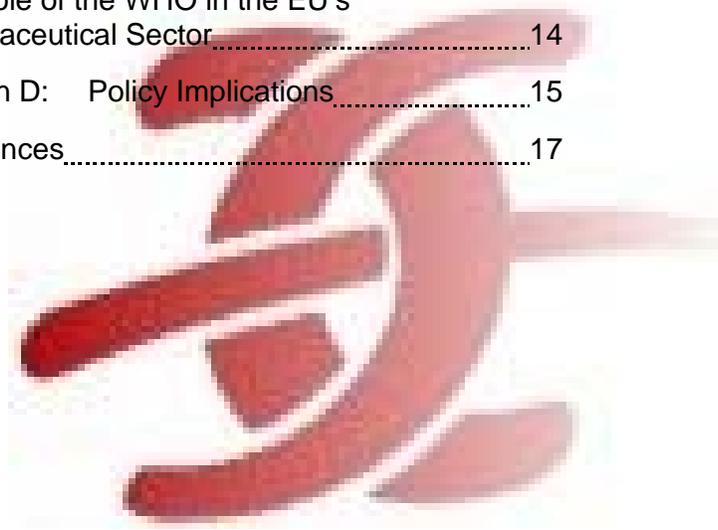


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Preventative Medicine: How Information can Modernize EU Healthcare

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Executive Summary

There are major differences in the way that Direct-to Consumer Advertising (DTCA) operates in the United States (US) and throughout the European Union (EU). The central issue that both continue to face is the persistent difficulties in the financing and delivery of their health services. In the US, although the financing of these services is still less than 50 percent of national expenditures, the delivery is totally in its private sector. However, in the EU, financing and delivery of health services remain largely a public enterprise. This diversity of finance and delivery between the two dramatically affects their approach to DTCA.

Cost containment is common to both systems. However, in the EU, because of its reliance on public investment for health education and employment, the lion's share of state budgets supports these two components. Unfortunately, population growth is inversely related to the expansion of health sector employment. In the US, most health education is privately financed, as is employment and pension benefits. Growth rates in these two categories are matched by increases in a population that consumes more health services.

Since the introduction of DTCA in the US during the mid 1980s, it has expanded rapidly. Early fears that it would lead to inappropriate pharmaceutical use and increased use of drug products have been dispelled by objective survey analyses, supported in part by the Food and Drug Administration (FDA) participation. These same fears, though, have a persistent hold on EU policy-makers. They are caught in an intricate political web of trying to maintain funding for health manpower capacities in spite of the fact that physician/nurse to population ratios are falling precipitously. Any sign that they would cut funding for health manpower would signal an incipient intention to abandon the fundamental precepts of socialized medicine.

To placate the public with a highly visible symbol of cost containment, at little cost to their political positions, public health authorities have singled out the pharmaceutical industries and their contemporary products. They have become the 'poster boys' of cost containment. But their ability to convince the public of success in this arena has worn thin. An EU survey by Burson-Marsteller's Brussels office revealed that compliance with the EU law prohibiting the advertisement of prescription medicines varies greatly among and between countries. In some countries, DTCA can be used if the prescription medicine is not on the state's

reimbursement list. In others, consumers are using the Internet to obtain information on them, buying these drugs after they are prescribed by a private physician. In the end, EU law or no EU law, there will eventually be convergence between the US and EU systems, led by consumers' rights for health information via the Internet.

Introduction

This topic falls broadly under the term: Direct-to-Consumer Advertising (DTCA), a concept permitting the public access to health information through various media outlets. DTCA has been allowed in the United States (US) since the mid 1980s but a change in the US Food and Drug Administration (FDA) regulation in 1997 opened the floodgates for broadcast prescription medicine advertising on TV as well as in print media. (1)

DTCA is addressed one way in the US, and in quite another way in the European Union (EU). Each reflects fundamental attitudes towards health in terms of their cultures, political systems, and economic structures. In the US, its healthcare system is weighted on the side of private financing and provision--and even where there is public financing, such as with Medicaid and Medicare, the actual provision of medical services is via the private sector, both in terms of facility use and personnel. In the EU, on the other hand, public financing and provision prevail in systems which are largely socialist in nature and operation. It should not be surprising, then, that there are major variances between the two systems when it comes to DTCA. However, since the US system will continue in its present mode, the questions are: for how long can the EU constrain access to health information for their citizens, and at what expense to their collective positions on innovation and international competitiveness.

This Analysis will have four sections: Section A is a Background description of fundamental disparities between the US and EU healthcare systems. Section B sets out the socio-economic differences, particularly in terms of the diversity in health manpower pools. It is conventional wisdom to hold increases in pharmaceutical utilization responsible for rising healthcare costs. This, then, is one of the major reasons advanced by EU policy-makers for their unwillingness to implement DTCA. The Analysis puts this issue to rest by demonstrating that national costs continue to rise due to expansion of medical manpower pools relative to decreases in population growth rates. Section C presents the evidence for and against DTCA by contrasting operational experience in the US and EU. Section D concludes with several policy implications.

Section A. Background

The US system has followed historical patterns set in motion in the 18th Century, where health was always considered a private matter. The most influential government intervention came in 1965 with the passage of the Medicare Act (for the elderly). It was followed a year later by the Medicaid Act (for the poor). Since both encompassed private provision of services, DTCA hasn't emerge as a restraint on a patient's access to information.

