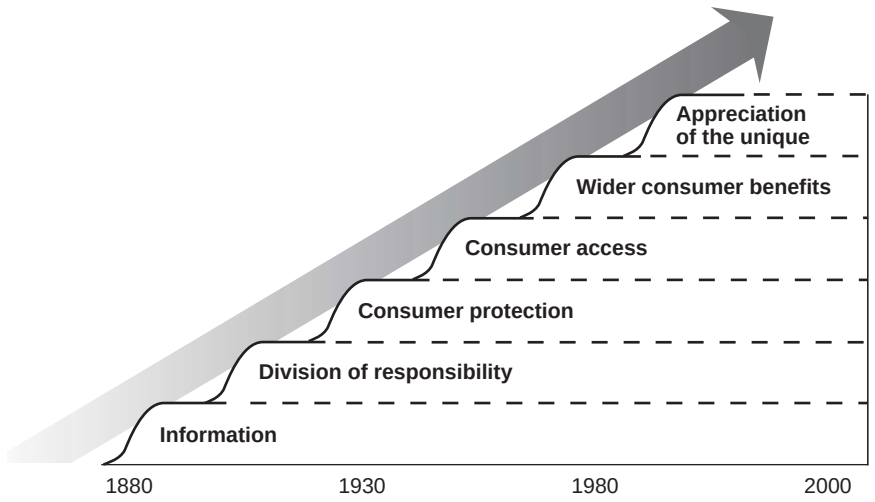
THE SIX PRINCIPLES

Business regulation has evolved over a long period of time, but institutional change has been especially notable since the beginnings of industrialization and urbanization at the end of the 19th century. It's evolution has reflected the ethos of the ages—responding to the abuses of power during the Progressive Era in the early 20th century, the emphasis on planning and cooperation during the two World Wars, the need for protection and security during the Great Depression, and the growing comfort with risk that emerged during the long period of prosperity in the latter part of the 20th century.

The foundation of regulation in the Progressive Era left an imprint that bears the hallmark of what today's new consumer is looking for—good information that empowers people to make informed decisions, regulators that are experts in their field, guarantees of minimum levels of public safety, and room for consumers to exercise choice. Over the last century, the contradictions within these principles (for example, it is hard to both protect consumers and give them a wide range of choices) have led to conflict and debate, but basic principles have evolved that have resolved some of the dilemmas and set the tone for regulatory policy choices in the future.

Figure 1–1 shows how there has been an important sequencing in the order of these principles—moving from a belief in the efficacy of good information, through clear mandates for protection, to regulators as advocates for wider choice.

Figure 1–1
The Gradual Accumulation of Regulatory Principles

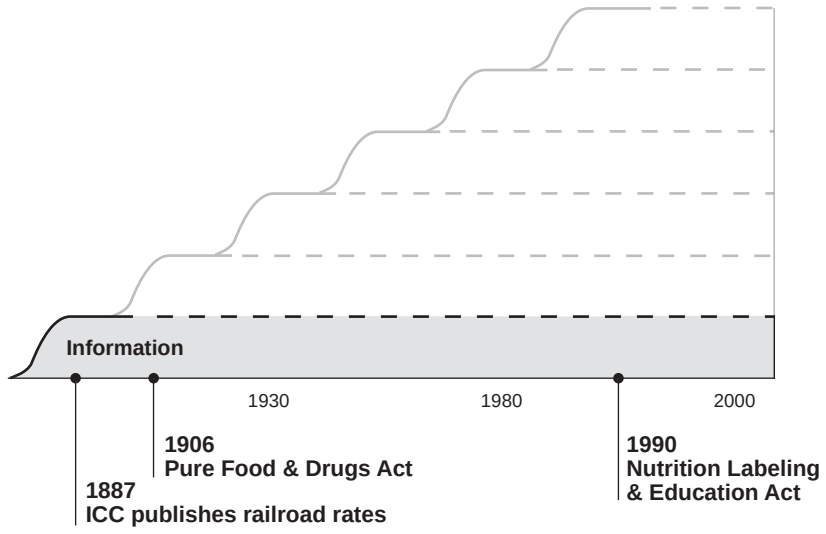


Source: Institute for the Future

Information Is at the Core

From the very start of aggressive business regulation at the end of the 19th century, there was a firm belief that good information is the key to effective regulation (see Figure 1–2). At the beginning of the 20th century, regulators put a great deal of effort into gathering and providing information—both inside and outside a regulatory structure. Books and news articles on the meat industry, urban life, and mislabeled drugs captured the public's attention. At the same time, reformers created a slew of regulatory agencies with sizeable budgets and staff expertise—the Interstate Commerce Committee, the Food and Drug Administration, and the Federal Trade Commission, for example. All of these agencies were given the resources to hire the topical expertise to then gather and make information available to the public so that the people could make their own decisions based on credible knowledge. This notion of good information is so important that, for many government agencies, the key to effective regulation is still in providing easily accessible information to the public.

Figure 1–2
Information at the Core

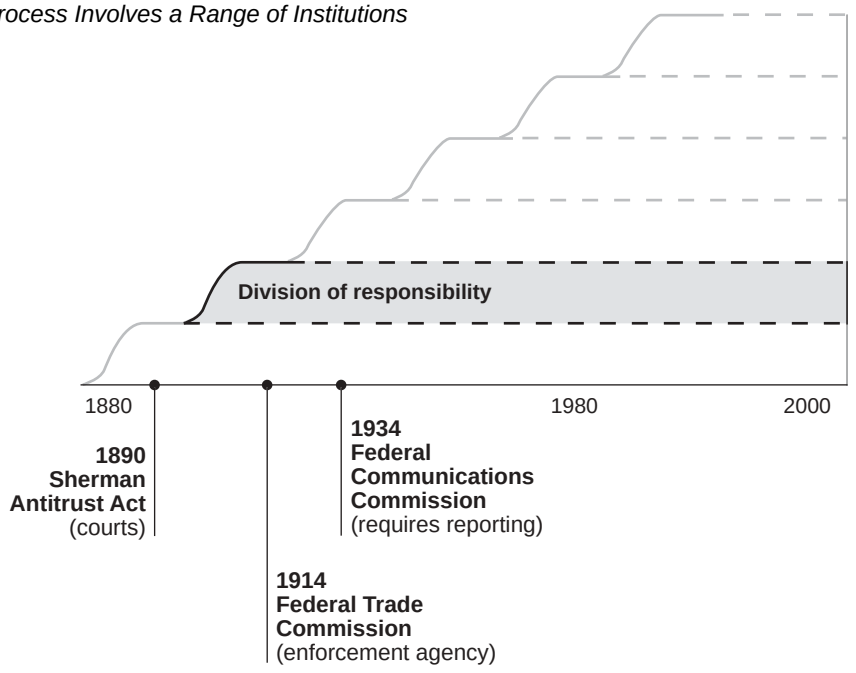


Source: Institute for the Future

Division of Responsibility

The second basic principle that was introduced at the turn of the 20th century was the division of responsibility—with different bodies involved in making the law, enforcing the law, and judging the law (see Figure 1–3). This means that the legislature would publicly debate and establish laws and procedures. The regulatory institutions themselves would administer the laws and set the rules of conduct. The regulatory bodies should have room for dissent and offer clear routes for appeal. And, the final arbiter of disputes around the fairness of the process of regulation would be the courts. At the same time, all parties would have the obligation of providing information directly to the public who would be the ultimate judge of regulatory fairness. Despite the need for openness—which by its very nature implies a time-consuming process—the decision-making process should be clear, open, and relatively quick.

Figure 1–3
Regulatory Process Involves a Range of Institutions

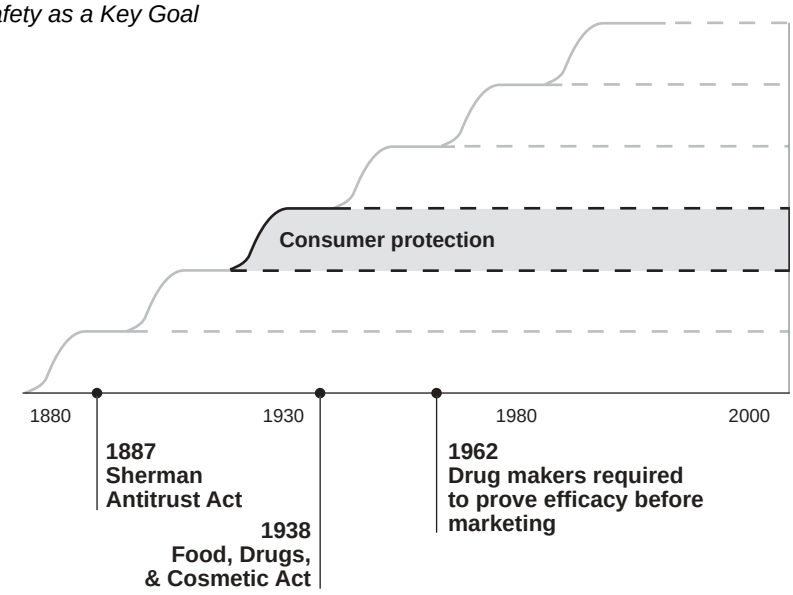


Source: Institute for the Future

Consumer Protection

Another key priority for government regulation of business that started at the turn of the 20th century and grew in prominence through the 1930s was the aggressive protection of the consumer from harm (see Figure 1–4). Safety regulation started in the 1900s in areas like food, drugs, and worker safety where consumers and workers needed protection from obvious dangers. But over time, the government became concerned in a number of critical product areas with potentially dangerous impacts that were not evident at first glance. Safety protections were extended to clothes, financial institution risk, complex technologies like cars and airplanes, unexpected complications from children's products, waste disposal, and subtle dangers from polluted water, air, and the environment.

Figure 1–4
Consumer Safety as a Key Goal



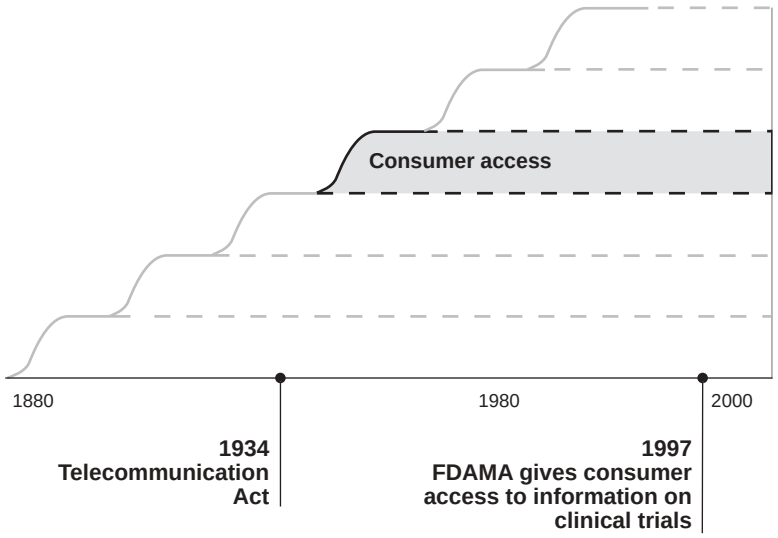
Source: Institute for the Future

Consumer Access

Regulation also played a role in ensuring access for all consumers to a set of basic services that are important elements in a modern society (see Figure 1–5). Regulations were set up to deal with the natural monopolies of urban living that included critical infrastructure elements such as mail, telecommunications, electricity, water, and urban transportation. But the principle of access was also extended into the wider networked worlds of rail transportation, long distance telecom, broadcast technologies, and the Internet.

As the 20th century progressed, other areas of life were defined as necessities. The same basic concept of universal access to some minimum level of food, housing, health care, and education gradually evolved into notions of public education, Social Security, Medicare, food stamps, and welfare.

