Chapter 7

Policy

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WHO Strategies To Curb Smokeless Tobacco: A Global Perspective

Roberto Masironi

ABSTRACT

Smokeless tobacco is a leading cause of disease in many developing countries where its use is common, e.g., in the Indian subcontinent. Among the industrialized nations, Sweden and the United States show increasing consumption trends, particularly among the young. Unless its market expansion is stopped, smokeless tobacco may become a problem also in countries where it is still practically unknown. Tobacco manufacturers have launched marketing programs to promote the use of smokeless tobacco. The World Health Organization recommends that a preemptive ban on manufacture, import, promotion, advertising, and sale of smokeless tobacco be introduced in countries where the product is not yet known. In countries where smokeless tobacco is already widely used, various types of prohibition and control are urged, in keeping with local circumstances. Australia, Hong Kong, Ireland, Israel, New Zealand, Norway, Saudi Arabia, Singapore, and the United Kingdom have banned smokeless tobacco products. The European Economic Community countries are about to adopt similar policies.

INTRODUCTION The use of smokeless tobacco has become a leading cause of disease in some countries and may become so in others unless urgent preventive action is taken. Smokeless tobacco is widely used in the Indian-Pakistani subcontinent, where it is estimated that 100 million people are using it (International Union Against Cancer, 1989; WHO, 1988). Under various names and consisting of various combinations of tobacco and other ingredients, smokeless tobacco is also widely used in Afghanistan, Bangladesh, Malaysia, the Islamic Republic of Iran, the Central Asian republics, Sri Lanka, and Thailand (WHO, 1986 and 1988), as well as in Bhutan (Dr. Yok Heng Tamang, personal communication, 1991). It is used, although to a lesser extent than a few decades ago, by the native circumpolar populations of Alaska and the Canadian arctic, but not Greenland (Hart Hansen et al., 1990). Among the industrialized countries, Sweden has the highest per capita consumption of smokeless tobacco, with 17 percent of its population using it at least occasionally and almost 30 percent of young adult males using it daily (Nordgren and Ramström, 1990). In the United States, more than 12 million people use smokeless tobacco, and 12 percent of young adult males are daily users (Connolly, 1991; WHO, 1988).

In the rest of the world, however, smokeless tobacco is almost unknown. In central and eastern Europe, nasal snuff was used in past centuries but now very little of it is marketed. In Australia, smokeless tobacco represents a minuscule 0.01 percent of all tobacco products consumed, and its use is estimated to be limited to between 3,000 and 5,000 people, mainly miners, oil riggers, farmers, and aborigines (Trade Practices Commission of Australia, 1989). In Japan, no smokeless tobacco is produced, and only a small amount is imported (Dr. M. Chiba and S. Watanabe, letters, 1991). In China, it is also practically unknown; very few people chew tobacco, and nasal snuff is used only by some local inhabitants of Tibet (Prof. Weng Xin-zhi, letter, 1991). Unlike tobacco smoking, which is widespread in all countries of the world, the use of smokeless tobacco is extremely uneven, being used extensively in some countries but virtually unknown in many others.

Tobacco manufacturers have launched well-orchestrated marketing programs to promote the use of smokeless tobacco in countries where the product is unknown. For instance, a tobacco company opened a factory in Scotland in 1985 to produce moist snuff for sale to other countries of Europe, Africa, and the Middle East. The factory was later closed as a result of pressure from health groups (WHO, 1988). The same company had established a regional office in Hong Kong to promote sales in the Pacific area and in Asia; this office also closed in 1987 as a result of a ban on smokeless tobacco by the Hong Kong government that year (Dr. J. Mackay, letter, 1991).

The recent manufacture and promotion of new forms of smokeless tobacco by transnational tobacco companies has increased the need for urgent action to prevent the spread of the ST habit to areas where it is currently unknown. Of particular concern is the fact that some new forms of smokeless tobacco are being marketed in ways that appeal to children and young people. In Denmark, for instance, 60 percent of children know what smokeless tobacco is, and 11 percent of 15-yr-olds, particularly boys, have tried it (Commission of the European Communities, 1991). While decreasing among adults, ST use is rising among young males in some developed countries (see Tables 1 and 2).

In Finland, snuff use had almost disappeared by the mid-1970's. After enhanced marketing efforts by national tobacco companies, smokeless tobacco consumption increased from 43,000 kg in 1981 to 105,000 kg in 1989. Users are mainly young people, particularly 16- to 18-yr-old boys. In a national survey done in 1987, about 5 percent of boys reported occasional or daily use (WHO [EURO], 1991).