In the Bismarkian Era, beginning in the late 1880s, European governments adopted systems of employer-employee mandatory health insurance programs. Eventually, particularly in the Post War period, these evolved into state-run and state-owned health delivery systems. In particular, their annual budgets for health are state-directed, with caps on pharmaceutical expenditures. These systems offer cradle-to-grave health coverage, are highly popular, and enjoy wide-spread political support. In time, though, yesterday's political promises ran head-long into present realities, forcing EU countries to implement cost containment programs.

These hit hardest at the pharmaceutical sectors of their economies, mainly because European governments had direct control over the inflows into state-run systems. Specifically, pharmaceuticals became the 'poster boy' for rising healthcare expenditures, although consumption was increasing relative to positive improvements in life expectancy rates. Health manpower, generally in the physician cadres, escaped the scrutiny of EU budget cutters, through these public sinecures were increasing at levels inversely related to population growth rates. Cost containment programs had five interventions:

- Reduce investments in the health equipment and pharmaceutical industries via constraints on R&D, accompanied by a dependence on foreign inputs for innovation.
- Government regulation on the pricing of products.
- Price preference and incentives for generic products, and for 2nd generation health products. This eliminates patented products and the newest generation of drug therapies.
- Reimbursement of pharmaceuticals only for hospital care.
- And, in terms of bullet (4), reimbursements to be controlled entirely by physicians whose incentive structures are driven by high bed occupancy rates. This rewards their clinical care services, while reducing the use of drug therapies. A higher cost therapeutic medicine may succeed in having the patient released earlier, but reduces bed day use.

At the same time that cost containment was being pressed within the EU, spending for health care services increased in the US. Yet, in the EU it was focused principally on access to pharmaceutical products, while in the US cost containment was across all sectors of healthcare finance and delivery—yet consistent with population growth rates.

Because these differences did not happen overnight, a historical perspective between the US and EU can be instructive and through this one can then view the relationship of pharmaceutical inputs to health manpower and the influence of each on public policy and cost containment.

Section B. Key Socio-economic Factors: Physician to Population Ratios and Per Capita Spending

The largest factor has been the divergence of population growth rates between the US and the EU, compounded the fact that in the latter case life expectancy is significantly higher than in the US. In all societies, the costs of healthcare increases with age. The elderly usually require specialty medical interventions in hospital-based institutions, and eventually very expensive long term care in the last few years of life.

As the population growth rates have been falling in EU countries, the number of physicians relative to that has increased. This has produced a tsunami wave of future public finance liabilities which can be viewed retrospectively in these states (data on the U. K. not available until 1970):

Table One: (2)

Country	Population (1960)	Physicians	Population (1987)	Physicians
Italy	50 million	22,655	57 million	63,000
Spain	30 million	35,685	39 million	133,000
France	46 million	44,600	56 million	139,000
Austria	7 million	9,573	7.5 million	14,512
Germany	56 million	79,350	61 million	172,009
Netherlands	11 million	12,809	14.6 million	34,573
Sweden	7 million	7,130	8.4 million	22,485
Norway	3.6 million	4,260	4.2 million	9,600
Portugal	9 million	7,075	10.3 million	26,381
Belgium	9.2 million	11,380	9.9 million	31,718

Table Two: Percent Increase in 1987

Country	Population	Physicians
Italy	14%	182%
Spain	30%	272%
France	22%	211%
Austria	.7%	52%
Germany	11%	117%
Netherlands	33%	170%
Sweden	20%	220%
Norway	17%	125%
Portugal	14%	273%
Belgium	7%	179%

These differences between high manpower outputs and low population growth rates have continued into the modern period, as shown cumulatively for the years 1988 - 2002:

Table Three:

Country	Population	Physicians
Italy	57.4 million	252,886
Spain	41.2 million	119,480
France	59.7 million	193,314
Austria	8 million	26,7575
Germany*	82.5 million	272,205
Netherlands	16.2 million	41,987
Sweden	8.9 million	26,775
Norway	4.5 million	15,429
Portugal	10.4 million	33,216
Belgium	10.3 million	33,216

* Includes absorption of Eastern Germany after 1992

France began in 1960 with a population of 46 million, ending 42 years later with 59.7 million, for a cumulative increase of 30%. However, its physician cadre expanded from a base in 1960 of 44,600 to 193,314 in 2002, an increase of 333%. In the period 1997-2002, the change in total national health expenditures in France as a percentage of GNP was only

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0.3%. In Germany it was 0.2%, and in Austria 0.1%. Generally, these changes can be attributed to cost of living and wage increases for health cadres.

In contrasts, the US had a 1.6% change in expenditures, a factor that is several times those seen in these EU countries.