Figure 1–5
Access to Necessities and Networked Products

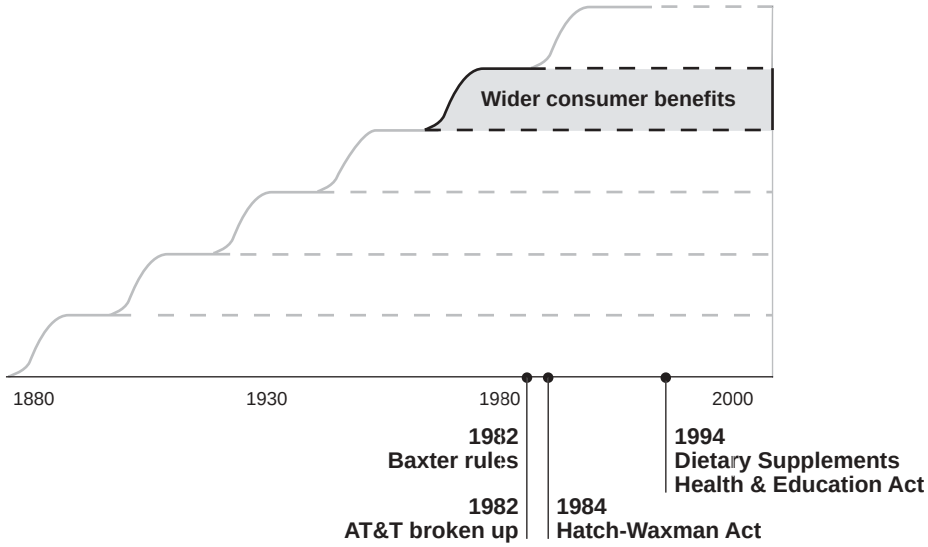


Source: Institute for the Future

Assessing Wider Consumer Benefits

In recent decades, a more expansive view of "consumer benefit" has developed with the growth of a large body of well-educated, sophisticated consumers. These consumers often feel that regulations limit the benefits that flow from a wider range of available choices. While the government as regulator is often the protector from harm, there is an increasing number of cases where the market can do a more effective job of presenting and fulfilling a diverse set of consumer needs. This principle states that regulations should assure that government policies protect the consumer when necessary, but also foster the flow of benefits to consumers—wider choice, efficient markets, and constant innovation (see Figure 1–6). In practice, this idea has been an important seed for change in the late 20th century.

Figure 1–6
Fostering Wider Choices for Consumers

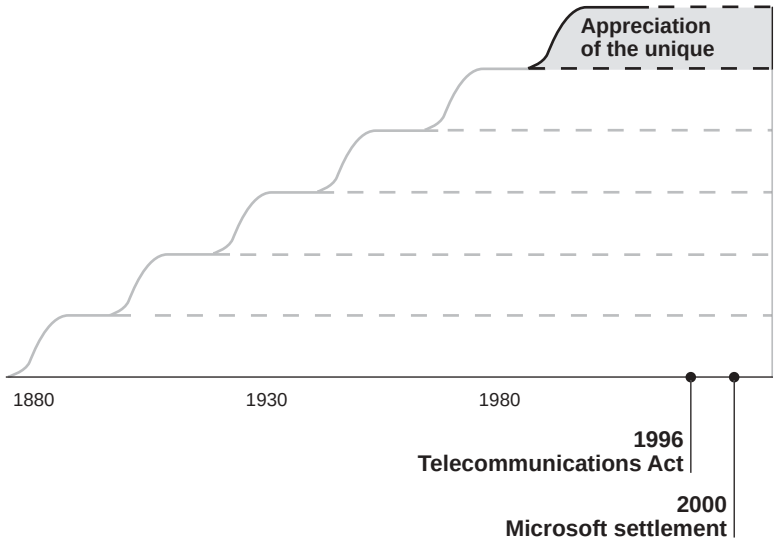


Source: Institute for the Future

Appreciation of the Unique

Today, effective competition can exist across a broad variety of areas—markets can be local, national, or global in nature; technology can permit effective competition across product categories; information about market conditions is easier to obtain; and services added to products can differentiate markets. And the sophistication of new consumers can produce a much higher risk profile that allows consumers to benefit from more open, efficient markets. Regulators must take all of these special characteristics of markets into account and adapt regulations to meet expanding consumer interests. To do this, regulators are moving away from narrow rules—for example, that owning a pre-defined percentage of the market is unacceptable and any actions that would increase a company's market share to or above that level is anti-competitive and will not be allowed—and relying more on understanding the unique characteristics of current market realities (see Figure 1–7).

Figure 1–7
The Emergence of Broader Markets and Wider Choice



Source: Institute for the Future

While the appreciation of unique conditions can make for good regulations, the idea sets up a potential conflict with the notion that regulators should establish clear rules that all can understand and easily follow. It also raises the specter of overload within regulatory agencies, as each case must be reviewed individually, and is likely to further increasing involvement, and potentially the power, of special interest groups.

THE PRINCIPLES AS A TOOL FOR FORECASTING

These six principles of business regulation emerged from our look at 100 years of regulatory evolution in the United States and are useful in our efforts to interpret contemporary changes. For example, the current debate over corporate responsibility reflects one of the longest-lived principles: honest and clear information made available to the public is the key to public choice.

The next three chapters review the key regulatory decisions in three areas—antitrust, telecommunications, and food and drugs—that have been the bellwethers of business regulation. Here we trace the evoloution of the six key principles by examining the past experiences of these specific industries (see side margins). This is a useful excercise when looking toward the future and toward resolving some of today's regulatory dilemmas.

Chapter 2

ANTITRUST: EMBRACING WIDER CHOICE

In the United States, antitrust is the most sensitive regulatory indicator of the business environment. As the prime definer of the competitive marketplace, it paves the path toward understanding where business regulation came from, its purposes, its practical working in the real world, and its future direction. It is the most important bellwether of regulatory change and adaptation.

Today, this bellwether is clearly pointing toward a consensus that regulatory policy will be driven more by economic analysis of market indicators than the application of narrowly defined rules. This trend will make applications of laws more diverse, raising the level of uncertainty about many specific actions and making enforcement more costly. The outcome of antitrust being a leader in setting a broad policy of competitive standards will influence the pacing and pattern of business regulations across a broad range of activities.

THE MOST SENSITIVE OF REGULATORY INDICATORS

Antitrust emerged with the evolution of the Industrial Age and was the first and most important regulatory doctrine at the dawn of the Progressive Era (1890-1914) in the United States. It helped establish the basic format of the modern regulatory structure of business that dominated the last 100 years—broad legislative authority, interpreted by a technically proficient executive agency, with individuals able to bring cases of abuse to courts, and the appellate court system judging the relevance of action taken, and the Supreme Court acting as the final arbitrator.

Antitrust laws have the unique role of combining broad substantive provisions with common law interpretations around the critical issue of what makes a competitive market. Antitrust issues prompt frequent meeting grounds where all parts of the government—executive, legislative, and judicial; federal and state; economic and judicial—come together.

LEARNING OVER TIME

There are have been many shifts in antitrust policy over time. And each one furthers the concept of how markets and competition should be defined. Table 2–1 shows the major steps in the progress of defining market competition through antitrust law and enforcement policies.

Table 2–1
Antitrust Regulation Over Time

1887	Interstate Commerce Commission	First expert agency with information as base.
1890	Sherman Antitrust Act	Legislative basis for opposing monopoly.
1904	Northern Securities Case	Supreme Court stopped major railroad merger.
1914	Federal Trade Commission	Agency with focused expertise on antitrust.
1933	National Recovery Act	Protect job by limiting competition.
1938	Tougher enforcement	Use antitrust policy to foster competitive markets.
1982	Baxter rules	Recognize varieties of consumer benefits.
1990s	Redefinition of competition	Acceptance of a much wider scope of market size.

Source: Institute for the Future

Origins in Public Information: 19th Century

Antitrust laws arose in response to the huge opportunities in scale economies that were the result of industrialization in the late 19th century. In the United States, the growing dominance of the railroads as the key link between raw materials, processing plants, and markets was the first to emerge as a long-term threat to competitive markets. The railroads were characterized by the huge capital necessary for building them out and the huge network effects once in operation—that is, the ability to provide additional benefits to all as new miles of track were added to a unified system. Once a rail line was established, it was hard for competitors to emerge.

Railroads quickly became the dominant means of transport in the markets where they operated and essential to interstate commerce. They were the first to raise the issue of high and arbitrary pricing power. After a decade and a half of debate over railroad regulation, Congress approved the creation of the first modern regulatory agency with the establishment in 1887 of the Interstate Commerce Commission (ICC) that monitored rates and charges. Its role was clearly defined, however, when the Supreme Court rejected ICC's efforts to go beyond requiring the open publication of rates and tried to set actual rates.

Information:
published rates will protect consumers

The Progressive Solution: 1890-1914

The issues of abuse of dominant economic power quickly moved from the single issue of the railroads to the growing number of very large enterprises emerging throughout the economy. The Sherman Antitrust Act (1890) condemned any monopoly or market dominance that resulted in the restraint of trade. The use of the interstate commerce clause of the constitution allowed the federal government to assert its primacy over antitrust issues, since virtually every large business transacts some of its business across state lines.

The antitrust act allowed for the government or individuals to bring actions against abuse of power and left it to the discretion of the executive branch and the courts to decide what was "abusive." But the conservatism of the contemporary courts and the lack of executive direction allowed a proliferation of large trusts and the number of merged companies to grow. These corporate entities had substantial control of many key markets by the

Protect consumers from harm:
legislature provides protection to consumers from very large companies that could utilize market dominance to impose unfair prices

turn of the 20th century—the Sugar Trust, Eastman Kodak in film, General Electric in electricity, U.S. Steel, DuPont in chemicals, and Standard Oil.

A major defining moment was when President Teddy Roosevelt had the Justice Department bring a successful antitrust suit against a railroad merger that would have set up an extensive rail monopoly in the Midwest (Northern Securities, 1904). This case established a key precedent that the executive branch of the government could act effectively with the courts against a monopoly power that was perceived as dangerous to a healthy, competitive market.

The antitrust authority was extended over the next few years. For example, the power to breakup existing dominant firms was established in the Standard Oil case (1911). This case established not only the power to oppose new measures but to stop those existing firms that were a danger to competition. An agency with economic and market expertise to regulate monopoly power—the Federal Trade Commission (FTC)—was approved by Congress (1914) along with the Clayton Act that forbid mergers between firms that threatened to reduce competition in any line of trade.

Regulatory process is broad: executive agency with market expertise works with courts to limit monopoly power

The basic legislation and institutions set in place by 1914 formed the basis for 20th century antitrust regulation. The Progressive accords set limits on monopoly dominance of clearly defined markets. They also set up a professional bureaucracy capable of setting rules and monitoring the effectiveness of those rules in maintaining competitive markets.

Protection and Safety: 1915-1936

The Progressive Era rules on market competition were applied with varying degrees of effectiveness through the next several decades. There were three contextual experiences that led to the modification of the base principles behind those laws. During the two World Wars and in the depths of the Great Depression, there was a consensus that companies could work cooperatively with each other in the national interest. For example, during both wars there were government-industry consortia that coordinated war production planning; during the Great Depression, the Roosevelt Administration passed the National Recovery Act (NRA) that allowed a broad range of businesses to cooperate on production and prices to protect them from failure (and the subsequent lose of jobs). Often national needs—cooperating to fight the Great War or overcoming a devastating depres-

sion—took precedence over the notion of market competition and the enforcement of antitrust laws took a secondary position.

Market Dominance Hurts Competition: 1937-1981

But, in the late 1930s a school of economists—especially Henry Simons, Jacob Viner, and Frank Knight from the University of Chicago—won the attention of President Franklin Roosevelt by stressing the importance of competition in setting the general tone of a healthy and effective market economy. The acceptance of this theory during the economic recovery of the late 1930s produced more aggressive antitrust enforcement by both government agencies and the courts. The standard that emerged was based on per se rules—a ruling based on the fact that an action took place, in this case market dominance by a single firm. This standard meant that it was not necessary that anti-competitive behavior actually had to take place. This more aggressive enforcement standard would be the underpinning for antitrust activity over the next 40 years.