WHO ACTION In the face of an impending new epidemic of tobacco-related diseases, and following reports on the health hazards of smokeless tobacco (IARC, 1986; US DHHS, 1986), the World Health Organization called together an international group of experts to review the evidence and propose strategies for national and international control of smokeless tobacco. The recommendations of that group are summarized here. According to the WHO expert group, the major objectives of any national smokeless tobacco control program should be the following (WHO, 1988):

- In countries where smokeless tobacco is not known yet, prevent its introduction, with special emphasis on preventing its use by children.
- In countries where smokeless tobacco is already in use, prevent any increase, and reduce the prevalence of its use in the population.
- In all countries, establish and maintain a social climate unfavorable to smokeless tobacco use.

The most effective means of preventing the emergence of new tobaccorelated problems in any country is to prevent the introduction of new tobacco products rather than to allow them to be introduced and take action only after the resultant health problems have become apparent.

Table 1 U.S. smokeless tobacco use

	Percentage of Users	
	Teenaged Males	50-Yr-Old Males and Females
1970	0.3%	2.7%
1980	2.7	1.3
1985	6.0	_

Table 2

ST use in Sweden

		Percentage of Users		
	Te	Teenaged		Yr-Old
	Males	Females	Males	Females
1955	0%	0%	21%	0%
1986	38	5	13	1

Health education and public information are important components of any national tobacco control strategy, but the most important preventive measure is *legislation*. Voluntary agreements are ineffective, because tobacco companies are likely to circumvent them. Because of the relatively large variety of smokeless tobacco products and different historical patterns of use, laws are enacted differently in different countries. Certain types of ST products are banned in some countries, while other types are only restricted, and still others remain unaffected. Table 3 contains a summary of the situation in various countries, to the extent we could ascertain it from a review of available legislative texts (WHO, 1991).

AREAS OF The same arguments that apply to legislation for the control of LEGISLATION smoking also apply to smokeless tobacco. The possibility of adopting legislation to control smokeless tobacco is actually more favorable than that for the control of smoking. Indeed, while it is not possible to ban cigarette smoking completely, since the use of cigarettes is too deeply ingrained in the socioeconomic structure of most countries, there is an opportunity to legislate against the introduction of smokeless tobacco products in the many nations where they are not yet on the market.

Smokeless tobacco is not only a health problem of individual countries, but an international problem as well. Fortunately, the experience gained in more than 30 years of smoking control activities worldwide can be drawn upon for planning and implementing smokeless tobacco control programs. Some nations have already benefited from the experience of other nations in dealing with smokeless tobacco. For instance, the governments of Hong Kong, Ireland, Israel, New Zealand, and some Australian states enacted

Table 3 **Legislative action to control smokeless tobacco**

Country	Year	Banned Import, Manufacture, Sale, and/or Promotion
Ireland	1985	Moist snuff only
United Kingdom	1986	All smokeless tobacco sale to minors
Israel	1986	All smokeless tobacco
Hong Kong	1987	All smokeless tobacco (except nasal snuff)
New Zealand	1987	All smokeless tobacco
Singapore	1987	All smokeless tobacco (except nasal snuff)
Tasmania	1986	All smokeless tobacco (except nasal snuff)
S. Australia	1986	"Sucking tobacco" (no other types)
Victoria	1987	All smokeless tobacco (except nasal snuff)
W. Australia	1987	All smokeless tobacco (except nasal snuff)
Australia (nationwide)	1989	Oral snuff
United States	1987	Sale only of all smokeless tobacco to minors
Norway	1989	"New" types of tobacco products (no ban on "traditional" chewing and snuff)
United Kingdom	1990	Moist snuff (no ban on nasal snuff and chewing tobacco) (overturned in December 1990, awaiting new ruling)
Saudi Arabia	1990	Chewing and moist snuff
China (Taiwan)	1990	All smokeless tobacco
E.E.C.	1990	Moist snuff (to be enforced beginning in 1992)

legislation from 1985 through 1987 to prohibit the importation, manufacture, advertising, promotion, and sale of smokeless tobacco products (WHO, 1988). Other countries have learned from this experience: Norway, Saudi Arabia, Singapore, the United Kingdom, other Australian states, and Taiwan have recently banned smokeless tobacco products (BASP, 1990; Connolly, 1991; Trade Practices Commission of Australia, 1989). E.E.C. countries other than the United Kingdom are about to adopt the same policy (BASP, 1990).

Mongolia and China are in the process of adopting legislation to ban or restrict ST use (Dr. J. Mackay, letter, 1991). A new law on the control of tobacco hazards in the People's Republic of China has been drafted to read, "All importation and production of chewing tobacco is banned" (Prof. Weng Xin-zhi, letter, 1991).

According to the WHO expert group, legislation to control smokeless tobacco is most effective in the following areas: ban or control of manufacture, import, promotion, and sale; taxation and other economic disincentives; restriction on use in public places and places of work; and health warnings. These are described in more detail below.

Ban or Control In countries where smokeless tobacco is not yet used, steps should **Of ST Commerce** be taken to prohibit by law the manufacture, import, promotion, and sale of ST products. In these countries, there is an opportunity, which may never be repeated, to prevent such products from coming into use. This approach, called a preemptive ban, has been widely publicized by the World Health Organization through a worldwide press release (WHO, 1987).

