lence varies from 1–6% in Scandinavia (Axéll, 1976; Saietz, 1975). Smoker's palate is reversible and non-precancerous as opposed to smoker's palatal keratosis encountered in subjects practising reverse smoking and most frequently found in Indian women (Mehta *et al*, 1977), but also in the Caribbean islands and among men in Sardinia. Tobacco habits, especially smoking habits, cause modification(s) of the clinical appearance/spectrum of several oral mucosal lesions.

Lichen planus

The prevalence of oral lichen planus is about 1–2% (Kleinman *et al*, 1991). The oral manifestations have been subgrouped into white and red forms. For all of them, there is a negative statistical relationship to tobacco smoking, for all except one—the plaque form of lichen (Neuman-Jensen *et al*, 1977; Axéll and Rundquist, 1987). Thus, differential diagnosis between tobacco-associated leukoplakia and plaque-lichen may offer a diagnostic challenge.

Recurrent aphthous ulcers

RAU may appear in many different clinical forms and at highly varying frequencies in one and the same individual. Typically, it is almost exclusively appearing on the non-keratinized mucosa (except on the tongue). Tobacco smoking seems to change the keratinization process also affecting the keratin filaments in the cells of the clinically non-keratinized mucosa. It has been shown that the prevalence of RAU is considerably lower among tobacco smokers than among non-tobacco users, the prevalence of episodes within a 2-year period being 14% and 22%, respectively, and for pipe smokers only 7% (Shapiro *et al*, 1970: Axéll and Henricsson, 1985).

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SMOKELESS TOBACCO AND ORAL HEALTH: THE SWEDISH EXPERIENCE

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The Swedish consumption figures for wet snuff are the highest in the world, about 0.7 kg per capita. In the age groups 15–75 years about 18% of the men and 2% of the women are habitual users of snuff and consuming at an average 19 g of loose snuff and 10 g of portion-bag-packed snuff.

The clinical characteristics of lesions associated with Swedish wet snuff have been carefully described in a series of papers since the mid-1970s, for reviews and details see Andersson (1991) and Axéll (1993). At the place where the quid is inserted almost invariably a clinically visible change appears. A 4-degree scale has been suggested for describing varying degrees of clinical 'severity' (Axéll *et al*, 1976), a scale that later has been been modified by American scientists to a 3-degree scale. Based on the clinical grading it has been shown that lesions become most pronounced after a high daily intake rather than after many years of consumption and also after use of loose snuff as compared to use of portion-bag-packed snuff. The snuff-induced changes also seem to be reversible.

For chewing tobacco there are very low sales figures in Scandinavia. Only about 15 tons are sold in Sweden as compared to about 5000 tons for snuff. Changes of the oral mucosa are very discrete and the histopathological picture similar to the one of a leukoedema (Axéll *et al*, 1992).

The question of carcinogenicity of snuff has been vividly discussed in Scandinavia. The IARC statement of 1985 that there is sufficient evidence that snuff causes cancer (IARC, 1992) has to some extent been supported by some Swedish scientists, and questioned by others. The statement has led to a law which orders the manufacturers to label the snuff product with a the text 'Causes cancer'. In the light of previous research and recent Swedish studies the validity of this label has been seriously questioned at a symposium at the Swedish Board of Health and Welfare in September 1996.

One of those recent studies was a case control study on oral cancer in Northern Sweden. The number of cases were 418. Relative risk (RR) for developing oral/pharyngeal cancer in present snuff users was 0.7 (95% CI 0.4–4.1) and for previous snuff users 1.5 (95% CI 0.8–2.9) (Schildt *et al*, 1997). Another case control study comprised 128 cases of oral cancer. RR for present snuff users was 1.0 (95% CI 0.7–1.6) and for previous snuff users 1.2 (95% CI 0.6–1.9) (Lewin *et al*, 1997).