From the late 1930s on, then, with a brief interruption during World War II when the government became the main buyer of virtually all goods in the United States, antitrust rules were enforced with more vigor, with market dominance being the major focus of government action. A series of actions and court judgments—covering areas like shoes, beer, and retailing—limited large firms in some markets to 5% or less of the total market (Brown Shoe in 1962). In its most publicized cases in the post-World War II era, the Supreme Court disallowed an expansion in the capacity of the dominant aluminum firm (Alcoa in 1945), restricted IBM's ability to bundle software and equipment and, late in the period, brought an action against the monopoly power of AT&T (which resulted in the 1982 consent decree between the Justice Department and AT&T, breaking up the national phone monopoly). The Supreme Court often ruled that efficiency was not a reason to approve a merger (for example, between Procter & Gamble and Clorox in 1967). As the Justice Department and the FTC set clear standards of enforcement they basically set the rules that determined or discouraged aggressive merger planning in the private sector.

Redefining for the Age of the New Economy: 1982-2002

In the 1960s, a new burst of activity by market-oriented Chicago economists—led by Milton Friedman, Frank Easterbrook, and Richard Posner—

Protect business: during a time of great economic stress regulation can protect business or enable it to be more productive

Protect from harm: a renewed focus on market competition sets a firm rule on size alone as the key determinant of a healthy market

attacked the notion that a single and simple measure of market share should be the basis for antitrust policy. They looked at the evolution of markets and saw a number of factors other than company size or market share influencing degrees of competition—a richer and broader economy that fostered business diversity, much more effective international competition, new technologies which both broadened market knowledge and permitted the freer entry of new competitors, and deregulation which allowed competition in markets where it had previously been restricted by law.

Look for a range of consumer benefits: consumer benefits can come through better service, new products, and greater efficiencies

The Chicago economists said that antitrust enforcement, by relying on a single standard of market share, failed to define the operation of markets accurately, ignored productivity gains, or stopped transactions without proof of competitive harm. They found many examples of firms that merged to achieve efficiencies that lowered costs, developed innovative products, or brought products or services to areas that didn't currently have them. They emphasized that all of these things can be beneficial to both the companies involved and to consumers. Their new thinking helped shift the focus of regulatory bodies and the courts to the complex issue of figuring out the peculiarities of competition in each market and the virtues of efficiency in size that could benefit the consumer.

The movement for reform resulted in a more permissive climate for mergers (General Dynamics 1974) and some key cases in the late 1970s ruled that an understanding of competitive issues was an important consideration in mergers (Continental vs Sylvania, 1977). These trends came to a head with the election of Ronald Reagan as President. He appointed William Baxter as Assistant Attorney General in charge of the Antitrust Office. Under Baxter, the basic guidelines for antitrust enforcement and mergers were rewritten.

Appreciate the unique: look at each merger for the variety of ways that consumers can benefit from or be harmed

The new Baxter rules set guidelines for measuring the competitive nature of the market, the value and benefits of efficiency that can be passed on to consumers, and the ways that companies need to prove the value. Both the Department of Justice and the FTC accepted the new rules. And while subsequently modified during the Bush I, Clinton, and Bush II administrations, they remain the basic rules of antitrust today.

Still, market dominance remains a key consideration. Over the last few years there have been agreed upon divestitures of portions of the firm's holdings before mergers with other large companies (e.g., in the mergers

involving Exxon and Mobil, BP and Amoco, Time Warner and Turner, and WorldCom and MCI).

And, there has been the special case of technology-rich firms. Young, fast-growing technology industries that depend upon assembly of parts or quick communications need standards that facilitate communications with suppliers and customers. In many supply chain industries this has led to the emergence of dominant standards. The most important antitrust cases over the last 50 years have probably been those brought against IBM (in the 1950s), AT&T (in the 1970s and early 1980s), and those against Intel and Microsoft (in the late 1990s and early 2000s). In the recent Microsoft and Intel cases, settlement negotiations led to resolution of the issues and modest behavior changes without breakup or serious market repercussions.

Appreciation of the unique: regulatory officials must trade the benefits of tech standardization against market power

ANTITRUST AND REGULATION: THE FUTURE

Antitrust policy is the broadest of regulatory activities because it defines the characteristic of a competitive market. It went through an evolution from relying on the spread of information by an expert body; to aggressive enforcement of a narrow definition of markets to protect consumers from monopoly power that emerged at the dawn of the industrial age; to a more open and richer view of measuring markets in a variety of ways to find a range of potential consumer benefits. Today's markets are characterized by much more competition from rivals in other industries: the result of new technologies that allow more communications and information flow; deregulatory actions like eliminating fixed rates and opening protected areas; and a rapid increase in international competition. The result has been a record number of business mergers since the Baxter rules were adoped (see Figure 2–1 on page 18).

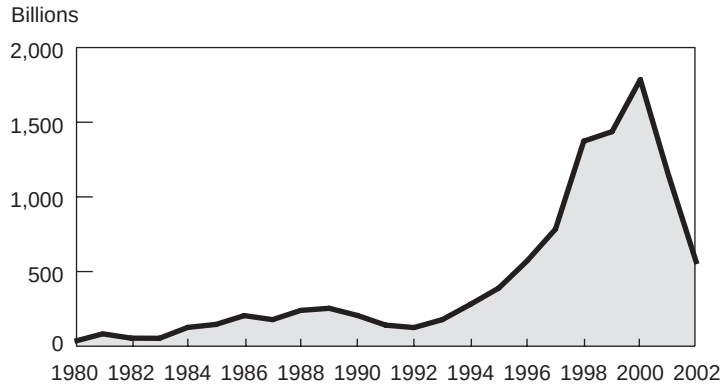
Antitrust has moved from a broad reliance on information alone in the late 19th century, to strict market rules, and finally toward a wide interpretation of how consumers can benefit. Clearly, antitrust enforcement has retained some teeth in opposing market domination, but it has accepted a higher rate of risk that some consumer benefit would flow out of larger enterprises playing in markets.

Responding to the basic drivers above, antitrust regulators will continue to press for widespread consumer benefits from business activity. They will continue to adapt the regulatory principles they have learned from the past century to the rapid changes in market characteristics over the next decade.

Look for the following to characterize antitrust regulation in the future.

- Information about markets—both threats and benefits—will be widely disseminated.
- Agency staffs at both the FTC and the Department of Justice will reflect more economic and business expertise.
- Regulators will continue to redefine unique features of market situations that will justify merger activity.
- U.S. regulators will continue to see domestic markets as a part of a global economy—and they will cooperate with others, such as the EU.
- Regulators will continue to grapple with the unique features of technology markets where standardization is important, learning to take into account the benefits that consumers get from standardization.

Figure 2–1
Mergers Soar After Baxter Rules
(Value of mergers in billions of dollars)



Note: Data for 2002 is an estimate.
Source: Institute for the Future; *Mergers & Acquisitions*.

Chapter 3

THE FOOD AND DRUG ADMINISTRATION: FOCUS ON INFORMATION, SAFETY, AND CHOICE

The Food and Drug Administration (FDA) has been at the core of defining four key principles of regulatory concern: the huge impact of information on consumer choice; the critical role of public safety; the protection of intellectual property without stultifying market innovation; and the larger range of choice for consumers that are more tolerant of risk. Rules established in the last 20 years have expanded the FDA's role in working with key industry players to provide consumers with an increasing number of options and choices.

Information:
private associations provide standardized information

ROOTS IN INFORMATION: THE 19TH CENTURY

The earliest effort in regulating drugs was voluntary and information based. While formal regulation of drugs and food didn't begin until the turn of the 20th century, a form of self-regulation was in place for the drugs as early as 1820 to increase pharmacists and doctors' awareness of pharmaceutical ingredients. The *U.S. Pharmacopeia (USP)*, a compendium of drugs known at the time, was published by a group a physicians, pharmacists, and colleges of pharmacy in 1820. The first *USP* presented a formulary of compositions and listed the chemical compounds, crude drugs, oils, and other substances typically found in a pharmacy. The American Pharmaceutical Association published the *National Formulary* in 1888. Both of these publications gave doctors and pharmacists valuable information to help provide their patients and customers safe products.

INCREASING PROTECTION FOR THE CONSUMER: 1900-1937

In 1862, the Department of Agriculture was established. One of its divisions was the Bureau of Chemistry, the earliest precursor of the modern FDA. The Bureau of Chemistry started with just a few men who did little more than request customs inspections of imported foods and some drugs. By 1880, the Bureau was engaged in limited food adulteration studies. Under an aggressive leader, Dr. Harvey Wiley, the food adulteration group was expanded. A group of young men—called the "Poison Squad"—ingested noxious substances, like formaldehyde and boric acid, and food additives, such as colorings and preservatives, in concentrated forms until they got sick. These activities earned him and his squad the status of folk heroes.

The real breakthrough came with the Progressive Era, with its focus on the importance of information. At the turn of the century, Upton Sinclair published *The Jungle*. This widely popular book described the filthy conditions of a meatpacking plant. In its most graphic and disturbing passage, a worker collapses into a lard canister and is ground and shipped for sale. The public was outraged by the book's story of the unsanitary conditions in food processing.

The combination of the wide publicity generated by the Poison Squad and *The Jungle* and ensuing concerns over the safety of food and drugs prompted Congress to pass the Pure Food and Drugs Act of 1906. The act was focused on safety and better information (see Table 3–1). It formally

recognized the *USP* and *National Formulary* as the official standards for strength, quality, and purity of drugs, as well as the tests to determine these qualities. The act also included provisions that imposed penalties for the misbranding of drugs. A misbranded drug was one that included one or more chemicals known to be dangerous or addictive and its label did not accurately represent the quantity of the substance. The main result of this provision was to provide assurance to consumers about labeled products.

The act also contained a clause regarding "false and misleading" labeling. Federal regulators used this clause aggressively to prosecute manufacturers that claimed their products were cures for headaches, baldness, cancer, and other ailments. One such case was appealed to the Supreme

Table 3–1
The Foundations for Food and Drug Regulation

1906	Pure Food and Drugs Act	Declared *USP* and *National Formulary* as the standards. Better drug labels required.
1938	Food, Drugs, and Cosmetic Act	Required the pre-market approval of drugs and made the FDA the authority on falsity of curative claims.
1951	Durham-Humphrey Amendment	Made the FDA the formal decision maker for prescription drug status.
1962	Kefauver-Harris Amendments	Drug makers required to prove efficacy, in addition to safety, before marketing new drugs.
1984	Hatch-Waxman Act	Changed rules to get generic drugs to market sooner and extended effective patent life for pharmaceuticals.
1990	Nutrition Labeling and Education Act	Required food manufacturers to include nutritional labeling on most food products.
1992	Prescription Drug User Fee Act	Imposed a user fee on new drug applications with the goal of the funds raised used to decrease drug approval times.
1994	Dietary Supplement Health and Education Act	Changed rules such that dietary ingredients used in supplements are no longer subject to the pre-market safety evaluations required of food ingredients.
1997	FDA Modernization Act	Extended user fees for another five years and codified the use of outside experts in new drug approval process.

Source: Institute for the Future

Protect consumers from harm:
honest labels

Court. In the end, the Court ruled that there was no authoritative medical opinion that overrides all others; therefore no charges could be brought against a company simply for making a claim to be a cure unless the seller intended fraud. What this decision meant was that the Bureau of Chemistry could only regulate food and drug commerce with reference to plain fact—that is, its function was to monitor the identification of a drug, only. The Bureau was not yet seen as the authority on effectiveness. While a bit of a regulatory setback, these actions did set precedent for future federal government activism in medicine and food.

PROVING SAFETY AND EFFICACY: 1938-1983

In 1927, the regulatory functions of the Bureau of Chemistry were reorganized to form the Food, Drug, and Insecticide Administration. The agency's name was changed to simply the Food and Drug Administration in 1930.

Under the administration of Franklin Roosevelt, the FDA began pressing for more regulatory power. Such powers were not forthcoming until another tragic event occurred. In 1938 Massengill, a well-known pharmaceutical company, released a new antibacterial drug called Elixir of Sulfanilamide. The drug, or active ingredient, in the elixir had undergone a variety of quality and safety tests, but when a liquid form was produced, the company failed to test the solvent. The solvent was diethyl glycol—commonly known today as antifreeze. The elixir was blamed for 107 deaths, most of them children, before it was recalled. Within months of the tragedy, Congress passed the Food, Drugs, and Cosmetic Act of 1938 (FDC Act).