In countries where smokeless tobacco use is already too well established for a comprehensive ban of this nature to be feasible, legislation should at least prohibit promotion of smokeless tobacco products through

- Direct and indirect advertising in all its forms;
- Sponsorship of sporting, artistic, and other events and media programs;
- Distribution of free samples of ST products;
- Use of sports and other popular personalities;
- Promotion of other products of the same name, packaging, and design, including items like T-shirts and toys; and
- Any other form of promotion, including those introduced from outside the country.

If advertising of smokeless tobacco products cannot be completely prohibited, it should at least be restricted by law to ensure the following:

- The impression is not given that ST is a safe alternative to cigarette smoking;
- Misleading links do not appear established between ST and positive values like success, youth, sports, open air, and the like;
- Advertising is restricted as to the type of media used, the size and layout of pictorial material, and so forth; and
- Health warnings appear prominently on ST packaging and on any advertising and promotional material.

In countries where smokeless tobacco products are sold, sales to minors should be prohibited by law. Vending machines should be banned or allowed only in areas where unaccompanied minors have no access.

In many developing countries, smokeless tobacco is a cottage industry and products are generally prepared by small local stores. In these countries, it is particularly important that major manufacturing industries are not permitted to develop. Priority should, at the same time, be given to identifying and promoting replacement crops that will provide profitable employment and economic substitutes for tobacco.

Taxation and Other Economic Disincentives

The World Health Organization has always advocated the use of increased taxation as a part of comprehensive programs for the control of both smoking and ST products. There is sound evidence tion can be used to discourage values people from starting to use

that taxation can be used to discourage young people from starting to use tobacco, and to encourage users to discontinue the habit, without decreasing government revenue. Ideally, a proportion of the tax increase should be used to finance health education programs. If it cannot be prohibited altogether, the importing of ST products can be discouraged through high import duties.

No government subsidies should be provided for any form of tobacco growing, manufacturing, sale, or export. If this is not possible, the World Health Organization recommends that governments ensure that no new form of tobacco becomes eligible for subsidies.

Restrictions Although not because of the same health criteria as those that relate to **On ST Use** passive smoking, the use of smokeless tobacco may nevertheless be unpleasant to nearby non-users. Restrictions on ST use may be justified in light of health and cleanliness problems associated with spitting and the disposal of chewed tobacco.

Health Warnings In countries where the sale and promotion of smokeless tobacco products are still allowed, health warnings should be mandatory on packages of such products as well as on any related advertising and promotional material. Similar to the rotating health warnings that appear on cigarette packages, ST products should carry health warnings about the harmful health effects associated with use of the products. Examples are shown in Table 4.

Table 4
Examples of health warnings on ST packages and advertisements

Country	Warning
France	Dangerous if abused.
Iceland	Snuff and chewing tobacco may damage the mucous membranes.
Ireland	This product may cause oral cancer.
Portugal	Tobacco damages health and, in particular, causes cancer.
Greece	Tobacco damages your health.
Sweden	Warning: Snuff and chewing tobacco contain nicotine. Therefore, snuff produces just as strong a dependence as tobacco smoking. The buccal cavity, mucous membranes and gums can be damaged and may require treatment.
United States	Warning: This product may cause mouth cancer. Warning: This product may cause gum disease and tooth loss. Warning: This product is not a safe alternative to cigarettes.

PRESENT ACTION In addition to the measures recommended by the WHO group of experts (WHO, 1988), further action is now under way, particularly in Europe. At the First European Conference on Tobacco Policy, held in Madrid under the auspices of both the World Health Organization and the E.E.C., 10 strategies for a tobacco-free Europe have been recommended (WHO [EURO], 1989). One of these reads, "To prohibit new methods of nicotine delivery, and to block future tobacco industry marketing strategies." This is a clear mandate to stop the development of a new hazardous addiction in Europe.

The countries in eastern Europe represent a special case, as they are now facing a new tobacco-related danger. These nations are emerging under new sociopolitical systems involving free-market economies. The transnational

tobacco companies are already exerting marketing and promotional pressure on these countries, as was revealed at the conference, "A Tobacco-Free New Europe," held in Kazimierz, Poland, November 21 through 23, 1990, under the auspices of WHO and the International Union Against Cancer. One recommendation of the conference was that governments of eastern European countries be requested to ban the introduction of smokeless tobacco, which is practically unknown in these nations (International Union Against Cancer, 1991). The E.E.C. is also taking action. The Commission of the European Communities has issued a directive that, if approved, would require member states to ban the import, manufacture, and sale of moist snuff starting in March 1992. Moist snuff is already prohibited from import into Switzerland, which is not an E.E.C. country (Swiss Federal Office of Public Health, 1987; Dr. B. Meili, letter, 1991).