As a percentage of GNP, national health care expenditures in France increased from 4.2% in 1960 to 9.7% in 2002, while in the US they rose from 5.1% to 14.6% in the same period. (3)

The population growth rates in the US have been increasing. Between 1960 and 2002, the number of physicians tracked along with that rise, moving from 259,400 to 691,692 in 2002, an increase of 166%. Meanwhile, the population increased from 173 million to 291 million, or an increase of 68%. The most relevant portrait of this is in the physician to population ratio. In the US it is 2.4 physicians per 1000 people, while in all EU the range runs between 2.9 and 4.5. (3)

When the ratio of practicing nurses per 1000 population to physicians is considered in 2002, the disparities are even greater, as shown below: (3)

Table Four:

Country	Nurses per 1000 population
Ireland	15.3
Netherlands	12.8
Norway	10.4
Germany	9.9
Denmark	9.7
Austria	9.3
United Kingdom	9.2
Finland	9

Source, OECD

In contrasts, the ratio of practicing nurses to physicians is 7.9 in the US. Again, these ratios have to be seen in light of decreasing population growth rates amid a largely socialized medicine structure in the EU and rising growth rates and a predominant private healthcare market in the US.

There are major differences in per capita spending, the sources of that spending, and in factors which influence both, such as population growth rates, life expectancy, and the number of physicians relative to each. For instance, per capita spending for the year 2002 was \$2,220 in Austria; \$2,515 in Belgium; \$2,580 in Denmark; \$2,736 in France; \$2,817 in Germany; \$2,367 in Ireland; \$2,643 in The Netherlands; and \$2.166 in Italy. (4) The uniformity of per capita expenditures is quite noticeable, indicating that cost containment has been applied universally. All of the ascension states, such as Hungary, Poland and the Czech Republic, are well under \$315 per capita. Since these are relatively new entrants to the EU, their influence on DTCA will be mentioned but briefly.

In contrasts, per capita spending in the US was \$5,267, or double national averages among EU countries.

The sources of that spending are highly skewed towards public provision and financing in the

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EU countries. Here, government expenditures on health as a percent of total national expenditures on health average 75 percent, with the highest being in the Netherlands at 100 percent and the Czech Republic at 92 percent.

This is a major difference. In the US it is only 44 percent for government spending, with the vast majority of this coming from payroll deductions from private employees to finance Medicare and Workmen's Compensation Programs. Although Medicare is a mandatory payroll contributory program for all employers and employees, it can only be accessed for services once a worker reaches age 65.

In terms of life expectancy, the non-ascension countries range between 73-77 years of age, with Spain at the high end of 77 years. In the ascension countries, there are all in the high 50s.

In contrasts—and these are large for EU countries, the US average life expectancy at birth is 66 years. Although many economists claim this is a very low return given the high per capita investment, there are anomalies in the way the US counts its expenditures. For instance, medical equipment is depreciated for tax purposes over a five year period, and depreciation of plant on accelerated schedules is considered to be an expenditure. Advertising and marketing costs are calculated in the expense of doing business. None of these items are taken into account when per capita expenditures are computed for EU countries.

There are pronounced differences between the two areas when it comes to annual population growth rates. In all of the EU countries, these rates have been falling precipitously over the past three decades. In the larger countries, such as France, Germany, Spain, Italy, and the Nordic countries, rates average well below 0.3 percent. In the Czech Republic, it is at a negative -0.1 percent. This translates into an aging population with increased needs for healthcare, often specialty services for high cost chronic illnesses, such as diabetes, cancer, and cardiovascular diseases. For diseases such as these, the last six months of life often consume more medical care resources than in patients' entire previous life.

In contrasts, the annual population growth rate in the US is 1.0 percent. Many believe it is higher in that the immigrant population is not counted in official statistics since they are illegal entrants, though they have access to Medicaid health coverage and other public provision through municipal and county hospitals/clinics.

The major differences in these data sets can be found in these factors:

- Rising health care costs in the EU are absorbed largely by public financing, and in the US by a combination of financing that is largely private.
- The burden of public financing for healthcare in the EU has three dimensions: a) public financing of medical school; b) public financing of salaries; and c) public financing of benefits, e.g., practice facilities and equipment, support staff, healthcare, pension, and long term care.
- As health personnel levels continue to increase, EU governments must find a scapegoat on escalating costs. Pointing the finger of blame at one of Europe's most prestigious professions is a losing political game. Besides, physicians have an undue influence on the legislative bodies which control public health budgets. The easy target, and one that the general populace can identify with, is pharmaceutical innovation, product selection, and pricing.
- Meanwhile, in the US, physicians fund their own pension programs, rent their own offices, pay for their support staff, have the freedom to seek out higher return clinical therapies, and purchase long term care insurance and pension plans.

The Meaning of this Data for Access to Patient Information

These factors have several significant meanings for access to patient information:

- In the EU countries, physicians most often have to find employment in the public sector, in lieu of private practice, affecting the rate of non-patient healthcare expenditures.
- Physicians create their own markets - everywhere, and so while they are publicly employed, they either seek to use that office for private gain, or hold down second jobs in the private sector - the gray market.
- As physician to population ratios decrease in the EU, greater pressures are placed on public budgets for salary support, pension benefits, and long term care.
- Since too many physicians are competing for too few patients, an informed patient is a threat to a physician's hold on the market.
- All European governments are in thrall to socialized medicine, viewing this as the least cost alternative to rising health expenditures by the public at large.
- As long as governments finance and provide healthcare services, they will seek to contain costs by whatever method is least costly from a political perspective.
- The method of choice is a restraint on innovation in the pharmaceutical sector. Opening up access to information for patients is seen by those who control this market: physicians, as an intrusion into their state-protected domain.