Perhaps the most important provision of the act was the requirement that manufacturers file a New Drug Application with the FDA before marketing a new drug. The application would list the drug's composition, report on safety tests, and describe how the drug was to be manufactured. This law required that new drugs were shown to be safe before marketing, marking the beginning of a new system of drug regulation.

The act also ushered in many other changes: cosmetics and therapeutic devices were regulated for the first time, proof of fraud was no longer needed to stop false claims on drug labels, and the concept of "misbranded" was expanded to include any drug whose label failed to identify and quantify the

precise ingredients, list the effects and possible side effects, and give directions and cautionary information that even the "least-educated" person could understand. These changes extended the powers of the FDA as it was now seen as the authority on "falsity" of claims on drugs labels.

Protect the consumer: drugs must be proven safe before marketing

Prescription Drugs—Decreased Choice for Consumers

The provision of the FDC Act that required more and easily understood information to be included on drug labels proved troublesome. While its purpose was to give consumers more and better information and not restrict consumer access to drugs, in the end it did restrict access. The FDA decided there were some drugs that simply could not be labeled safely. These drugs were required to be used by or on the prescription of a physician.

This was a significant departure from the past, where pharmaceutical companies made the decision as to whether a drug was sold by prescription or not. Because the new law caused so much confusion for drug makers—it was hard to guess when the FDA would claim a drug could not be safely labeled—they were wary of selling many of their products over the counter. Better safe than sorry (and get sued by the FDA), many more drugs were classified as prescription only. The end result—a new class of drugs was created that consumers had restricted access to. Ultimately, the confusion over who decided if a drug was to be sold via prescription or over-the-counter was cleared in 1951 with the passage of the Durham-Humphrey Amendment, which gave the FDA formal authority to decide if a drug would be available only by prescription.

Consumer protection: doctor's prescription protects consumer from risks

Thalidomide Tragedy

A West German pharmaceutical company introduced a new sedative in 1957. It was called thalidomide and it alleviated the symptoms of morning sickness in women during the first trimester of pregnancy. By 1962, it was clear that thalidomide had caused serious birth defects in thousands of babies in Western Europe. (The drug was under investigation by the FDA for possible adverse neurological effects and had yet to be approved for use in the United States.) Images of "thalidomide babies" with deformed limbs prompted consumer and government cries for new regulations. The Kefauver-Harris Amendments were quickly passed in 1962. The FDA now had to pre-clear all human trials, drug advertising, and labeling, and drug

Consumer protection: prove efficacy of drugs before distribution

companies were now responsible for demonstrating the safety and effectiveness of new drugs. This last provision proved to be a very tall order, and a very costly one.

WIDENING CONSUMER CHOICE: 1984-2002

Proving efficacy is much more difficult, expensive, and time-consuming than simply proving safety. After the Kefauver-Harris Amendments were in place, time spent waiting for FDA approval of drugs and the expense and duration of determining proper testing procedures combined to cause huge delays in drug development and production. Drug development declined significantly after 1962, and the overall process of testing and approval of new drugs through the FDA increased to more than ten years by the end of the 1970s.

During the 1980s, time spent waiting for FDA approval continued increasing. Consumers were being hurt by higher drug costs and delayed access to the fruits of scientific research. At the same time, pharmaceutical companies were seeing the effective life of patents for new drugs dwindle with longer approval times. However, the generic drug industry was opposed to extending patent life (which would delay the introduction of generic products into the market).

The Generic and Patent Compromise

A compromise was found in the 1984 Drug Price Competition and Patent Term Restoration Act, more commonly referred to as the Hatch-Waxman Act. Hatch-Waxman removed constraints on generic drug manufacturers and benefited branded drug manufacturers by extending patents for time lost in the FDA approval process.

The biggest change for generic drugs was that generic manufacturers only had to show that their products were the bioequivalent of patented drugs to win approval, rather than having to conduct costly studies to provide independent information on safety and efficacy. The change greatly speeded up the introduction of generic drugs, giving consumers more choice and major savings. The generic drug industry has seen its market share more than double since 1984 (see Figure 3–1).

The patent extension provision allowed branded drug manufactures to apply for up to five extra years of patent protection, with the total patent

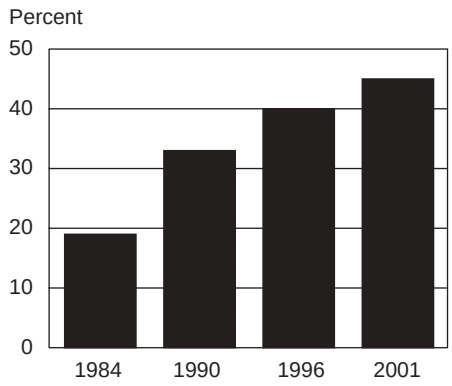
term limited to 14 years from FDA approval. The new law resulted in increased effective patent life—up from an average of 7-10 years to 9-12 years. The generic drug makers, pharmaceutical manufacturers, and consumers benefited from the new law and the FDA was expanding the range of benefits flowing to a widening base of stakeholders.

Consumer access: patent protection supports innovation while easier path for generics brings alternatives

Addressing Long Approval Times

Hatch-Waxman had brought improvements in the areas of price, markets, and intellectual property protection, but the issue of long approval times had yet to be tackled. Time spent in the FDA approval process for new drugs peaked in 1986 at almost 33 months. By the early 1990s, time in the approval process had declined, but was still averaging about two years. By this time, it was widely recognized that the delays were not due to complicated applications but by backlog. The AIDS crisis brought this to a head. The FDA responded to demands by AIDS activists to approve potentially life-saving drugs much more quickly. Ultimately, it was the FDA's experience with reviewing and approving AIDS drugs quickly that lead it to conclude that the overall process could be speeded up if it had better resources and more reviewers. Congress, however, was not willing to increase fund-

Figure 3–1
Generic Drug Market Share Doubles After Hatch-Waxman Act
(Percent of overall prescription drugs sales in generic drugs)



Source: IMS Health

ing for the agency. A solution to this problem was found in the Prescription Drug User Fee Act of 1992.

This act established a mandatory fee (approximately $200,000) to be paid by pharmaceutical companies when they submit an application for new drug approval. The fee requirement was to be in place for only five years. With this new funding, the FDA was able to hire hundreds of workers and approval times began to drop almost immediately. The stipulation that the funding would have to be renewed at the end of five years gave the FDA a huge incentive to streamline its processes, become a more efficient agency overall, and to be sensitive to its customers' (e.g., the pharmaceutical industry and consumers) needs. User fees had proven successful. With the additional funds, the FDA was able to increase its review staff by 60% between 1993 and 1997, and drug approval times dropped from an average of 22 months in 1992 to 15 months in 1997. The FDA was now a more efficient and responsive regulatory body when it came to new drugs. User fees were re-approved and increased in 1997 as part of the FDA Modernization Act (FDAMA) and again in June 2002.

Consumer access: demanding and risk-tolerant consumers gain access to the fruits of scientific research faster and to more information

Also in response to consumer demands, FDAMA created ClinicalTrials.gov. The Web site provides the public and the medical community with easy access to information on clinical trials for a wide range of diseases and conditions—information that consumers were demanding. The site is administered by the National Institutes of Health in collaboration with the FDA and other federal agencies. It contains information on more than 6,000 studies ongoing primarily in the United States and Canada, but also in the broader international community.

Back to Its Information Roots—Food and Dietary Supplements

During the 1970s and 1980s, limited nutritional information was available to consumers on food package labels. If fact, FDA rules prevented packaged food manufacturers from putting nutritional information on their labels. But by the mid 1980s, consumers were becoming more interested in nutrition, and the marketing strategies of food manufacturers began to focus on that interest. Food companies began to make nutritional claims on their packaging. While some of these claims were helpful to consumers, some seemed too good to be true and others were deemed unbelievable.

In the late 1980s, two reports released by the U.S. Surgeon General and the National Research Council at the same time concluded that there is a

relationship between diet and risk of chronic disease and both reports recommended similar dietary changes (e.g., Americans should reduce their intake of fat [especially saturated fat], cholesterol and sodium; maintain appropriate body weight; and consume adequate amounts of calcium and fiber). These reports and the lack of good nutritional information in addition to questionable marketing practices by food companies led to the passage of the Nutrition Labeling and Education Act of 1990.

This law required food manufacturers to include simple and clear nutritional labeling on most food products and gave the FDA the authority to regulate the form and content of the nutrient descriptions. The familiar "Nutrition Facts" box that appears on packaged foods became the standard format for providing information to consumers.

One of the other impacts of the law was to give the FDA the power to regulate the health claims on dietary supplement labels. It announced that it would now regulate supplements as drugs. The resulting consumer (and dietary supplement industry) backlash over the complicated and time-consuming procedures involved led to the passage of the Dietary Supplement Health and Education Act of 1994. As a result of these provisions, dietary ingredients used in supplements are no longer subject to the pre-market safety evaluations required of food ingredients. It is only if after a dietary supplement is on the market and the FDA demonstrates the product unsafe, that the FDA has the authority to ban the sale of the product.

Information as power: better food information and access to a broader range of dietary supplements are made available to consumers

USING THE PRINCIPLES IN THE FUTURE

The challenge for the FDA over the next decade and beyond will be to take into account the dramatic shift in consumer activism and sophistication that is so evident in today's marketplace. Consumers are processing more information about choices in the marketplace, they are experimenting more, and they are shifting their profile of what risks they are willing to take to achieve their goals.

The FDA has a unique and complex role in that it covers new pharmaceutical products, generic versions of those pharmaceutical products, dietary supplements, and food (among many other products). While the FDA traditionally has applied very different rules and processes to these areas, the new sciences of genomics and nutrigenomics are creating a gray area that extends into each of these areas.

Look for the FDA to follow the key regulatory principles and continue to do the following.

- Gather and disseminate high-quality technical information and make it available to the widest possible group of users.
- Protect consumers from potential harm from new drugs and foods.
- Increase consumer access to the fruits of new scientific research as quickly as possible and let them assume more risks at their discretion.
- Help consumers understand the potential benefits that flow from drugs, dietary supplements, and food.

In addition, look for the FDA to continue to work to speed the process of approval for new drugs, ease the path for generics, and move more prescription drugs into over-the-counter status. The biggest issue will be a gradual rethinking of how it treats health claims and deals with labels in light of the fruits of nutrigenomics research that will begin to appear on prescription drugs, dietary supplements, and food products in the next few years.

Today, there is a growing cadre of sophisticated and demanding consumers that want it all—safety, lower costs, and access to the benefits from scientific advances. In addition, they are willing to accept more risk. The FDA will need to find the balance between keeping consumers safe and getting desirable, and sometimes riskier, products to market quickly.

Chapter 4

TELECOM REGULATION: PROMOTING COMPETITION, INNOVATION, AND UNIVERSAL ACCESS

Telecommunications has evolved during the 20th century as the real-time link between households and businesses in the United States. As such, it has grappled with a special set of regulatory issues that involve fostering cutting-edge technologies, services available to all, and open access to the infrastructure. Telecom deregulation will slowly evolve as regulators continue to weigh the incentives for new applications against the protection of the network. The blurring of the boundaries within the communications market will make regulatory innovation difficult.

THE EVOLUTION OF TELECOM REGULATION

Regulation of the telecom industry emanated from antitrust regulation and has historically served as a gauge of public consensus surrounding competition and innovation versus universal service and interoperability. Table 4–1 shows the major milestones in telecom regulation.

Unregulated Growth and Limited Competition: 1876-1909

The early years of the telephone and telecommunications industry were dominated by the rules of patent protection. After Alexander Graham Bell patented the telephone in 1876, his patents effectively limited competition until their expiration in 1893 and 1894. When Western Union, the telegraph operator, used technologies developed by Elisha Gray, Thomas Edison, and others, AT&T (the company Bell founded) filed a patent infringement suit. Court rulings favoring AT&T ultimately led to the sale of Western Union's phone operations to AT&T in 1879 and an agreement that AT&T could develop its systems free of competition until 1894.