In conclusion, it can be said that action is now being taken, both nationally and internationally, to stem the spread of ST use. Until several years ago, there was no legislation specifically to restrict smokeless tobacco; now an increasing number of countries have adopted legislation for that purpose.

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Legal and Administrative Strategies for Control and Prevention of the Use of Smokeless Tobacco

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ABSTRACT

The Irish government considers that the public health is more important than the economic effects of a fall in tobacco consumption over a period of years. For the past 25 years, the Department of Health has operated a strategy, based on education and legislation, to reduce demand for and supply of tobacco. Public support for the strategy has facilitated implementation of strong legal controls and prohibitions on tobacco sales and use. The importation, manufacture, and distribution of oral smokeless tobacco are totally banned by law in Ireland. The laws banning oral smokeless tobacco have twice been challenged in the courts by U.S. Tobacco International, Inc., with success in one case. Currently, the ban is in place but awaits final judgment. National laws of European Community Member States are subject to E.C. legislation, which is based on the Treaty of Rome. Irish laws and decisions of Irish courts therefore have a wider, European influence. The E.C. and some of its Member States have adopted Irish antitobacco legislation as a model.

INTRODUCTION The legal prohibition of commerce in oral smokeless tobacco in Ireland arose initially from official action by the U.S. Public Health Service in the early 1980's, which was a response to rising public concern in the United States about the increasing use of the product there. Through the agency of organizations such as the International Chief Dental Officers' Conference of the International Dental Federation, supported by the World Health Organization's Oral Health Unit, public health dental officers around the world were alerted by their American colleagues to the potential and serious consequences to the health of the public if the American experience were to be exported to and repeated in other countries.

Accordingly, in 1985 the Irish Minister for Health made a decision to ban oral smokeless tobacco in the moist snuff form. This decision received support shortly thereafter in the U.S. publication of *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General* (US DHHS, 1986).

HISTORY

For a quarter of a century, the Department of Health in Ireland has been engaged in developing and implementing programs designed to reduce the supply of tobacco products and the demand for them.

Tobacco use is the single most significant cause of death in middle age in Ireland. Illnesses resulting from tobacco impose an enormous strain on the health services. Among a total population of 3.5 million people, about 0.5 million days per year are spent in hospital as a result of tobacco-related illnesses, at a cost of more than £15 (\$25) per year for every person in the country (Lyons, 1988). Other health care costs, disability costs, and costs of time lost from work place an equally high burden on the economy.

The Irish government, having examined and considered all aspects and implications of the tobacco issue, decided that public health considerations outweigh by far the economic impact that a reduction in tobacco consumption would cause over a number of years.

STRATEGY The Department of Health has implemented its antitobacco policy by means of a double-pronged strategy. From the start, an education and information program has been conducted in various ways through the mass media, the educational system, and official and voluntary agencies. The second part of the strategy is the legislative program by which legal controls and/or prohibitions are in place with respect to tobacco advertising, sponsorship, promotion, labeling, smoking in public buildings and offices, and selling tobacco products to children and young people.

Advertising of tobacco on television was prohibited in 1971 and on radio in 1975. The education and information program increased the public's knowledge about the hazards associated with tobacco, and this in turn led to widespread public support for measures to curtail tobacco use even further in the interests of users and non-users alike.

Public opinion polls had shown such a high level of support for the Department's strategies that a new Tobacco Act (1988) was brought forward to further curtail and restrict tobacco consumption. The 1988 Act is crucial insofar as it contains the ban on importing, making, and distributing oral smokeless tobacco.

LEGISLATION Ireland's ban on oral smokeless tobacco is contained in the Tobacco (Health Promotion and Protection) Act, 1988. The preamble to the Act summarizes its provisions: (a) prohibition and restriction on the consumption of tobacco and restriction on the consumption of tobacco products in designated areas and facilities; (b) restriction on the sale of tobacco products to persons under 16 years of age; (c) prohibition on the importation, manufacture, and sale of certain tobacco products; (d) amendment of previous legislation; and (e) provision for other connected matters.

Specifically, the ban on oral smokeless tobacco is contained in Section 6 of the 1988 Tobacco Act, as follows:

- Any person who imports, manufactures, sells or otherwise disposes of, or offers for sale or other disposal, or advertises, an oral smokeless tobacco product shall be guilty of an offense and shall be liable—
 - (a) on summary conviction, to a fine not exceeding £1,000, or
 - (b) on conviction on indictment to a fine not exceeding £10,000.
- (2) In this section "oral smokeless tobacco product" means any product or substance, made wholly or partly from tobacco, which is intended for use, unlit, by being placed in the mouth and kept there for a period, or by being placed in the mouth and sucked or chewed.

This is a comprehensive ban, which is feasible to implement in Ireland where there has never been an oral snuff habit.