However, even with the tight hold of socialized medicine on EU expenditures through reference pricing and preferential reimbursements for 2nd generation drugs (e.g., generic drugs are fully reimbursed), the proportion of public to private expenditures in pharmaceuticals relative to general health expenditures for 2002 is instructive. In Germany, 76 percent of pharmaceutical expenditures are in the private sector; in Spain it is 81 percent; 69 percent in France; 80 percent in Austria; and, 83 percent in Ireland. (3)

Whether or not EU policy-makers prefer to see this transition in pharmaceutical spending and lose control over regulatory pricing, it is largely--and increasingly out of their control. The burden of paying for it is being absorbed by their private citizens through out-of-pocket payments. Much of this is due to the government reforms of 1986, 1990 and 1991, each of which introduced measures to restrict pharmaceutical reimbursements for prescription drug products, e.g., only for hospitalized patients. (4)

Nonetheless, it is widely thought that these countries all have socialized medicine. This perpetuates the myth among policy-makers that pharmaceutical expenditures constitute an intolerable public expense which must be controlled.

This view obscures the fact that the real rise in public health expenditures is due to their governments' employment of physicians and other health cadres at rates inversely related to population growth. Physicians need nurses and both need orderlies; healthcare managers need accountants and accountants need secretaries; dentists need hygienists ... pharmacists need to write prescriptions, and on it goes. Now, with the Internet Age in full flower, EU citizens will continue to seek out new drug therapies, independent of their government's failing attempts to curtail sales by denying them access to information.

Politically and culturally, the EU countries can no more turn off this manpower spigot than they can change to a market oriented healthcare system. In particular, physicians enjoy an honored status in these societies and they have a direct influence on government policies. They always know what is best for patients - who in the past, slavishly accepted their diagnosis. Given that, it must now be somewhat disconcerting for physicians to have to deal

with informed patients. Like physicians everywhere, though, they will slowly gravitate to market forces and personal preferences, writing private prescriptions off the clock. The data on the proportion of private to public pharmaceutical spending supports this contention.

Section C. The Evidence: Contrasting Views

The United States

In the US, DCTA advertising totaled approximately \$2.6 billion in 2000. This is about 2 percent of total prescription drug expenditures, which were estimated at \$312 billion. (Adams, C. "FDA plans to review policy allowing direct-to-consumer drug ads for TV", The Wall Street Journal, March 28, 2002, p. B1) Many believe that DCTA spending comes at the expense of R&D and that actually more is spent on the former than the latter. In 2001, total R&D spending was \$30.3 billion, while DCTA was one tenth of that, or \$2.8 billion, up slightly from the year 2000. (5)

Expenditures for out-patient prescription drugs have been increasing about 15 percent annually. Several studies have found that about three-fourths of these increases have been caused by expanded usage and switching to newer and more effective drugs, while price increases have accounted for only about one-fourth. (6)

These two facts suggest that even if DCTA advertising increases prices, such an effect has been quite limited simply because overall price increases have been small. But there is little reason to expect DTCA advertising to significantly increase prices at all. Research has generally found that advertising tends to reduce prices, rather than increase them, primarily because advertising makes markets more competitive. (7)

DTCA advertising is concentrated among a few therapeutic classes. These include agents for the treatment of conditions whose symptoms are easily recognized by consumers (such as arthritis, seasonal allergies, and obesity), and agents for the treatment of chronic diseases that are often undiagnosed (such as high cholesterol, osteoporosis, and depression). For instance, according to the American Diabetes Association, an estimated six million Americans have undiagnosed diabetes. They make up about 6 percent of the US population but account for 15 percent of national health care expenditures. For Medicare, the percentage is even higher because 1 out of 5 people over age 65 has diabetes. Twenty-five percent of Medicare costs go toward diabetes. The majority of this expenditure goes to the complications of diabetes, complications that put patients in the hospital or on the surgery table and can make them disabled for life. In 2002, there were some 52,000 amputations in US hospitals, most of them due to complications of diabetes.

The American Heart Association considers diabetes a major risk factor for cardiovascular disease (CVD). (8) Many people in the US have undiagnosed conditions for both diseases. If the US health care system can get diabetes under control, then it can also affect the major cause of mortality in the US: CVDs, saving lives and money. It is critical to diagnose both diseases early and treat them aggressively. And DTCA is helping physicians to reach this important goal by using various media outlets to bring diabetes and CVD to the attention of people who might have them. It is prompting people who may have diabetes or CVD in the family or may be feeling unusually tired to see their doctors and be checked out. For people who are already diagnosed, the ads reinforce the fact that this is a chronic disease and that patients need to stay on their medicines.

What is the cost of untreated diseases? The best studies on this subject have been done on vaccines. Here, the cost of vaccines is lower than the cumulative costs of treatment,

hospitalization, lost working days, and productivity. For instance, it has been calculated that for every single US dollar spent on mumps-measles-rubella vaccine, more than US \$21 were saved in direct medical care costs. Thus, what is saved is a measure of medical care costs. (9)

To make informed choices and navigate within a complex health care system, consumers must have easily available, accurate, and timely information, and they must use it. This is especially critical in the era of managed care in the US. In many cases, physicians can no longer act as the patient's advocate. In Health Maintenance Organizations (HMOs), the physician is often forced into the uncomfortable position of being an adversary in that he/she makes more money by providing less care. Although medicines, by helping avoid complications from diabetes, can save money in the long run, HMOs focus on the short run, the bottom line for the current quarter.