Table 4–1
Telecom Regulation Milestones

1876	Bell granted patent on telephone	Gave AT&T effective monopoly on phones and service.
1910	ICC jurisdiction expanded	Telephone and telegraph placed under jurisdiction of ICC.
1913	Kingsbury Commission	AT&T agrees to independent operators interconnection.
1934	Telecommunications Act	Recognized AT&T as national monopoly; FCC established.
1963	FCC approved private microwave communications circuits	MCI given access to local networks for its long distance service.
1982	Consent decree	AT&T broken up.
1996	Telecommunications Act	Federalized the deregulation process to expedite competition.

Source: Institute for the Future

At the time that AT&T's patents expired, it had built the only nationwide telephone network. Similar to railroads, telecom services require intense, upfront capital investment, with a growing network being able to provide greater benefits to all through each additional user. These characteristics provide a huge advantage to the first to successfully build out a wide network. AT&T excluded independent operators from its telephone network. Therefore, telephone competition showed up primarily in isolated local markets where independents could quickly and easily build competing services.

Protect intellectual property: monopoly is acceptable in light of patent protections

Between 1900 and 1915, 45% of U.S. cities with populations over 5,000 had competing, non-integrated telephone exchanges. At the apex of independent competition, between 1902 and 1910, this number surpassed 55%, primarily in smaller communities. None of these independent networks was interoperable, either with each other or with AT&T. Similar to instant messenger services today, telephone users chose providers based on service, quality, price, and which providers their friends, family, and other associates used. But independent services served primarily local needs.

The Progressive Compromise: 1910-1933

Once again, the Progressive Era was a critical time in the development of regulation—in this case, for telecom. In 1907, AT&T began an aggressive buyout campaign that included offering better rates and more integrated services—forcing many competitors to declare bankruptcy or sell. AT&T also purchased a controlling share of Western Union—giving it an effective monopoly in two industries. The government saw the dangers of monopoly power. It started by looking at telephones as similar to railroads, and acted to bring AT&T under the government's regulatory umbrella. It placed the telephone, telegraph, and the cable industries under the jurisdiction of the ICC in 1910.

AT&T was sensitive to the strong antitrust actions brought against industries such as tobacco and steel. There was tension between the benefits of an integrated network and the dangers of monopoly dominance. By 1913, independent Bell competitors were entreating the government to act against AT&T's monopolistic buy-outs. Widespread competition in local telephone service had brought about isolated pockets of communication and the lack of interoperability was becoming a larger issue for commerce

and the consumer's interest. The Kingsbury Commission was set up by Congress in 1913. Its efforts resulted in an agreement in which AT&T agreed to divest control of Western Union, connect its toll lines with independent exchanges, and acquire competing independent operators only after consent of the Justice Department or ICC.

Ironically, the access to the AT&T network that independents had been vigorously campaigning for played a large part in their ultimate demise. After the independents became a part of the AT&T network, they offered little differentiation of service. Therefore, as long-distance calls became more important to the emerging customer base, AT&T's position as the unquestioned leader of the telephone market continued to grow. At the same time, consensus began to grow that universal service was arguably better achieved in the absence of competition.

Consumer access: universal access to the value of a network overrides fear of dominance

Triumph of Universal Service: 1934-1982

During the Great Depression, the feeling that consumer interests were best served by a single telecommunications provider was elevated to law. The 1934 Telecommunications Act recognized AT&T as a natural monopoly and named the company as the "sole provider of telephone equipment and services." The Act also established the Federal Communications Commission (FCC) and transferred jurisdiction of the telecom market from the ICC to the FCC.

The government's main goal within the telecom market was to provide universal, low-cost, high-quality telephone service. Ensuring network integrity became a large piece of this, leading to AT&T's centralized control over all market developments. AT&T manufactured telephone and network equipment and performed all services associated with both. No foreign parts could be attached to any phones or phone lines. For example, phone cords were permanently attached to phones and extended directly through the wall and out to the street. If an individual wanted to move her phone line from the living room into the kitchen, an AT&T technician came to her house and rewired the line—with phone attached—to exit the kitchen, rather than living room, wall.

Consumer benefit: security of consumer service takes priority over consumer choice

AT&T also had total control over the lines running to the home and across the country. As such, the research arm of AT&T, Bell Labs, grew to encompass all telephone and telecommunications developments. Quite naturally, innovations that threatened or offered alternatives to the AT&T

network—like wireless technology and packet switching—were not given a high priority at the Labs. AT&T maintained its infrastructure with a goal of quality service and relatively low-cost access, not for innovation and new services.

The initial limitation of the AT&T monopoly came from restrictions on AT&T's movement into other industries. In 1949, the Justice Department, under the Sherman Antitrust Act, brought a suit against AT&T, seeking to split off its manufacturing arm, Western Electric. By 1953, the computer industry was 14 years old and could boast inventions such as ABC, Mark I, ENIAC, and UNIVAC. These two forces resulted in the 1956 Consent Decree, which allowed AT&T to keep Western Electric but restricted it from entering the computer and information services business. In part, AT&T agreed to this to limit direct competition with IBM in either market. While the AT&T monopoly lived on for 25 more years, the 1956 Act was a turning point in limiting its power and reach.

Consumer choice: new technology is the key to opening new choices for long distance services

Also, competition began to increase as the government began to redefine how regulations should benefit consumers. In 1957, the Hush-a-Phone case ended the limitation of foreign attachments on Bell phones, ruling that they did not adversely affect the quality of service that consumers could get from AT&T. In 1959, the FCC approved private microwave communications circuits, opening up competition in network services. In 1963, MCI began offering long-distance services in competition with AT&T, with mandated interconnection to local phone companies.

The 1982 break-up of AT&T was the end result of a second antitrust suit brought in 1974. AT&T divested itself into a central core dealing with the long distance and corporate markets, 22 regional operating companies (which later reorganized into the Baby Bells), Bell Labs, and Western Electric. The goal was to encourage the building up of strong local companies that would eventually compete in each other's territories.

Consumer benefit: utilize market competition to bring innovation and wider choice

ISSUES OF ACCESS: 1983-2002

Over the last two decades, the telecom industry has undergone significant technological developments that have changed the nature of competition and led to a new round of deregulation. First, bandwidth became available at low marginal costs, driving the price of local and long distance down dramatically. Second, wireless technology began to compete with traditional telephone service, particularly at the local scale. Third, the demand for net-

worked computing, access to the Internet, online services and global networks increased significantly. In fact, inter-modal competition increased, with both local and long-distance providers competing with new entrants such as wireless, cable, and Internet companies.

Surprises with the Baby Bells

At the same time, real competition in local area phone service—the goal of the AT&T breakup was very slow in coming. State public utility commissions were reluctant to open the local phone infrastructure to competing firms because they wanted to ensure secure service and maintenance for existing customers. And consolidation led to the formation of four regional Bell companies from the original seven. Rapid technological change against the background of slow institutional adjustment led to a new round of deregulatory legislation more heavily based on the principle of specific, market-data driven regulations.

1996 Telecommunications Act

The 1996 Telecommunications Act effectively federalized the deregulation process in order to expedite competition. The 1996 act brought competition and deregulation out of the jurisdiction of each individual state, seeking to facilitate competition across all nearly all telecommunications markets—local, long distance, data services, and cable—both wireless and wireline.

Appreciation of the unique: regulators need to foster competition in a blurred telecom market

To foster competitive conditions, Congress fostered new entrants into new markets. For example, the 1996 act stipulated that both the Bells and long distance carriers could enter each other's markets. Before the incumbent Bells could enter the long-distance market, however, Congress required them to meet local competition requirements. Congress set in place, and the FCC oversees, the process for the Baby Bells to open their existing networks and lines into the home to competitive local exchange carriers for a set government-determined price. Until meeting these rules in individual markets, the Bells are restricted from providing long distance service in that market—both for voice and data services, such as broadband Internet access.

The act empowered new telecom companies to emerge—the high-tech boom with its emphasis on bandwidth use produced a tremendous capital

investment boom in bandwidth among new and existing companies. The revenue of new entrants to the local phone markets grew dramatically after 1996. At the same time, the market revenues of wireless providers rose rapidly as well (see Table 4–2). WorldCom, for example, grew from a small reseller to a major fiber-optic conglomerate.

In turn, though, the collapse of the high-tech boom in the summer of 2001 brought a dramatic slowdown in new capital investment. Still, the wide availability of excess bandwidth capacity assured a competitive situation in telecom services.

THE DEBATE LIVES ON

Even in a deregulated environment with competitors covering a spectrum of old and new, the FCC must strike a balance between promoting competition, creating an attractive investment opportunity, and ensuring universal access and consumer protection within the telecom market. These are often contradictory tasks, especially with multiple players promoting conflicting interests.

Opening the Telecommunications Market

The current debates include three big issues.

- *Saving the wireless players.* The wireless sector has been growing rapidly. It rose from 9% of total telecom revenues in 1995 to 25% in 2001. But the wireless players have been hit hard by the collapse of the

Table 4–2
Rise of New Competitive Entrants
(Revenue for competitive local exchange carriers, billions of dollars)

	New fixed-line competitors	*Wireless service providers*
1993	0.2	10.2
1996	1.0	25.9
2001	12.9	76.5

Source: Federal Communications Commission, *Trends in the Telephone Service*.

investment boom. Part of the rapid growth came from an opening of vast new bandwidth spectrums that the government controlled and auctioned off to wireless companies in the mid- and late-1990s. As some of those wireless firms have gone bankrupt and others have been unable to raise the funds necessary to use the spectrum because of debt burdens, the government and the courts have been adjudicating the responsibilities of the bidders and what happens to the spectrums in the case of default. The FCC has tried to ease the snarl by clarifying responsibilities of parties and returning some of the funds debt ridden companies paid for spectrums they cannot now use.

- *Access to the network.* The 1996 Telecommunications Act pushed to make it easier for alternate carriers to enter the local market. The rise of new players in the Bells' local markets has been notable. Regulators continue to be protective of the Bells so that they will continue to invest in infrastructure and new equipment. In effect, the real competition is coming from the wireless providers with cable companies and Internet providers approaching viable alternative service models (see Table 4–3).
- *Bandwidth competition*. The proliferation of enhanced copper wire connections and the laying of thousands of miles of fiber optic cables dropped the marginal cost of bandwidth dramatically. But so far, cable-based services have the regulatory edge over phone-based services. Their broadband services are not delivered via the telephone network. So while new broadband players have to fight to gain access to regulated local phone networks in order to offer DSL service, cable companies don't.

Table 4–3
Market Penetration Rates of New Players
(Percent of new players in each market)

	1982	*1992*	*1996*	*2001*
Long distance market	2	38	52	59
Wireless providers in total market	-	5	12	25
Local phone market	-	-	1	10

Source: Federal Communications Commission, *Trends in the Telephone Service*.

In making its regulatory decisions, the FCC is striking a balance between promoting competition, creating an attractive investment opportunity, ensuring broadest possible access to consumers, and keeping rates as low as possible. This outcome is important because it shows how in a market where new technologies are moving rapidly, market penetration rates can change very quickly as new entrants find a market niche. And courts, legislators, and regulators have accepted these rapid shifts as healthy for business and consumers.

Recent court rulings have further muddied the water. The Supreme Court ruled that the Bells must open their networks to competitors. Simultaneously, the D.C. Court of Appeals ruled that current regulations that guarantee access to new entrants are not neutral and stunt the incentive for existing providers of local service sufficient revenue for investment and ultimately reduce consumer benefit.

THE TELECOM WORLD IN 2012

The telecom world will look markedly different in five to ten years. Whether or not broadband service through phone lines is deregulated, cable companies will have a huge regulatory and technological advantage over the next five years. In addition to exclusive ownership of and access to cable modem lines, cable companies can charge higher "competitive" rates than competitive phone rates because of their control of entertainment content. They thus enjoy a greater profit margin. This gives cable operators both more capital and likely acceptance of price increases.

The Bells will continue to operate under some level of competition requirements, providing access to new entrants for any investment they make in broadband capacities. This reduces the amount they are willing to invest in new technology and services and limits profits from any undertaken build-outs. The new local entrants do not seem to be sustainable, under their current business models of reselling excess capacities or building new networks in the current market environment. Those that survive will do so because they build out their own networks rather than piggyback on those of the incumbents. Long distance carriers are also unlikely to survive in their current incarnation. With massive debt and without lines into the home, long distance companies are likely acquisitions for cable or bell companies.