As already mentioned, a somewhat similar type of ban was previously introduced, in 1985. The first ban did not involve new legislation at that time, as it was introduced under previous legislation (Health Act, 1947). The 1947 Health Act, by virtue of its Section 66, allowed the Minister for Health to prohibit the import, manufacture, sale, or other disposal of a restricted article or substance when it was likely, when accessible to the general public, to be used for purposes involving risks of serious injury to health or body. The 1985 ban (Health [Restricted Article] Order, 1985) was confined to the Skoal Bandit form of oral smokeless tobacco—that is, sachet-type products.

In addition to the legislation mentioned above (i.e., the 1985 Regulations and the 1988 Act), there are a couple of other important pieces of relevant legislation. The first of these is the Tobacco Products Act (1978), which gives the Minister for Health extensive powers to control all aspects of advertising, sponsorship, and promotion of tobacco products. The second is the Tobacco (Number 2) Regulations (1986), which greatly extend the Minister's powers in implementing the 1978 Act.

LITIGATION The 1985 ban on oral smokeless tobacco, under the 1947 Health Act, was challenged in the Irish High Court by U.S. Tobacco (Ireland) Limited and U.S. Tobacco International, Inc. U.S. Tobacco won the case, on the grounds that, when framing the Act, the legislature did not intend that it be used for this particular type of purpose. The Court held that the Minister for Health had exceeded his powers, and so the first ban was nullified.

Unfortunately, the lawyers had decided to fight the case without reference to the health risks of smokeless tobacco use and to defend the ban on purely legal technical grounds. With hindsight, this was seen as a mistake. After the defeat in the High Court, a decision was made in the Department of Health not to appeal to the Supreme Court, as the second ban, in the new proposed Tobacco Act (1988), was well on its way toward implementation as Section 6.

The second ban also was challenged in the Irish High Court by U.S. Tobacco. The case was heard late in 1990, and the decision, which upheld the ban, was given on February 22, 1991 (High Court, 1990, 1991).

It is instructive to study this second court case: U.S. Tobacco claimed that Section 6 was invalid, as it breached the Treaty of Rome (1957), by which the European Community was formed, at Article 30, and that it was unenforceable because of noncompliance with E.C. Council Directives 83/189 as amended by 88/182 (E.C., 1983 and 1988), and 89/622 (E.C., 1989)—the "Notification" and "Labelling" Directives, respectively. Article 30 states: "Quantitative restrictions on imports and all measures having equivalent effect shall, without prejudice to the following provisions, be prohibited between Member States."

U.S. Tobacco contended that Section 6 offends the principle of proportionality in that the same objective could be achieved by a less repressive measure than the ban. The corporation contended also that the current legal restrictions in Ireland on smoking tobacco could be applied to

smokeless tobacco and that they would be adequate to protect the health and lives of humans in Ireland.

The law involved is European Community law. It covers three topics: (a) Articles 30 and 36 of the Treaty of Rome, (b) the principle of proportionality, and (c) the rights of Member States when there are uncertainties in current research. Article 30 of the Treaty is stated above. Article 36 is as follows:

The provisions of Articles 30 to 34 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

The State agreed that Article 30 was breached but contended that Article 36 gives an exception from it. Under Article 36, the case law is clear that exceptions are justified on grounds of necessity for "protection of health and life of humans." Exceptions are not allowed, under the principle of proportionality, if the health and life of humans can be as effectively protected by less strict measures. Insofar as there are uncertainties in the present state of research, Member States can decide the degree of protection they wish to assure for the health and life of humans.

The evidence fell into two categories: first, the conclusions of authoritative bodies, and second, opinions of expert witnesses.

Conclusions of Authoritative Bodies

According to volume 37, page 116, of the International Agency for Cancer Research Monographs (IARC, 1985), "There is sufficient evidence that oral use of snuffs . . . is carcinogenic to humans."

From the preface (page vii) to the report of the Advisory Committee to the U.S. Surgeon General (US DHHS, 1986), "The scientific evidence is strong that the use of snuff can cause cancer in humans."

The World Health Organization Study Group (WHO, 1988b) stated, "There is conclusive scientific evidence that the use of smokeless tobacco causes cancer in humans" (page 18).

According to the First European Conference on Tobacco Policy (WHO, 1988a), "These products are associated with increased risk of contracting oral cancer and other diseases of the mouth."

Testimony of The expert testimony was extremely detailed and went on for **Expert Witnesses** 6 days. All of the State's witnesses were of the opinion that there is an association between oral smokeless tobacco and oral cancer. The judge had no hesitation in accepting their evidence.

The evidence of U.S. Tobacco's expert witnesses did not convince the judge, as can be seen from his assessment, which took the form of answers to three questions:

- (a) Was the ban justified when introduced in July 1988?
- (b) If so, is it still justified?
- (c) If the answers to (a) and (b) are "Yes," could the objectives of the ban be achieved by less restrictive means?