In this environment, the patient needs all the help he or she can get about the disease and possible treatments. Armed with such information, the patient may be able to successfully navigate the HMO maze and get needed treatment. DTCA is an excellent source of that information. Patients who have seen ads for diabetes medicines are informed and easier to work with—they know that treating the disease can make a difference down the road. They are more willing to take new medicines that can help them avoid the complications of diabetes.

In a national telephone survey of 3,000 adults, it was found that 25 percent who had visited their physician after seeing a DTCA received a diagnosis of a new condition. Some of the most common problems discovered: high cholesterol; hypertension; diabetes; and depression. (10)

According to the Centers for Disease Control (CDC), the number of asthma sufferers more than doubled from 1980 to 1998. The American Lung Association estimates that direct healthcare costs for asthma exceed \$7.5 billion a year, with lost productivity costing another \$3.8 billion. Children miss more than 10 million school days because of asthma.

DCTA ads give 17 million Americans who suffer from this disease information about asthma therapy options and encourage them to work closely with their healthcare provider to gain optimal control over their asthma. According to health research firm Scott-Levin, 44 percent of asthma sufferers thought DCTA was helpful.

In a November 2001 study by the Kaiser Family Foundation on whether advertising helps in diagnosis, it found that: (11)

- A large majority of those who had just seen an ad said that it did an excellent job or good job telling them about the benefits the medicine is designed to treat (84 percent), the potential benefits of the medicines (72 percent), and who should take the drug (66 percent).
- Prescription drug ads prompt many people to talk to their doctors about the medicines they have seen advertised.
- Those with the greatest health needs - the elderly and those who report they are in fair or poor health - are even more likely to talk to their doctors, though not more likely to receive a prescription for the medicine.

With the advent of a patient-directed healthcare system through DTCA, influenced in large measure by the HMO movement, market forces become more apparent. It may well be that it is not advertising that increases the price of products, it's the lack of it. That is, knowledge is the best prescription, and ignorance has long term costs to individuals and society as well. (12) DCTA does encourage more drug consumption. But the reverse side of this coin is

that it can lower health care costs when drug therapy precludes the need for other, more expensive therapies. (13)

In 2003, Prevention Magazine published results of a six year trend survey developed in cooperation with the FDA on the effects of DCTA. The survey was conducted by Princeton Survey Research Associates in December 2002. Some results: (14)

- Approximately 65 million American consumers have talked with their doctors about a prescription drug as a result of DCTA.
- Approximately 30 million consumers talked with their doctors about a medical condition for first time after seeing a DCTA advertisement.
- DCTA advertising encouraged many consumers to seek treatment for undiscussed health problems, e.g., there was a 91 percent awareness of a drug for erectile dysfunction.
- For high school graduates, 34 percent talked with a doctor after seeing a DCTA advertisement.
- For those with incomes less than \$25,000 per annum, 31 percent talked with a doctor after seeing an advertisement.
- Thirty-eight million consumers say they have gone to a Web site or print advertisement, or called a toll-free number to get additional information about an advertised drug.
- In an assessment of whether DCTA advertisements provide the information consumers need to talk to a doctor about the risks and benefits of advertised medicines, 68 percent responded favorably.
- In terms of the Internet, 96 percent of consumers surveyed saw it as a source of useful information about prescription drugs.
- Of those with no health insurance, 19 percent talked with a doctor after seeing an advertisement.
- And, 98 percent of consumers—an estimated 196 million adults, have seen advertisements for at least one of the medicines included in the survey.

DCTA for prescription medicines is now a ubiquitous part of American society, appearing virtually everywhere on television, on radio, and in magazines and newspapers. Consumers value the information contained in DCTA advertisements. Eighty-four percent think the advertising tells people about new treatment options; 80 percent think it alerts them to symptoms of health conditions they may have; and 83 percent think it encourages people to find out more about the medical conditions advertised medicines are intended to treat. Moreover, 68 percent of consumers think the advertisements provide them with the information they need to talk to their doctors about the risks associated with taking advertised medicines, and 67 percent think the advertisements provide the information they need in order to talk about the benefits of advertised medicines. (14)

The European Union

As demonstrated above, consumer interest in self-care is strong and growing in the US; as will be shown below, it shows incipient signs of being just as strong in the EU. This trend in Europe is taking place in spite of official policies to actively discourage access to innovative medicines and therapies it. It is illegal to advertise prescription drug products to the general public in the EU. Article 88 of EU Directive 2001/83/EC prohibits direct-to-patient information on any medicinal product that requires a prescription or contains psychotropic or narcotic substances. Consequently, many patients lack access to information about the most advanced treatment options for their diseases.