Also the risk for circulatory and heart diseases have been evaluated in recent Swedish studies. One case control study comprised 585 cases with 10% snuff users and 589 controls with 15% snuff users. RR for myocardial infarction in snuff users was 0.89 (95% CI 0.62–1.29) as compared to 1.87 (95% CI 1.40–2.48) for tobacco smokers (Huhtasaari *et al*, 1992). In another study data from health screenings of 135 036 construction workers (6297 snuff users) were analysed. The RR for habitual snuff users to die of cardio-

vascular disease was 1.4 (95% CI 1.2–1.6) as compared to the RR for smokers 1.9 (95% CI 1.7–2.2) (Bolinder *et al*, 1994).

No increased risk among snuff users who had never smoked was registered in a recent case control study among men with the inflammatory bowel diseases Crohn's disease and ulcerative colitis (Persson *et al*, 1993).

Thus, it appears that snuff habits as they appear in Scandinavia carry very low risks for contributing to serious health hazards including oral cancer. However, this does not mean that use of snuff should be encouraged—on the contrary. The fact that no serious local or general health hazards have been detected in Scandinavian epidemiological studies does not guarantee an absence of such risks. Further, it is an unequivocal fact that using snuff almost always causes lesions of the oral mucosa, damages salivary glands and also in some cases causes gingival recessions.

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SMOKELESS TOBACCO: THE IRISH AND EU EXPERIENCE

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Smokeless tobaccos were used in Ireland within living memory, especially in rural areas. A small number of men chewed tobacco and there was the occasional use of nasal stuff by both men and women. These practices have fallen into disuse and would no longer be socially acceptable. There does not appear to be any history in Ireland of moist snuff use or snuff dipping. Indeed, during oral oncology courses, the practice of snuff dipping has to be explained to our students.

Ireland and the UK have shared a common trade area going back to before our membership of the European Union. The Irish Health Department (Ministry of Health) became concerned, therefore, when it learnt in 1985 that a UK government agency had provided a development grant to enable the United States Tobacco Company to build a factory in Scotland for the manufacture of portion snuff to be sold as 'Skoal Bandits'. Later that year the Department of Health received a query from a potential importer asking if the product was covered by existing legislation on tobacco advertising, if the Minister felt that the product was harmful and if the Minister intended to introduce legislation to regulate the sale of portion snuffs. The Minister and his officials sought urgent assistance from the UK Health Department, the United States of America National Institutes for Health and the Massachusetts Department of Public Health. Following that advice it was decided to ban the importation and sale of portion snuffs using the only suitable existing legislation, the Health Act of 1947. Section 66 of the act applies to: "*any instrument, appliance or apparatus . . . the use of which by the general public . . . involves a risk of serious injury to health or body . . .*" and makes it an offence, "*unless authorised by the Minister, to import, manufacture, sell or otherwise dispose of or offer to keep for sale or other disposal, or advertise a restricted article . . .*" with a penalty of a £100 fine or 6 months imprisonment or both. Under this law the Minister issued the following statutory order: "*Whereas the Minister for Health is of the opinion that tobacco in the form of finely-cut, moist tobacco contained in sachets or pouches and intended for use by being placed in the mouth, is likely, when accessible to the general public, to be used for purposes involving risk of serious injury to health or body; now therefore the Minister for Health hereby orders as follows: tobacco in the form of finely-cut, moist tobacco contained in sachets or pouches and intended for use by being placed in the mouth, shall be a restricted article for the purposes of Section 66 of the Health Act 1947.*' (Health (Restricted Article) Order, 1995)

In 1987 United States Tobacco sought to overturn the ban in the High Court (US Tobacco Int. Inc, 1986). The President of the High Court ruled that as the Health Act 1947 covered "*medical and toilet preparations and certain other articles*", smokeless tobacco was too remote from that definition for parliament to have intended that it should be covered by the Act.

As the Irish parliament was then considering legislation to restrict the use of tobacco in places of public access, an amendment was urgently drafted to restore the *status quo ante*. This became the Tobacco (Health Promotion and Protection) Act 1988. Section 6 contains a complete ban on oral smokeless tobaccos: "*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 offence and shall be liable . . . on conviction . . . to a fine not exceeding £10 000.*

. . . 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 ban is more comprehensive than that under the 1947 Act which covered only portion snuffs.