The judge's answers were as follows:

- (a) Yes, there was enough evidence that smokeless tobacco could cause oral cancer. People had to be protected by ensuring it was not available by means of a total ban.
- (b) Yes, it was not proven there is a scientific controversy. The plaintiff's witnesses disagreed with authoritative bodies, but no responsible body agrees with them—the evidence is the other way. To impose the ban it was sufficient that there was evidence that cancer might be caused or that the risk was increased. As the State is obliged to protect its citizens, it had enough evidence to take action. It would fail in its duty if it were to act otherwise.
- (c) It is submitted that existing restrictions (on smoking tobacco) would be adequate, but it is not submitted that they would be as effective as the ban. They are not adequate, not sufficient, not as effective, and are "a second best."

E.C. Council Directives

the Notification Directives (E.C., 1983 and 1988) require that draft technical regulations be communicated to the E.C. Commission. Section 6, however, is not a technical regulation, specification, or standard. Agricultural produce is excluded from the 1983 Directive, and the 1989 Directive did not come into force until January 1, 1989, and was not operable when the 1988 Act was passed in July 1988.

The Labelling Directive (E.C., 1989) is concerned only with harmonizing laws, etc., regarding health warnings on packages of tobacco products. It does not affect the right of a Member State to lay down its own rules concerning the import, sale, and consumption of tobacco products, for example, a ban, which is not imposed for reasons of labelling but for the public health.

Judgment In conclusion, and in the judge's own words, "the plaintiff's claim fails in toto and must be dismissed" (High Court, 1990, 1991).

INTERNATIONAL Irish legislation in relation to restrictions on sales, promotion, and advertising of tobacco has served in the past as a model for subsequent European Community laws, regulations, and directives. The

subsequent European Community laws, regulations, and directives. The introduction to the E.C. of a similar legal ban on oral smokeless tobacco is under consideration at present. It is, therefore, possible that before long there will be an E.C. ban similar to the Irish one.

A number of other countries have already adopted measures aimed at banning or controlling the importation, manufacture, and sale of smokeless tobacco products. Within the E.C. and following the Irish initiative, in February 1988 the United Kingdom announced its intention to ban moist snuff. Since March 1990 in the United Kingdom, "no person shall supply, offer to supply, agree to supply, expose for supply or possess for supply any oral snuff" (excluding nasal dry snuff) (Consumer Protection, 1989).

Belgium adopted a Royal Decree, effective December 31, 1990, which lays down that "it is forbidden to market moist snuff tobacco in pouches aimed at being placed as such in the mouth."

Luxembourg and France impose restrictions on the advertising of smokeless tobacco products. In France (under the Law Concerning Measure Against Tobacco, 1976) and Belgium (under the 1990 Royal Decree), health warnings are required on smokeless tobacco packages. France is currently examining a draft law (Law Concerning Measure Against Alcohol and Tobacco, 1990) aimed at banning all forms of direct or indirect advertising of tobacco products.

Outside the European Community, Hong Kong, New Zealand, and Israel have banned all forms of smokeless tobacco (Public Health and Municipal Services Ordinance, 1987; Toxic Substances Act [amendment], 1985; and Ministry of Trade Industry Codes, 1986, respectively), as have Japan and Taiwan (European Bureau, 1990). Singapore adopted measures banning the importation and sale of chewing tobacco and moist snuff, and Saudi Arabia has banned moist snuff and chewing tobacco (European Bureau, 1990). The Isle of Man prohibits the importation of moist snuff under the Custom and Excise Acts Orders (Amendment No. 2) of 1986. In the United States, "Masterpiece Tobacs" was banned because it did not comply with the Food and Drug Administration rules (European Bureau, 1990).

Iceland's Act on Prevention of Use of Tobacco (1984) bans all tobacco advertising and promotion. India, Canada, Sweden, and the United States have enacted legislation that makes the inclusion of health warnings on smokeless tobacco packages compulsory. Massachusetts was the first U.S. state to declare moist snuff a hazardous substance, and a ban was considered but not enacted because of the large consumer demand for the product (European Bureau, 1990).

FUTURE STRATEGY

In 1988, the First European Conference on Tobacco Policy (WHO, 1988b), organized jointly by WHO and the European Community, produced a 10-point strategy for a "Europe without tobacco." Point 8 of the strategy concerns the banning of all new tobacco products containing nicotine. The conference adopted the following recommendation for strategy on this issue:

The participants endorsed the recommendations of the WHO Study Group on Smokeless Tobacco Control and urged Member States to use these recommendations as a basis for action. Particularly important are the Study Group's recommendations for a smokeless tobacco program:

• Where smokeless tobacco is not used, prevent its introduction, with special emphasis on preventing its use by children;

- Where smokeless tobacco is already used, act to reduce the prevalence of use in the population; and
- Establish or maintain a social climate unfavorable to smokeless tobacco use.