In March 2000, Heads of Government for the EU met in Lisbon and agreed on an economic reform program designed to achieve the strategic goal of "building the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion". The pharmaceutical sector has the potential to make a major contribution to the achievement of the Lisbon goals. In a subsequent report on a European perspective to these goals, it was stated that pharmaceuticals "is a large, high growth, globalized, and innovation intensive industry. Its products—drugs—are directed to satisfy consumer needs in an area—health care—which is vital for society. Health care and therapeutics are among the most relevant issues in the definition of the concepts of welfare and democracy in the new Century". (15)

In early 2001, the High Level Group on Innovation and Provision of Medicines was created under the title of the G10 Medicines Group. In February 2002, it produced a report which included 14 recommendations on improving competitiveness of the pharmaceutical industry. At the end of 2003 the Council of Ministers responded to the G10 Recommendations by adopting conclusions in both the Competitiveness and Health formations of the Council. One of its Recommendations called for better information to patients, stronger pharmacovigilance and relative effectiveness within member states. It recognized too the contribution that a strong and competitive pharmaceutical industry in Europe can make to the improvement in public health. (16)

Of the recommendations pertaining to this Analysis, these are important: (16)

- There should be a set of indicators for the relationship between various EU and Member State regulatory structures (licensing, pricing and reimbursement) and availability and uptake of pharmaceuticals.
- Member States should secure the principle that a Member State's authority to regulate prices in the EU should extend only to those medicines purchased by, or reimbursed by, the State. Full competition should be allowed for medicines not reimbursed by the State.
- The restriction on advertising of prescription medicines to the general public should continue.
- Consideration should be given by the European institutions to, in cooperation with all stakeholders to produce a workable distinction between advertising for prescription drugs and the provision of general information in media outlets that would allow patients actively seeking to be self-educated on their own health care to do so, and to develop standards to ensure the distinction.
- And, the Commission should consider providing core funding for European patient groups to enable them to participate independently in the debate and decision making on health matters in the EU.

Given all of these high level policy inputs and expressions of intent from EU governments, what have been the results? In February 2004, Burson-Marsteller/Brussels was commissioned to undertake a mapping exercise to assess the state of implementation of the G10 Recommendations across EU member states. Although the G10 report was published two years ago, by 2004 progress—if any, should have been discernible. Yet, this is what it found: (16)

- All too often, European institutions are good on rhetoric and poor on implementation.
- In Austria, advertising of prescription and non-prescription medicines with the same brand name and targeted at a specific disease is not allowed. The advertising of OTC medicines is allowed. Patient leaflets and summaries of product characteristics are not considered advertising. General information about diseases is allowed so long as

it does not enhance the sales of a specific product.

- In Belgium, the maximum reimbursement price is based on the price of the generic equivalent on the market. Belgium prices are based on the lowest European levels. The general view is that the government's price control policy has little respect for the value of innovation. The government implements the rules on advertising strictly. There are no databases with information about pharmaceuticals and no public/private partnerships in the field.
- In the Czech Republic, generic drugs are reimbursed fully by the government, while others require co-payment. The emphasis of the government is on cost containment. Industry can provide information on diseases and therapeutic options, but mentioning product names is not allowed. The Internet is heavily used as an information medium for patients and disease websites are well developed. Information technology usage is high.
- In Denmark, when the government denies a new product reimbursement, the reason is often based on its high prices. It has instituted a number of measures to control pharmaceutical costs including temporary price ceilings and increasing consumer co-payments. There are no co-payments for the medicines used in hospitals. Generic drug pricing is not regulated. Patient information is completely regulated and controlled by the state. The government fears that any opening of the advertising ban will lead to excessive advertising of prescription products. The laws on information to patients are quite restrictive and are implemented very strictly.
- In Finland, there is an advertising ban for prescription medicines, in line with EU law. However, Finland is quite liberal in interpreting the law by allowing information material to be disseminated by companies in cooperation with patient organizations. Many citizens use the Internet as a source of information.
- In France, as part of a broader plan to reduce the budget deficit, the government has adopted several measures to limit expenditures on pharmaceuticals. These measures control not only overall drug spending but also individual company sales, promotion expenses, therapeutic class sales, and specific product sales. France is one of the most strictly regulated countries regarding information about medicines. The government fears that any reduction in the restrictions on information to patients will lead to excessive advertising of prescription products.
- In Germany, it has relied on prescribing controls imposed on doctors to reduce pharmaceutical sales. Only patients who specifically request innovative products may receive them, while those who do not are prescribed older, less effective medicines. Only 12 percent of patients in the subsidized sick fund insurance system receive the newest innovative drugs, while 48 percent of patients in the private system obtain them. Advertising of non-prescription medicines is allowed. The government is considering launching a medicines Internet data base.
- In Ireland, the government previously had a much more conservative attitude on the use of prescription drugs. This has changed in recent years, to a large extent due to the influence of the Internet. Industry partners with the government on different initiatives to raise awareness among the public and to conduct public health campaigns. Industry has started an "electronic compendium" with patient information, and industry also works with patient organizations to develop joint publications.
- In Italy, it has sought specifically to restrict promotional activities by pharmaceutical companies. In 2003, it enacted a new tax on promotional spending and many regional authorities have sought to regulate directly the ability of pharmaceutical companies to communicate with Italian physicians about new products. Cost containment is very high on the political agenda and government is very skeptical about initiatives of the innovative pharmaceutical industry. Non-European companies tend to be discriminated against in Italy, regardless of their contribution to patient welfare.