Again United States Tobacco sought to challenge the law. Two principal reasons were advanced; one based on EU law and the balance between health protection and free movement of goods and the other based on a perceived imbalance between the risk to health and the remedy imposed by the Irish government *viz.* a complete ban rather than health warnings on packaging as with other tobacco products.

The case was heard in the High Court 1990 (US Tobacco (Ireland) Ltd, 1990). The case was regarded by the government as an important public health matter and a panel of expert witnesses was assembled from Ireland and the USA. The two sides were represented by very senior lawyers, each of whom was later to serve as Attorney General. Witnesses for the company were called from the UK, the USA and Sweden. Expert witnesses for the company argued that oral smokeless tobaccos were not carcinogenic and that while there would be other experts who would hold that they were carcinogenic, this was a matter of scientific controversy. There was conflict of evidence between expert witnesses for the company on the carcinogenic effects of nitrosamines in animal experiments and one expert witness for the company stated thtat he did not believe that smoking causes lung cancer. A dental expert called for the company argued that there was no significant evidence in Scandinavia for a carcinogenic effect from moist snuff but that other soft tissue changes were seen; he agreed that the ban was justified on those grounds. Evidence was heard that no tax had been paid on the manufacture or importation of chewing tobacco for many years. It was argued, therefore, that smokeless tobaccos were new products on the Irish market and could therefore be regulated differently from existing forms of tobacco. Judgment in favour of the government position was given in early 1991. The court ruled that the ban was justified both in Irish and in EU law and that individual EU member states had the right to decide on health and safety where the scientific evidence is uncertain. The judge rejected the contention that there was scientific controversy on the carcinogenic effects of smokeless tobacco. He ruled that printed warnings on packages would be insufficient for protection of the health of the public. Following this decision, United States Tobacco Ltd appealed against the finding to the Supreme Court.

While the case was in progress, the EU had been considering a ban on smokeless tobaccos and officials followed the progress of the Irish case with interest. An EU directive of 1989 had regulated the advertising of tobacco products (EU Directive, 1989). A new directive (EU Directive, 1994) amended the title of the 1989 directive to include the words "*and the prohibition of the marketing of certain types of tobacco for oral use,*' and a new Article 2(4) was added as follows: "'*Tobacco for oral use', for the purposes of Article 8a, means all products for oral use, except those intended to be smoked or chewed, made wholly or partly from tobacco, in powder or particulate form or in any combination of these forms—particularly those presented in sachet portions or porous sachets—or in a form resembling a food product.*" Article 8a states: "*Member states shall prohibit the placing on the market of tobacco for oral use as defined in Article 2(4).*"

In 1995, possibly in the light of the European ban, United States Tobacco Ltd withdrew its Supreme Court appeal against the Irish ban.

With the accession of Sweden to the EU in 1995, there arose a problem because of the traditional use of moist snuffs. Sweden was granted an exemption from the directive but the Swedish government was ordered to prohibit the export of smokeless tobacco products to other EU states.

The EU ban covers moist snuffs including portion snuffs, but exempts chewing tobaccos. The Irish ban covers all smokeless tobaccos. How should we now view those bans? Traditional Swedish use of moist snuffs does not appear to be associated with any significant increase in oral cancer incidence (Axéll *et al*, 1978). Chewing tobaccos, however, must remain suspect as the older evidence for carcinogenic effects has never been rebutted. Thus the EU ban may well have had the effect of prohibiting a relatively less harmful form of smokeless tobacco while exempting the harmful form.

If the ban on moist snuffs cannot be justified on grounds of carcinogenesis, can the ban be justified on other grounds? There are arguments both for and against. Certainly, if tobacco were a new product it would be banned on the grounds of the risk to health; all tobacco products cause some damage. Products marketed at teenagers are problematic; we do not know if use of smokeless products in teenagers leads to smoking later or if smokeless tobacco is a useful way to wean smokers off cigarettes, or, indeed, if smokeless tobacco is neutral in the initiation of smoking. Knowledge of these factors would have a considerable bearing on any study of the validity of the EU ban.

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