Regulators will set the tone of the market by continuing to push for some competitive access and availability of service options for all. Yet,

regulators are also likely to allow takeovers of indebted companies, such as the recent indication that the FCC would let one of the Bells takeover WorldCom. This will reduce competition in the marketplace but will lead to consumer benefit in the form of maintenance of services and more-likely build out of new services. In the longer run, consumers will benefit in lower prices from the excess capacity—especially as firms buy built capacity for pennies on the dollar—and in technology choices through the competing models. Look for the Bells to continue to dominate in local telephone services, and for cable companies to lead, but Bells continually gain ground, in the market for new services, such as high-speed data services. Also, as deregulation does not mean "no regulation," regulators will continue to intervene. Given the competitive advantages the regulators have given the cable companies and the forced access issue for high bandwidth through telecom services, they will likely try to make the rules platform neutral. In other words, there will be a continued muddling through the issues of integrating the opportunities of the new technologies in a world where assured services are important. Look for regulators to be driven by the following.

- The need to protect the local networks that consumers and businesses rely on for daily service.
- Some form of rate protection in areas where effective competition is restricted by high capital cost of entry.
- A desire to get more options available to the consumer.
- National legislation, national regulators, state PUCs, the courts, and advocacy groups at the local level acting to represent a variety of interest in each major decision.

Chapter 5

REGULATORY LESSONS FROM OTHER INDUSTRIES

If we look at key business regulatory issues in other areas, we find the same basic principles in operation as regulators sort through today's biggest issues. In this chapter, we compile the critical lessons that come from trends or disputes in five other areas: the electricity market, privacy, financial services, corporate oversight, and intellectual property.

THE ELECTRICITY MARKET

Electricity regulators followed telecommunications regulators in trying to open markets for competition. Like telecommunications, they saw this as a way of moving away from tightly controlled natural monopolies or markets with very strong network effects into a more competitive environment where new players would bring new ideas, new capital, new products or services, and, hopefully, lower competitive prices.

With fewer new technologies and a greater dependence on an assured supply by users, electricity deregulation has had a hard time trying to foster innovation in the market, especially as sufficient protections weren't put in place to protect consumers from markets in some key areas. The prime example of this is the energy market in California where breakdowns in a partially deregulated market produced rolling blackouts in the winter and spring of 2001. PG&E, one of California's two major energy distributors, declared bankruptcy when it found itself caught between a cap on retail-prices and uncontrolled price increases in the wholesale market. A few other deregulated markets in areas of strong network effects have experienced similar issues—the deregulated and broken up rail system in England had issues with keeping quality of service and spending capital to maintain the infrastructure, for example.

Lesson 1

Flexible and adaptable regulations are needed to assure supply in natural monopoly markets and also to foster competitive innovation and provide more consumer choice.

These problems or abuses clearly point to a need to make sure that the market set up for deregulated network businesses is carefully structured to assure supply under varying market conditions. In these markets, regulators should retain enough authority to provide an assured supply. Under slower more controlled circumstances, deregulation of electricity and energy markets—in states such as Pennsylvania and Massachusetts—has worked to provide some competitive forces while assuring continuous supplies.

PRIVACY

The Supreme Court and other courts in the United States have consistently ruled that free speech rights are Constitutionally protected and are very extensive. In several recent cases they over-ruled laws that placed restrictions on free speech—despite broad public support for the restrictions. In one of these cases, a U.S. District Court banned the use of filters to block access to sexually explicit content on Internet connections open to use by children in public libraries. The law was rejected because the filters also block unintended, Constitutionally-protected content—health and sexuality information, for example. A strong coalition of civil libertarians and professional librarians opposed the use of filters.

In a second case, the Supreme Court struck down the Child Pornography Prevention Act (1996) as overly broad and unconstitutional. The law, in part, sought to outlaw "virtual child pornography." The Court rejected the law because it banned materials that are neither legally obscene nor produced by exploitation of real children. Again, the protection of free speech overcame the community's desire to protect children from inappropriate material.

How do pornography rulings relate to privacy and business regulation? In the end, the protection of information and the ability to use it is what the courts are protecting. Therefore, these rulings have a direct impact on the use of customer data that companies collect in their normal course of business. Except in exceptional cases where the legislature carves out a particular area for protection, the court has held that customer data collected by a company are protected property and can be used freely by the company. The exceptions include very sensitive information like medical information, but even this kind of information can be used and shared for some purposes.

In addition, proposals for new legislation at the national and state levels have not made substantial progress. There was a recent debate in the

California legislature on a financial privacy bill (The Financial Information Privacy Act) that would give individuals greater control over use of information about contacts, bank balances, and spending patterns—stressing the opt-in provision, the bill would have required personal approval for use. The debate showed the complex set of factors at play, even in the most liberal of environments. On the one hand there were consumer organizations and privacy advocates who represent consumers concerned about the protection of their personal information; there was substantial public support in newspaper and editorial comment. On the other side, there were a number of banks, insurers, and other businesses that use financial data to present consumers with a richer set of commercial alternatives or with easier to handle opt-out provisions. In practice, the bill that would have provided an opt-in provision, was unable to garner a majority in either branch of the legislature and would have been vetoed by the Democratic governor even if it had. The failure of the bill, in a state that is often seen as a strong advocate for the consumer, is an example of how difficult it is to find a public consensus when the issues and varying interests at play are so varied.

Lesson 2

Constitutional protection of free speech provides strong support for the gathering and dissemination of business-based information about consumers.

FINANCIAL SERVICES

The financial world presents the clearest case of how an increase in the public's perception of safety created the environment for substantial deregulation during the 1930s. Financial markets in the United States have been under tight regulation since the financial debacle of 1929 that helped thrust the United States into the decade-long Great Depression. The Glass-Steagall Act (1933) and other regulations from that period kept banks from opening out-of-state branches and restricted banks, securities firms, and insurance companies from even partial ownership in companies in related financial industries. (For example, banks couldn't sell insurance nor own shares in firms). In turn, securities could only be sold through agents, usually in large volumes because of high transaction costs. To protect banks and savings and loan associations, ceilings were placed on interest rates offered in checking and savings accounts.

After 25 years of prosperity following World War II, however, financial practices began to change. Consumers, looking for easier payment mechanisms and more rewarding places to put their money, started to use credit cards and then debit cards in place of checks. They also began to change they way they saved and invested their money. At the same time, individual

Lesson 3

Financial institutions were permitted a much broader range of activities when it was shown that consumers wanted more choices and were willing to assume greater risk.

holdings of shares in companies, whether directly or through mutual funds, increased dramatically. And, many corporations moved from defined-benefit to defined-contribution plans and 401(k) savings plans, giving more people responsibility for managing their own investments. The widespread availability of alternative forms of savings and transactions choices made it easier for the government to radically reform institutions.

The deregulation of financial institutions followed the radical changes in consumers' actual practices. In the 1970s, regulations on bank activities were gradually eased as interest-rate ceilings were lifted, certain states permitted interstate branches, and very limited amounts of insurance activities were allowed. The incremental approach was finally abandoned in the 1990s. The Riegle-Neal Interstate Banking Act (1994) eliminated geographical restrictions on holding companies and branch networks. And, the Graham-Leach-Bliley Financial Modernization Act (1999) removed restrictions on ownership and operation of banks, insurance companies, and securities firms across boundaries—allowing them to operate full-fledged, multi-industry operations under a single financial holding company.

Regulation of financial services is a clear case of how the growth of a more sophisticated financial market with greater diversity, a wider spreading of risk, more open information flows, and more effective competition from new sources reduced the need for detailed and narrow institutional regulation. Regulation could instead focus on broad-based regulation like capital reserve ratios for banks.

CORPORATE OVERSIGHT

The recent rash of corporate misconduct incidents—Enron, Andersen, Tyco, Adelphia, Citigroup, and WorldCom, to name some—has raised the issue of misleading or fraudulent financial reporting. Since there was a very large number of people who invested in companies that were purposely misstating their financial outcomes, there has been widespread popular revulsion and call for reform.

Despite the uproar—and the lack of confidence in the investment markets that was a consequence—there seems to be a wide agreement that the solution is in more trusted public information. The result was the recent Sarbanes-Oxley Act (2002) that requires publication of clear accounts while holding the officers of the company strictly liable for misrepresenta-

tion. In addition, auditors are restricted from doing closely tied consulting. The challenge has been to set reporting standards that can cover the wide range of new, flexible financial tools and the range of securities and derivatives open to business managers without taking away the incredible power that can come with institutional flexibility, innovative reward systems, and access to wider financial markets.

Lesson 4

Financial information is open to abuse—it has an inherent risk of fraud and misuse; but open and well-publicized reports available to all market participants is the best guarantor of the consumer's interest.

INTELLECTUAL PROPERTY

Intellectual property rights largely defined the boundaries around many of the issues that arose during the high-tech boom of the 1990s, and these issues may well define the world of competition in the technology sector in the future. The most contentious technology related issue today is the gradual extension of intellectual property rights. There are at least three recent examples.

- *Data ownership.* The courts have tended to protect those who have processed data or built a transaction database—this includes those, like Reed Elsevier, who have created company performance databases or those, like e-Bay, who have sought to protect their transactions records.
- *Extension of copyrights.* In 1998, Congress increased the length of protection for copyrights, extending them for 20 years—from 75 years to 95 years—for works owned by a corporation; and for the life of the holder plus 50 years for individual copyright holders.
- *Digital piracy.* The Digital Millennium Copyright Act (1998) set strict new rules on the duplication of protected intellectual property. Repercussions from it forced Napster to stop its free online music distribution service—despite its 67 million registered users—because Napster's technology was enabling illegal duplication and distribution of copyrighted music. Legislators are working on new laws requiring new electronic devices to have built-in anti-copying technologies.

These issues are of critical importance because they are attempting to define the boundaries for sharing information that qualifies as intellectual property in a world of new digital technologies. The tendency, so far, has been to put restrictions on the users of the technologies.

Lesson 5

Like free speech, intellectual property rights get their basic protection from the Constitution; the principle in operation is that consumers will benefit more from creation and innovation than from rapid and easy dissemination of protected intellectual property.

Going Forward

Current regulatory efforts are based in the application of the six principles outlined in Chapters1-4. The sum of the principles means that there will be a regulatory reaction when consumers are clearly hurt, but that when there is not overwhelming evidence of harm, regulators will continue to push for reforms that will provide wider choice to consumers—the choice sometimes means only better information, sometimes new players in markets, sometimes offerings of new technologies. It is also noteworthy that there are increasing cases where disparate players are working together on either side of various issues—as in the debate over access to generic drugs, the debate in the California legislature over privacy, or the debate on blocks on pornographic Web sites in libraries.

The next chapter looks at how the principles and lessons will be affected by a set of key driving forces and what this means for business regulation in the future.

Chapter 6

A Fragmented Regulatory Future

Through our examination of several long-term industry examples, we have seen that regulation of business in the United States has been driven by a limited set of principles that interact with a given set of social and technological contextual factors to produce key shifts in regulatory trends. In this chapter, we turn to the next ten years and to those factors that are likely to be the most important drivers of regulatory decision-making in the future.

Driving Forces

There are some key driving forces that we have touched on repeatedly throughout this report. Here we look at the strength of these eight key driving forces and what they mean for the future.

New Consumers

There are important demographic changes that are transforming regulation. Just as the urbanization of the United States created the background for the regulatory reforms of the Progressive Era, the rise of the sophisticated new consumer at the end of the 20th century has created the basis for another transformation of business regulation.

The characteristics of new consumers are clear: they are better educated, live in households with higher incomes, work in white collar information-based jobs, and have access to the new digital forms of information. New consumers also behave differently in their use of information: they tend to process more information, get it from more channels and sources, prefer sources of information that are interactive, and seem willing to assume more risk.

And, new consumers have a different view of how they can use their attributes—education, income, and work experience—to control and influence the world around them. This has already had a huge impact on regulation—reinforcing the emphasis on choice as a value, providing a greater diversity of inputs on the impacts of regulation, and widening to some degree the notion of acceptable risk.