ADDENDUM In March 1991, U.S. Tobacco lodged an appeal to the Supreme Court in Ireland against the High Court judgment (1990). The basis of the appeal is the contention that the judge in the High Court misdirected himself in law and in fact. In the Supreme Court the appeal will be heard by the full court of five judges sitting together. The outcome of this most important case is awaited with great interest.

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National Cancer Institute's Role In Reducing Tobacco Use

Robert Mecklenburg

ABSTRACT The tobacco industry exploits the public good—trading human lives, economic well-being, and the environment for profit. The industry knows that its earnings are built on consumer addiction, loss of health, and death. Waking the public to the needless and despicable consequences of a morally bankrupt industry requires determined action by a wide variety of private and public sector organizations. Each organization, doing what it can do best, can help turn public opinion from tolerance to outrage, and public behavior from use to abstinence. The National Cancer Institute, through its research and dissemination of knowledge, is a vital partner in this quest for a healthy society. This paper provides an overview of NCI's mission and current activities related to the control of smoking and smokeless tobacco use. Major research and demonstration projects, health professional roles, and public and private-sector NCI partnerships are described.

NCI MISSION NCI aims to provide knowledge and guidance for reducing cancer AND MANDATE incidence and mortality in the United States and around the world. Evidence strongly links tobacco use, primarily smoking, with many types of cancers (US DHHS, 1982). About 30 percent of all cancers are attributed to tobacco use. Both smoking and ST use increase the risk for cancer of the mouth and pharynx about fourfold, with the relative risk for both tobacco forms related to the duration and intensity of exposure (US DHHS, 1990a; Winn, 1981).

Goals set by the U.S. Department of Health and Human Services include an objective of reducing cigarette smoking to no more than 15 percent among people aged 20 and older (US DHHS, 1991). The smokeless tobacco objective is to reduce prevalence of use among males aged 12 through 24 to no more than 4 percent (US DHHS, 1991). These two goals are also objectives for NCI's Smoking and Tobacco Control Program.

One study suggests that 25 to 30 percent of all regular ST users also smoke (Eakin et al., 1989). Children and youth may become addicted to ST, then later become smokers. Smokers may perceive ST as a safe alternative to smoking and change to ST for maintaining their levels of nicotine. Both forms of tobacco are addictive, produce health problems, and create intervention challenges (US DHHS, 1986a). To be successful, strategies to meet national health objectives must address both smoking and smokeless means of nicotine administration.

These objectives call for action, but just any action will not do. It is essential that major tobacco use interventions be supported by scientifically sound, established methods. Thus, NCI developed an 18-yr plan to develop hypotheses, define evaluation criteria, examine scientific evidence to date, support well-designed studies in areas where evidence seemed insufficient, and build large-scale intervention trials (US DHHS, 1990b).

TOBACCO USE INTERVENTION PROGRAM

Since 1983, specific NCI research efforts in the Division of Cancer Prevention and Control have been directed toward the development of scientifically sound and practical tobacco use interven-

tions. Through fiscal year 1990, nearly \$250 million had been invested in tobacco use research and control. Sixty studies on smoking intervention have been completed or are in progress, and an additional eight studies focus on ST (US DHHS, 1990b).

Of the eight ST studies, four are directed to students, one is limited to dental clinic patients, one targets Little League youth, one targets Native American youth, and one targets 4-H members. Preliminary results suggest that methods found to be effective in helping smokers quit can achieve similar results among ST users.

The Community Intervention Trial for Smoking Cessation (COMMIT) is a large, controlled study of randomly assigned subjects. COMMIT involves, directly or indirectly, more than 6 million people in 22 paired study and control communities to test intervention methods that were found effective during smaller studies (US DHHS, 1990b). COMMIT is a university-based research project that includes schools; worksites; professional, religious, civic, and government organizations; and the media. The COMMIT trials began in 1989 and are scheduled to run until 1993. Although intended to focus on heavy smokers, the study suggests approaches to the psychological and social patterns and physical dependencies of ST users. Already invaluable baseline and operational information has been obtained, but future results hold high promise.

Findings from COMMIT should significantly contribute to a larger initiative, the America Stop Smoking Intervention Study for Cancer Prevention (ASSIST) (US DHHS, 1990b). ASSIST will have an impact on patterns of tobacco use nationwide. States will administer contracts for organizing and operating coalitions that promote a multifaceted approach to influencing people to avoid and discontinue tobacco use. From 50 to 100 million people are expected to be included in this project. An organizational phase for ASSIST will run from 1991 to 1993, and an operational phase from 1993 to 1998.

ST was specifically identified in the original Request for Proposals that was sent to the states for ASSIST. These guidelines defined smokers as tobacco users rather than just individuals who smoke tobacco (cigarettes, cigars, pipes). For purposes of ASSIST, ST users are included in the definition of "smoker" (ASSIST Program Guidelines, October 1991, Glossary of Terms, unpublished).