- In The Netherlands, a self-regulatory Code of Conduct operates on information to patients. It is a product of public/private partnership and pharmaceutical companies are allowed to inform patients about products, including brand name, on the Internet and through other media. Government also appears effective in ensuring the "very well functioning structure of self-regulation" for information to patients. It considers that by allowing more publicly available information, patients are given more responsibility for their own healthcare. It is recognized that there is little way in which control can be exercised over much information, especially that which is available from the US, and especially that available on the Internet.
- In Portugal, firms may advertise ethical drugs directly to medical professionals, but direct-to-consumer information about prescription medicines is prohibited and enforcement is strict. But advertising of OTC medicines to the consumer is permitted.
- In Spain, officials comment that "cost containment has to be balanced with added therapeutic value". Advertising is not allowed for reimbursed medicines and companies may not provide information on their products. Non-reimbursed medicines can be authorized to be advertised on TV and in newspapers. Internet advertising is not legally permitted, but according to the government, it is difficult to control in practice.
- In Sweden, OTC products can be advertised freely. It has in place a system known as FASS, an on-line register where patients can find information about pharmaceuticals with both trade market and generic names (with links to companies).
- In the United Kingdom, direct advertising to patients is banned (though national law may not be, strictly speaking, in compliance with EU legislation) and the Internet cannot be used to communicate directly with patients. The government is moving in the direction of greater freedom for industry on patient information. It is trying to encourage patients to take more responsibility when it comes to gathering information about medicines.

In going through the prevailing attitudes on innovation and access to patient information in these EU countries, there is a lack of consistency on adherence to the EU law: it only specifically prohibits advertising for prescription medicines, or for products that contain psychotropic or narcotic substances. But with the WHO ATC/DDD system, all new products, especially those from the US, are considered to be prescription medicines. Older medicines on the same ATC list can be fully reimbursed if they are generic products. In Belgium, the maximum reimbursement price is based on the price of the generic equivalent on the market. In Austria, only reimbursed pharmaceuticals are regularly prescribed by doctors and these require no co-payment by the patient. Since the level of reimbursement is determined by the State, there is a preference for older drugs.

In the Czech Republic, new medicines have prescription limits, i.e., to be prescribed by specialists only. In Denmark, there are no co-payments for the medicines used in hospitals—an incentive for physicians and patients alike. And TV commercials can be run for OTC medicines.

Romania, as a new entrant to the EU, is seeking to implement cost containment by limiting general practitioners to 200 prescriptions per month. These forms are printed and distributed by the government. Then, each pharmacist is limited to fill those prescriptions from each doctor at a total value of \$200 during the entire month! One cancer patient can easily consume a pharmacist's entire allotment in a single prescription. This produces two results: a) under the table payments to obtain one of the 200 prescriptions from the GP and the pharmacist, and b) hospitalizations in order to obtain a fully reimbursed drug product. The latter benefits physicians working in hospitals, usually specialists.

Even with those countries that follow this law, they make exceptions for OTC advertising, or

advertising for non-reimbursed drugs (e.g., not on the government's list), or for drugs that require a co-payment by the patient, or for drugs sold in the private market. All recognized in one way or another that the Internet is changing everything on patient access to information, the spirit of this law notwithstanding.

As a complement to the survey results mentioned above, contemporary comments from health leadership and media portrays the ambivalence between public and private views on patient access:

"It is hard to believe that consumers inform themselves thoroughly prior to buying a car yet accepts the prescription from the physician like the rabbit takes a carrot".
Head of the German Physicians Drugs Commission, 2000.

"Paternalism, which allowed doctors to do what they want and leave the patients in the dark is giving way to patient power".
The Economist, 3 Feb. 2002

But more information will create a demand for choice; and effective medical treatment is more likely where doctors bother to listen to their patients and patients know enough to ask the right questions and demand truthful answers".
The Economist, 3 Feb. 2002

"With well-informed patients and increased patient rights, costs can be saved. Comprehensive information for the patient is the lynchpin for the health sector".
Chairman of the 1st German Patient Convention, Leipzig 2000

"Anyone can put anything about therapy for a disease on the Internet, but the drug industry cannot".
The Lancet, March 28, 1998

"Every citizen must be equipped with the skills needed to live and work in this new information society".
Presidency Conclusions, Lisbon Council, March 2000

"It is essential that the new information technology is harnessed to empower European citizens to play an active role in managing their health and to improve the overall quality of healthcare".
European Parliament Report on the Programme of community action in the field of public health, April 2001.

The Role of the World Health Organization in the EU's Pharmaceutical Sector

In May 1968, well before formation of the European Union, the Twenty-first World Health Assembly passed a Resolution on Pharmaceutical Advertising (WHA21.41). This set forth ethical and scientific criteria for advertising. It stated: "advertisements to the public should not be permitted for prescription drugs, for the treatment of certain diseases and conditions which can be treated only by a doctor and of which certain countries have established lists, or in a form which brings about fear or distress". (17)

Subsequently, after the EU came into being, WHO developed general requirements for drug registration which were adopted by Member States. This is termed the ATC/DDD (anatomical therapeutic chemical; defined daily dose) Classification System. It is administered out of WHO's Collaborating Centre for Drug Statistics Methodology, located in Oslo, Norway.