The Future

The number of these new consumers is growing rapidly. Demographic analysis shows that the share of the adult population with some college education, living in households with over $50,000 in real income, with substantial private assets, or with a white collar-information intensive work experience is growing at 4% each year. This group makes up nearly 50% of the U.S population today and will increase to 55% by 2010.

Survey data tends to show that there is no clear consensus around what is the best information but that more consumers are using more information of varying kinds. And, the pattern of increased use of commercial information rises with each level of income and education. The most rapid changes in behavior are taking place in the mid-deciles of the population—and our data indicate that the share of population taking on these more aggressive attitudes toward information (gathering more information and using more sources, for example) is growing each year.

Growing Importance of Information

The share of consumers who are interested in using information more intensively is growing. This trend is leading to different forms of business-to-consumer communication with a greater stress on interaction and personalization. (Personalization of information here means that the information is either tailored to a consumer's needs, targeted to him specifically, or is intentionally timely.)

Information has always been a part of the regulatory environment. But while the Progressives saw information as empowering, they quickly came to the conclusion that regulatory agencies had to be able to use the information gathered from businesses to impose a carefully monitored outcome. The economic disasters of the Great Depression reinforced the perception that regulated and closely controlled industries were the safest in terms of

the public good. But the 50-year period of expansion that followed World War II created a sense of confidence in the underlying safety of business and created the basis of the demographic revolution of the new consumer. These two elements revived the original Progressive notion that active citizens with good information were the key to successful public control of business.

It is interesting to note the focus of the biggest regulatory issue of 2002—corporate corruption. It was an issue that involved a broad swath of consumers—those who held shares in companies or in mutual funds and those who were actively involved in private pensions—as well as banks and insurance companies, employees, and tax authorities. But all the parties involved interpreted the issue in terms of information. That is, the key issues were around what information needed to be made public, who was to verify that information, who was responsible for making it available, and what penalties would be imposed for disseminating incorrect or untrue information.

The Future

Information use will continue to be the critical definer of the new consumer. Thus, information empowerment will be at the center of any regulatory issue that affects business over the next decade. And, it is important to note that this information increasingly comes from the marketplace and is mediated through market mechanisms like stock exchanges, rating agencies, a plethora of new media channels, Internet sites, and consumers talking to each other. The public no longer sees the government as the center of information processing and publicity, rather private agencies and citizens are seen as the key information disseminators.

Changing Nature of Risk

New consumers have also redefined risk. The composition of financial holdings is one good example of the changing nature of new consumers' tolerance for risk. Households are now much more willing to hold their assets in riskier investments—equities rather than more stable deposits and bonds—than they were just a decade ago. In 1990, U.S. households held about 20% of their total financial assets in equities; by 2001, 41% were in equities. Households are also much more willing to accept control over their investments than they used to be. Whereas, only 45% of households' private pension holdings were in equity in 1990, the share increased to

63% in 2001. And it is important to note that the share held in riskier financial vehicles did not drop during the sharp fall in the stock market during 2001-2002, though discretionary investments fell dramatically.

The Future

The stock boom in the share markets drew many householders into the market in the late 1990s, and there was a lot of frustration when the markets busted. But to date, despite the fact that many consumers are now a bit shy of investing in the market, there is no indication that there is a rush back to reliance on Social Security or defined-benefit retirement plans. This growing adaptation toward increased risk-taking will continue as more consumers gain higher levels of income, education, and job or career security as the decade progresses. This trend will increase the share of consumers who are interested in increasing their range of choice and options, even if it comes with a slight increase in risk and it will have a profound impact on regulatory actions.

Technologies That Blur Boundaries

Scientific advances and new technologies have always had role in driving new regulations. But today, we are witnessing the beginnings of several technological revolutions—genomics and nanotechnology to name just a couple—that are likely to blur traditionally defined regulatory boundaries over the next decade. For example, the genomics revolution will, in part, transform the world of food. (For more on how genomics will impact the food industry, see "The Nutrigenomics Revolution" in the *2002 Ten-Year Forecast*.) Specifically, nutrigenomics—the science of applying genetic information to nutrition—will generate new products that cross and blur the boundaries between traditional foods, dietary supplements, and drugs. This isn't just the case with new food products. For example, consider an implanted, insulin-delivery device to treat diabetes—is it a drug (insulin) or a medical device? Under current rules, such a treatment would have to go through two approval processes—through the FDA's pharma arm and its medical device arm. The regulations for approval are very different for the two categories and approval for such hybrid treatments is typically very slow. More and more of these kinds of technologies are being developed.

The Future

Over the next ten years, new technologies are likely to flow at a faster rate than regulators can create and apply new rules. The FDA and others will face serious challenges in regulating the fruits of future scientific advances first in creating and revising definitions for product or service categories, and second in deciding how to regulate new, desirable, and potentially risky products and services. There is the potential for some regulatory agencies, such as the FDA, to become overwhelmed by new technologies without adequate staffing—both in terms of numbers and expertise. Consumers that are willing to take more risks, especially with products that improve their health, like food, drugs, and medical devices, will put increased pressure on regulatory agencies to access new technologies quickly.

Redefined Markets

Traditionally the most important characteristics used by antitrust regulators were size of market and market share. Over the last 20 years we have seen movement away from pre-defined notions of "acceptable" market share and the incorporation of measures of consumer value—choice, efficiency, innovation, and price—in competitiveness calculations. Overall, the new, more complex system brings benefits to many consumers. As some commentators point out: regulations are not meant to protect existing industries but to benefit consumers. However, over the next decade, the simple act of defining a market and who is an effective competitor for a consumer's attention will become even more complicated and could pose challenges for regulators. As we move farther down the road toward a global economy, defining the size of potential markets and market share will continually get harder.

The Future

With local producers now competing with Chinese and Brazilian manufacturers it is hard enough to define a market. But with the Internet now competing with phone services, free local newspapers competing with national magazines, targeted radio shows competing with TV news, and food products competing with pharmaceutical products, it is growing increasingly dificult for regulators to define a competitive market.

The Burdens of Business Failure

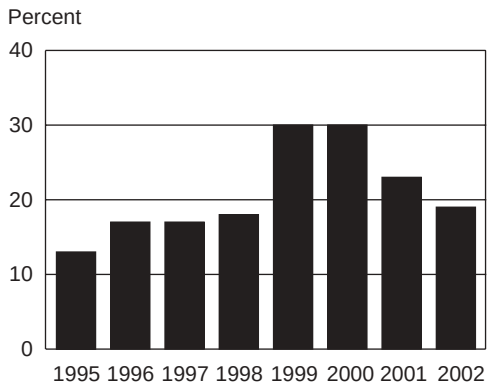
We have just experienced a recession and a sharp decline in the stock markets—right after a majority of Americans had bought into those markets in a fit of optimism about wealth and the promise ever-rising assets. The recession was generated by a sharp decline in business investment, focused on the dot-com, software, and telecom sectors—all of which went bust. In 2001 and 2002, the general problem of a lack of confidence in business was compounded by a seemingly unending stream of revelations about abuse and misuse of corporate power and knowledge.

While consumer confidence in business leaders rose during the share market boom, it fell back again with the burst of the New Economy bubble and revelations of abuse (see Figure 6–1).

The Future

The boom of the late 1990s built up confidence in the leaders of the business community and drew investment funds from individuals in record amounts. In turn, the bust, along with the attendant corporate scandals, will lead to growing skepticism about business in the years to come and more support for regulations that limit the discretionary authority of corporate leaders.

Figure 6–1
Confidence in Business Leaders Is Way Down
(Percent with a great deal of confidence in Wall Street leaders)



Source: Harris Interactive

Personal Security and Privacy

Concerns over threats to privacy increased in the 1980s and 1990s as new technologies enabled the collection, manipulation, and dissemination of vast amounts of personal information. In 1978, only 64% of the population was concerned. Concern steadily increased to its peak in 1996 during the early days of the Internet at nearly 90%. Today, the share of those concerned has dropped slightly but remains at more than 80%.

The terrorist attacks of September 2001, the anthrax scare, and the continuing tensions in the Middle East have increased people's concern about their personal safety. In the wake of September 11, new laws that increased law enforcement powers of surveillance and wire-tapping were quickly approved. In the weeks after the terrorist attacks, public approval for a national ID card soared to 70% according to a Harris Interactive survey. Security seemed to have taken precedence over privacy.

However, this was not the end of the battle between privacy and security. In fact, this battle has been underway for a very long time, and will not end soon. For example, just six months after the terrorist attacks, public support for national ID cards had dwindled to 26% in a Gartner survey. Even federal lawmakers had slowed the pace of new laws relating to increasing security and began to focus again on privacy rights. In August of this year, Senators Schumer (D-NY) and Edwards (D-NC) proposed the formation of a commission that would examine new surveillance technologies and then propose rules for implementing new technologies and investigative strategies with the goal of balancing security and privacy concerns.

The Future

The conflict between keeping the populace safe and secure and respecting deeply held rights to privacy is not going away. There are strong trends that are acting to keep even the some of the most private information available for public use—the concerns over security, the benefits that companies get from having such information available, and the benefits that better-educated consumers are discovering in the discreet use of their personal information. But there are also privacy concerns that are important and valid. In fact, over the next ten years, the tension between privacy and security will increasingly be a part of many regulatory debates, but in the end the valid use of personal information is not likely to be restricted.

Elections

Regulatory change reflects politics. There is no question that we are at a period of time where political forces are evenly divided between parties and political perspectives. The 2000 Presidential, House, and Senate races were the most closely contested since the middle of the 19th century. And despite Republican gains in 2002, their advantage is slim. In addition, European elections reflect similarly even splits among the major parties. (For more on this topic, please see the article, "The Shift in Political Parameters" in the *2002 Ten-Year Forecast*).

The Future

The decidedly even political split will make it hard over at least the next five years to push regulatory policy off its current course.

REGULATORY FORECAST

Each of the driving forces we have identified will operate over the next decade and will increase in influence. This will tend to exacerbate the regulatory influences we have come to experience over the last 20 years—increasing the pressure for wider consumer choice, increased tolerance for risk by middle-class consumers, and opening up voluntary means for those who want to accept market-based solutions. We anticipate that, in general, there will be dominate pressures to increase choices for new consumers, utilize the benefits of information for both consumers and businesses, accept the exciting possibilities of biotech and genomics (despite the unknowns and potential risks), and to share in the benefits of the global marketplace. It will be very difficult for regulators to step back and to use government controls to limit these choices.

Every regulatory choice that affects business represents a trade-off amongst these basic principles: more information versus legal protections from public scrutiny; efficient professional agency oversight versus costly individual litigation in the courts; consumer safety versus wider choice for all; protection from the unknown versus the individual benefits of risky behavior; and a standard set of widely known and accepted rules versus the flexibility that comes from appreciation of unique circumstances. Figure 6–2 shows the longer term-dialog between just one of these tradeoffs—consumer protection versus an acceptance of the risks associated with

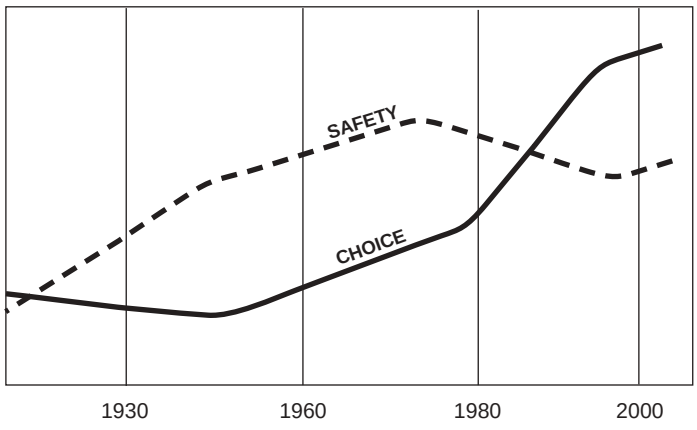
wider choice. It tracks basic societal perceptions over the last 75 years across a broad range of areas where business regulation has been debated.