PROFESSIONAL ROLES

NAL The medical profession has great incentive to become involved in smoking control. Physicians often see patients sicken and die from tobacco-related diseases. Indeed, surveys of patients and physicians suggest that from one-third to one-half of medical practitioners provide at least some smoking intervention services during encounters with patients (Frank et al., 1991; Gerbert et al., 1989; US DHHS, 1976). Surveys also indicate that dentists are involved to a lesser degree (Geboy, 1989; Gerbert et al., 1989;

Secker-Walker et al., 1989) but may not consistently use the best intervention methods (Secker-Walker et al., 1987).

NCI recognized that both the medical and dental professions are strategically situated to provide effective intervention. About 70 percent of Americans see a physician at least once a year (US DHHS, 1986b). About 63 percent of the population see a dentist each year, including 75 percent of children and youth (Hayward et al., 1989). Studies suggest that selected tobacco use interventions are effective when provided in the dental clinic environment (Cohen et al., 1989) and are as effective as physician intervention services (Cohen et al., 1987).

The time that physicians and dentists spend with patients offers an excellent opportunity to influence behavior. Medical and dental visits provide many opportunities for one-to-one discussion about tobacco use and health consequences and methods for quitting. Medical visits for prenatal care, child health, and upper respiratory or cardiovascular conditions provide special opportunities to discuss reasons for quitting. Dental checkups are usually performed at regular intervals and often are prevention oriented. Dental visits also provide opportunities for effective interventions because tobacco effects are commonly found in the mouth. Oral lesions that are visible to patients lead to teachable moments that help motivate patients to stop. Both physicians and dentists can prescribe nicotine replacement therapy, when indicated. Followup visits for many routine dental services can also be used for followup of tobacco use interventions.

NCI has developed and conducted training programs for medical and dental clinicians, focusing on train-the-trainer programs for medical and oral health teams who are willing to teach colleagues. Dental education institutions are encouraged to integrate key issues into their curricula and to establish behavioral outcome objectives. The NCI manual, *How To Help Your Patients Stop Smoking*, designed for physicians, does not specifically address smokeless tobacco, but the clinical intervention methods can apply to ST intervention (Glynn and Manley, 1990). The NCI manual, *How To Help Your Patients Stop Using Tobacco*, is used with the oral health team and educator training programs (Mecklenburg et al., 1990). The title and contents of this manual specifically refer to "tobacco use" rather than "smoking," reflecting the importance of influencing patients to avoid and discontinue the use of ST as well as smoking tobacco.

PUBLIC AND PRIVATE PARTNERSHIPS NCI recognizes that intervention successes are the product of a partnership between the research community and educators, community leaders, policymakers, and program administrators.

NCI promotes the reduction of tobacco use by collaborating with many private and public organizations. Examples of NCI partnerships include the following:

• NCI partnerships with the academic community are important to its extramural research program. Research and education institutions continually strengthen the scientific basis for rational patient care

- and public health action. COMMIT is an example of a university-based tobacco use intervention research project.
- NCI works with public and private-sector organizations to form effective community contacts. Private volunteer, business, and community service government organizations have access to large segments of the public. These organizations want assurances that their efforts will be effective. ASSIST is an NCI collaboration with the American Cancer Society, state health departments, and many other groups with special skills in working with the public (for example, business, religion, education and public service organizations, and the media). NCI's National Dental Tobacco-Free Steering Committee is an alliance between NCI and 11 national dental organizations that are committed to influencing the public to avoid and discontinue tobacco use.
- Within the National Institutes of Health, NCI and the National Institute of Dental Research are jointly planning and identifying several cooperative ventures against ST and in support of the prevention and early detection of oral cancer, with each institute building on its special strengths.
- NCI collaborates with other U.S. Public Health Service agencies, such as the Office of Disease Prevention and Health Promotion for tobacco, cancer, and oral health objectives for the year 2000; with the Centers for Disease Control, especially its Office on Smoking and Health; the National Center for Health Statistics; and more recently, the Health Resources and Services Administration and Indian Health Service for training of Public Health Service clinical personnel in tobacco use interventions.
- NCI collaborates in tobacco control activities by other government agencies, such as the Department of Veterans Affairs and the Department of Defense. These departments are working with many of the same private and public-sector organizations noted above.
- Finally, NCI provides tobacco use intervention support to the World Health Organization and to other countries. The Basic Dental Research Unit of the Tata Institute of Fundamental Research in India deserves special recognition for its 25-yr effort to develop oral cancer control methods, including pioneering work in developing tobacco use interventions.

SUMMARY

The NCI program, in collaboration with numerous organizations, is influencing the public to reduce its use of tobacco. ST control is a significant element of NCI's commitment. The mission of NCI with regard to tobacco control is twofold: First, to strengthen the science base for intervention services through its epidemiological and biomedical research programs, and second, to ensure that sound scientific methods reach the right people, at the right time, and in ways that are most likely to create a united effort for reducing cancer incidence and mortality and other tobacco-induced health problems.

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