Before a new drug can be introduced in the EU marketplace, a pharmaceutical company must obtain an ATC/DDD classification from Oslo. Once an ATC/DDD is granted, a company need not further register the drug in any country within the EU.

Given the importance of cost containment within the EU, this classification system particularly affects the entry of new products from the US. For instance, if that product was an antihypertensive drug, it would be considered for classification with all similar drugs on the current ATC/DDD list. Something akin to the "garbage code" phenomena then applies. Researchers in Oslo reviewing drug utilization on this therapy wouldn't be able to sort out its specific contributions to, say, reductions in disability or potential increases in productivity within the adult population, as the evaluation would be against those same (older) drugs currently registered in the EU. Then, even if the new drug gains an ATC/DDD classification, it is placed on the existing price list for similar (older) drugs.

And, since—as a new drug, it would also be a prescription medicine, advertising would be prohibited, and full reimbursement would only be possible if it is used in a hospital.

Any generic product deemed to be equivalent on the ATC/DDD list would be fully reimbursed.

Section D. Policy Implications

The focus of governments across Europe is as heavily oriented as ever towards cost containment, with in many cases an absolute neglect of the value of innovation for patients being evident. In 1999, European pharmaceutical companies spent only 59 percent of worldwide R&D expenditures in the EU, down from 73 percent in 1990. The US was main beneficiary of this downturn. This is best reflected in the fact that of the ten top new medicines by sales to enter the global market, eight were from the US and only two came from the EU. As a percent of Gross Domestic Product invested in R&D, the US leads with 53 percent, followed by France at 9 percent, and Germany at 8 percent. (18)

There are nonetheless major fissures being opened to force change towards DCTA, mainly via the Internet at present. Soon, though, the crushing burden of public taxes to support ever-rising numbers of health personnel relative to population growth rates will overwhelm the diminishing forces of socialized medicine and emerge as a priority on cost containment. Even though health manpower continues to increase and population decrease relative to that, the waiting list for services lengthens. In Romania, its main public teaching hospital is limited to 15 liver transplants per year—though the number of surgeons in this medical specialty continues to rise. Together, then, the expansion of health manpower pools and the lengthening waiting lists constrained by arbitrary quotas constitute an explosive political mix which probably will result in patients taking matters into their own hands.

This can be seen vividly in the proportion of private to public pharmaceutical expenditures: Germany, 76 percent; Spain, 81 percent; France, 69 percent; Austria, 80 percent; and, Ireland, 83 percent. Obviously, the governments have noticed this trend also, as the change in total health expenditures as a percentage of their GNPs between 1997-2002 has been minimal, e.g., 0.2 percent in Germany; 0.3 percent in France; 0.1 percent in Austria; and 0.1 percent in Spain. Since these are nominally socialized medicine states, these increases are probably for budget support to public health personnel, mainly for cost of living increases.

There is no empirical evidence to support the notion that DTCA increases overall usage of pharmaceutical products, or is a direct cause of increases in health expenditures. There is empirical evidence, however, that the FDA's Regulatory Policy for DTCA:

- Improves the public health.
- Enhances the patient/physician relationship without interfering with the practice of medicine.
- Does not lead to misprescribing or over-prescribing.
- And, adequately communicates risk.

Accordingly, the policy is advancing FDA's interest in protecting the public health. (19)

In contrast, there is ample evidence that the EU's policies on its neglect of innovation are causing long term consequences to its international competitiveness. Critical pharmaceutical industries once resident within the EU have moved their headquarters and R&D centers elsewhere, e.g., GSK to the US, and Novartis to Singapore for R&D on tropical and infectious diseases. Three of the key reasons: a) open market pricing; b) protection of intellectual property rights; and c) DTCA.

The G10 Medicines Group was on target with its recommendations of February 2002 to the EU Council of Ministers. Unfortunately, the Council was unable to convince Member States to provide better information to patients, or to have them recognize that a strong and competitive pharmaceutical industry in Europe can improve the public's health. The G10 effort was not the first time EU countries tried to stimulate their R&D industries. The most prominent recent example is found in the EU's 1993 White Paper on *Growth, Competitiveness and Employment*, which cites the health and medicines industry as one of only three sectors where the task of providing for the needs currently unmet could make a significant contribution to restoring economic growth". (20)

In time, there will be convergence between the US and EU on DTCA, but in the EU it will be driven, however slowly, by the public's right to participate in its own healthcare.

First, though, the EU countries must discontinue the heavy subsidies to their pharmaceutical industries—as these hold them captive to government pricing policies. These subsidies take many forms. In France, government owns the majority share of companies, such as Pasteur Merieux. In the U. K., the government operates a system of profit regulation that constrains prices to yield no more than a targeted overall rate of return on capital, with the tacit assurance that there will be a profit at the end of the day.

Denmark subsidizes the R&D component of its pharmaceutical industries.

Of the various forms of media exposure open to the public, the one most likely to change EU attitudes towards DTCA most quickly is the Internet. Governments are almost impotent when it comes to a patient's determination to access this medium.

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