The trade-off represented in the figure is symbolic of the slow adaptations of regulation to the needs and perceptions of society as the external environment changes. The driving forces discussed here identify new causes for the public to seek government protection from an economy in recession and a world that feels less secure and more intrusive. But there are also several of basic forces that will remain in effect, most importantly the longer-term trend of sophisticated consumers continuing to look for areas where the government can facilitate choice and assure that they can get benefits from private entrepreneurial activity as well as protect them from fraud and abuse.

Today's Regulatory Debates

Our regulatory agencies and lawmakers are engaged in several debates today about the directions that business regulation is moving. To date, the outcomes of each debate seems to indicate that while there will be some modifications of past trends, the acceptance of information, choice, and market competition continues to hold.

Figure 6–2
The Safety-Choice Trade-Off



Source: Institute for the Future

Generic Drugs

There is a continuing debate over the lifting of constraints on the introduction of generic drugs into the marketplace. A diverse set of players—large corporations who pay health care premiums, health insurers, generic drug manufacturers, unions, and consumer groups—all are actively pushing for easier access. Their efforts are paying off—a bill that would make it easier to generics to be introduced made major progress when it passed in the Senate in July 2002. But the goal is to push ahead into the biotech area where there is no specific regulatory process to approve generic equivalents of biotech products.

Biotech drugs—derived from living sources and consisting of complex proteins and other large molecules—are not covered by the Hatch-Waxman Act of 1984 that deal with generic equivalents. Aside from the affected industries (big pharmaceutical firms and generic manufacturers), there are diverse groups on both sides—consumer advocates of the chronically ill worried about safety and consumers and corporations paying large health care bills are looking for a wider set of choices. We are likely to see the redefinition of a key market long under the influence of companies operating under strong (drug) patent protection.

Opening the Telecom Markets

There has been a long and complex tangle in moving away from the monopoly provider of telecom service in the United States—AT&T. The breakup of AT&T did not completely solve the problem since it merely created seven regional local companies that were non-competitive—it did open the long-distance market for competition, however. But the recent technology explosion that led to rapid penetration of wireless phones, cable alternatives and voice connections on the Internet have provided for a seemingly wide variety of options for consumers. But too rapid capacity expansion in the late 1990s means that some of the key players are threatened with financial failure.

There is no right answer for regulators in defining terms of access or granting of protected markets or any clear ideological divisions—the goal

is to help an industry through an important longer-term technology transition and to provide enough strong players who can compete in offering a variety of different services. The indications are that the options are opening, but slowly and regulators need to deal with arcane but important issues about who can buy which assets of failed or weak companies—that is, should the local Bells be allowed to purchase the long distance operations of the failed WorldCom?

Privacy, Information, and Corporate Ethics

The recent debate in California around a financial privacy bill shows the complex factors at play. On the one hand there were consumer advocates who represent consumers concerned about the protection of their personal information. On the other side were businesses that speak for many consumers who prefer to get advertising materials that are more relevant and targeted to their particular needs. The failure of the bill in a state that is often seen as a strong advocate for the consumer is an example of the complex set of issues and varying interests that are and will increasingly be at play in the regulatory decision-making process.

Reorganizing Electricity Competition

The huge mistakes made in deregulating the California and some East Coast electricity markets had many thinking deregulation was dead. However, in August 2002 the Federal Energy Regulatory Commission (FERC) announced a plan to reorganize the nation's electric system and reinvigorate deregulation. Rather than take the hands-off approach as it has in the past, FERC has identified market devices that have proven successful and is seeking to export and implement them nationwide. The agency hopes that clear rules, backed by enforcement, will put deregulation back on track, with stronger protections for security of supply for consumers and clear rules and roles for energy suppliers and distributors.

Each of these debates took place during a time of low levels of confidence in business by consumers. But each also shows that the response of the regulator was to modify and adapt market-based regulations rather than do away with them. The net change shows a mild response to the old trade-

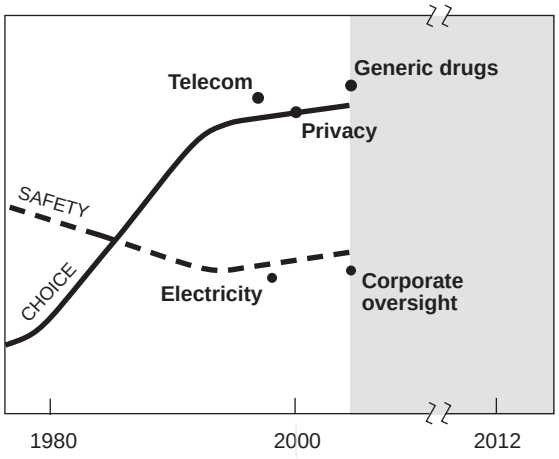
off issues (see Figure 6–3). We may be at a point where we are no longer rapidly extending the "distance" between consumer safety and consumer choice, but there are no indications that we are about to narrow the gap that opened during the 1980s either. In fact, if anything, we are pushing toward extending consumer options and choices wherever it seems safe to do so.

Regulation 2002-2012: Fragmentation

Unless there is a fundamental change in some of the key driving forces—a major collapse in the stock market, a substantial rise in unemployment, or wars, terrorist attacks, or crime waves that change perceptions of daily lives well beyond today's levels of heightened concern—we will continue to see business regulation that attempts to tip the scale a little on the side of providing choice and taking potential consumer benefits into account. This will be especially true as we move out of the current downturn in the business cycle.

Business regulation will attempt to balance the six principles that we have identified in this report. Each of the six represents an era when the need for

Figure 6–3
The Safety-Choice Trade-Off in Light of Recent Business Regulation Issues



Source: Institute for the Future

that particular perspective seemed to be an overwhelming need. But the process of weaving these principles together raises difficulties in itself. Future regulation will incorporate the following characteristics or qualities.

- *Complex trade-offs.* Regulatory issues are less likely to involve the simple trade-offs, such as between risk and safety or courts and an independent agency, and more likely to involve trade-offs across these categories, with independent agencies more likely to take a more aggressive stance on standards of information than the court system.
- *Compromise.* Future regulation will more frequently be the result of compromises made by a host of advocacy groups. The recent generic drug bill brought together an unlikely coalition of players—generic drug makers, non-health care corporations, insurers, and union leaders. To date, the coalition's efforts have helped see the passage of what many saw as a going-nowhere bill in the Senate. But more importantly, the collective voice of a range of interests who had compromised with each other on their varying goals was able to be heard over the very powerful pharmaceutical lobby. And the unique coalition cuts across what for decades were seen as ideological divides.
- *Fewer recognized standards.* More often, regulation will be driven by the unique claims of a particular situation. In the past, both courts and regulatory agencies sought to establish straightforward, well-publicized principles, such as market dominance in clearly defined local geographical markets equaled monopoly power, or that the safety of every user was the basic goal of drug approval. Now agencies and courts are trying to look at wider markets to balance the potential benefits of many or weighing the cost of not having certain innovations available as factors in the approval process.
- *Less ideology.* As we move toward a regulatory world that appreciates and evaluates the unique conditions presented and as more groups come to define the benefits that will come to their members from a new rule or interpretation, we will see more diverse coalitions—unions and employers; hunters, environmentalists, and farmers; libertarians; shoppers and database managers; home office workers and cable providers. All of these ad hoc coalitions will cut across traditional patterns in reg-

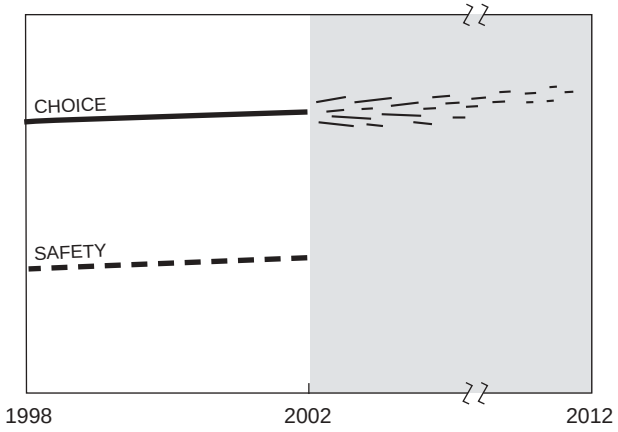
ulatory debates and there will be less reliance on a dominant ideology to guide regulatory decisions.

The regulation arena will look like the diagram in Figure 6–4 with new regulations not following one path but fragmenting along several. While fragmented, the thrust will remain on providing choice.

IMPLICATIONS

Given the collection of principles in operation and the key driving forces acting on the regulatory environment, we expect the next decade will be an era of regulatory fragmentation. As regulators have more market characteristics, consumer benefits, and issues to consider and as new technologies make their way to market, they will be forced into making decisions that are decidedly divergent. There will be no single rule or ideology dominating action. In fact, as the number of factors that have to be considered before a decision is made increases, the process will be come more complicated. Several implications for business planning flow from this new era of regulation.

Figure 6–4
A Fragmented Regulatory Path in the Future



Source: Institute for the Future

- *Slower.* As regulators consider the full range of issues, the decision-making process will likely slow down. As industries await new formal rules, self-regulation will become even more important. The slowdown might also be exacerbated by a lack of adequate staffing in some agencies. In an era of government downsizing, some key regulatory agencies, such as the FDA and antitrust authorities, might find themselves increasingly back-logged and under pressure to go back to basic rules and patterns of control.
- *Better, if slower, rules.* However, if regulators can keep up with the workload, it is likely that the decisions that do flow from the process will be better ones. They will likely have taken into account a wider range of issues and will have been supported by diverse coalitions of interest groups. These rules will be more tailored to the practical issues at hand and less susceptible to legal challenges. These rulings will be more acceptable to parties in current disputes, but they will also be less susceptible to be used as precedents for the next issue on the horizon.
- *Cooperation and contention between regulators and industry.* Today, the FDA works very closely with the pharmaceutical industry in order to bring safe, new drugs to market as quickly as possible. In fact, the FDA Modernization Act required better communication by the agency with industry. Other industries should learn from the FDA/pharma example and work with regulators to generate mutually beneficial rules. But conflicts among industry players—the pharma companies and generic manufacturers and the makers of nutritional supplements, those grappling with issues of market dominance, parties who have varied interest in protecting individual client privacy, new entrants seeking controlled entry to traditionally regulated markets like telecom and energy—will assure that any attempts at cooperation will likely be outweighed contention.
- *Pay to be regulated.* The pharma branch of the FDA is in a unique situation with those that it regulates as well. Pharmaceutical companies pay a substantial fee when making an application for a new drug. Income generated from these fees has allowed the pharma arm of the FDA to hire enough experts to carry the workload. With tighten budgets in the government sector and a likely need to increase the expertise of regula-

tory agencies, more industries may see fees imposed on them by regulators, including others regulated by the FDA as only the pharmaceutical industry today enjoys the benefits of its fees.

- *International efforts on the rise.* Over the next ten years, it will become harder for regulators in one country to ignore their counterparts in other countries. For markets to be truly efficient in a global economy, regulators across borders will need to cooperate more often. The EU is working hard to find commonalities among regulation policies in countries from a wide range of traditions and cultures. As the EU becomes a continent-wide regulator, everything it does will set up a potential conflict with regulatory policies. Look for the EU-U.S. split on issues as diverse as antitrust enforcement and telecom access rules, to patent law and drug approvals to become issues of great importance and potential division.
- *Focus on the unique increases conflict.* The examination of antitrust and other issues on a case-by-case basis could lead to an increase in challenges and lawsuits being brought against regulators and companies as consumers and other interested parties feel their unique case was left out of the process. The courts may play a bigger role and the costs of regulation will rise. By the end of the decade, there may be a growing cry—from all across the ideological spectrum—to return to the "old days" of known and straightforward rules.

A FRAGMENTED WORLD

The ever increasing complexity of the regulatory environment—unique rules, more characteristics to consider, and new technologies—will collide with other factors like rising regulatory costs, lack of a clear context for strategic business decisions, and popular confusion over expectations of many regulatory rules. In a world where we have come to accept multiple principles and encourage the voices of diverse parties to express their interests, fragmentation and diversity are a sure outcome. Be careful what you wish for!