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Commentary

Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options

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Public health policy needs to be assessed for effects on human rights as well as public health. Although promoting harm reduction products to cigarette smokers might lead to greater total public health harm, if the products become too popular, human rights issues also need to be considered. Avoiding, or objecting to, the fair presentation of information on effective harm reduction products to smokers to allow them to make an informed choice to reduce health risk can represent a violation of a human right – the right to information. The necessary conditions are not met for protecting public health by restricting information on certain risk reduction products. As examples, based on current evidence, smokers have a right to information on snus (Swedish moist snuff) and medicinal nicotine as harm reduction options that would reduce substantially the risk of death to individuals. Smokers also have a right to truthful information about lower-tar cigarettes that have been erroneously promoted as risk reducing.

Introduction

Two recent, major publications have helped shape consideration of pharmaceutical or tobacco products for reducing harm to cigarette smokers who are unwilling to cease nicotine use completely. The first book resulted from an international workshop funded by the Robert Wood Johnson Foundation, the American Society of Addiction Medicine, and the Addiction Research Foundation (Ferrence, Slade, Room, & Pope, 2000), and the second book was the result of an expert committee convened by the prestigious Institute of Medicine of the National Academy of Sciences and partially funded by the U.S. Food and Drug Administration (Stratton, Shetty, Wallace, & Bondurant, 2001). In nicotine-related public health policy, there has been a desire to avoid promotion of harm reduction products that, while reducing toxicity to individual users, might increase public health harm because of increased numbers of users.

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Ferrence et al. (2000) noted one of the important questions: 'Would there be a net benefit to society if novel products reduced risk but increased use?' Later in the book, Henningfield and Fant (2000) indicated that, in evaluating a harm reduction product, it is important to include 'the potential immediate and long-term health effects at the population level' (p. 240). A later chapter urged that a key question in evaluating harm reduction products is whether the product 'ends up reducing harm for the population as a whole' (Reuter, 2000, p. 337). The Institute of Medicine report (Stratton et al., 2001) assessed the science base for tobacco harm reduction. Before endorsing any product, the committee wanted to see evidence on increase in harm 'to the population from encouraging initiation or continuation of smoking'. The Executive Summary had as its final conclusion, 'Conclusion 6. *The public health impact of PREPs [Potential Reduced Exposure Products] is unknown. They are potentially beneficial, but the net impact on public health could, in fact, be negative*' (p. 6).

The principle of protecting the health of the public has been offered, then, as one guiding principle in the development of harm reduction products; but these major works (Ferrence et al., 2000; Stratton et al., 2001) offer no consideration of another established principle: the

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human right of individuals to receive information relevant to their health and their health choices. The right to information derives from the principle of respect for autonomy. (The principle of autonomy is also the source of the requirement for informed consent for individuals who take part in research.) If people are deprived of information relevant to their health, they will necessarily be deprived of choices that might protect their health (Freedman, 1999). In a tradition deriving from the Nuremberg Code (1949) and the United Nations Universal Declaration of Human Rights (1948), the American Public Health Association concluded, 'Human rights must not be sacrificed to achieve public health goals, except in extraordinary circumstances, in accordance with internationally recognized standards' (Bird, 2001). Assessments need to be made if a public health goal justifies restrictions on human rights (Gostin & Mann, 1999).

The present commentary asserts that (a) snus (Swedish moist snuff) and medicinal nicotine, based on present evidence, make dramatic reductions in health risks to individual smokers; (b) there is an established right to information that affects health; and (c) the potential public health harm is not clear and convincing enough to justify suspension of advice about reduced risks to individuals from these products. Other possible issues involved with reluctance to promote known harm reduction products will be discussed briefly. These include (a) concern that addicts are impaired in making free choices, (b) belief that no harm reduction products of any kind are warranted, (c) refusal to advise at all in the absence of strong governmental regulation, and (d) preference to let the industry solely promote its own products.

Two significant harm reduction products for individuals who smoke cigarettes

This commentary is not the place for a detailed review of harm reduction products; for that, see the Institute of Medicine report (Stratton et al., 2001). The Institute of Medicine report avoided recommendations about harm reduction products, declared every product as a 'potential' harm reduction product, and proposed an elaborate, extensive scheme for assessment (based on toxicology, epidemiology, as well as proper governmental regulation). Though such assessment is desirable, the feasibility or practicability of the Institute of Medicine report is far from clear. It is sufficient in this commentary to establish that a product lowers risks substantially to individuals. While further research is needed, the toxicology and epidemiology of smokeless products and medicinal nicotine are well enough understood at present to be confident that these products are substantially less dangerous than cigarettes. For purposes of this argument, it is unnecessary to establish a precise estimate of risk and unnecessary to show that the product is absolutely 'safe.' This commentary focuses on two types of products to illustrate, snus and medicinal nicotine.

Snus reduces tobacco harm dramatically in comparison to cigarettes (Ramström, 2000; Henningfield & Fagerström, 2001). Rodu and Cole (1994, 1999) have presented evidence for substantial harm reduction from smokeless tobacco in general. Since about half of cigarette deaths arise from lung cancer and respiratory disease (English et al. 1995; Peto, Lopez, Boreham, Thun, & Heath, 1994) and since smokeless products are not otherwise more dangerous than cigarettes, smokeless tobacco products can be estimated to reduce mortality by at least half, because they do not cause lung cancer or respiratory disease. Snus is lower than other moist snuffs in known toxins (N-nitrosamines and polynuclear aromatic hydrocarbons) (see Ramström, 2000). There has been concern about smokeless tobacco and oral cancer. Noting the high rate of snus use in Sweden and citing five studies, the Institute of Medicine report stated, '[T]he use of snus in Sweden has generally not been associated with oral cavity cancer' (p. 428). The Institute of Medicine report also indicated, 'In a large population-based study looking at risk factors for squamous cancer of the head and neck, Lewin et al. (1998) found no increased risk with the use of Swedish snuff' (p. 301). There also are no secondhand smoke or fire risks from snus. The findings are mixed on whether snus contributes to cardiovascular disease (Ramström, 2000; Henningfield & Fagerström, 2001; Rodu & Cole, 1999). Snus is not safe, but, on the basis of toxicological principles (no smoke toxins from smoke exposure to the lungs) and current epidemiological knowledge, snus is significantly less dangerous to individual users than cigarettes.

Medicinal nicotine products (nicotine replacement therapies) such as gum, patch, nasal spray, and inhaler also are likely to be much less dangerous than cigarettes (Kozlowski, Strasser, Giovino, Erickson, & Terza, 2001). They deliver no smoke or tobacco toxins (except nicotine) to the user. Medicinal nicotine products have been judged to be so low in risk that some of the varieties are available as non-prescription pharmaceuticals in many countries around the world, including Australia, Austria, Brazil, Canada, Denmark, France, Spain, Sweden, Taiwan, and the United States (Corrao, Guindon, Sharma, & Shokoohi, 2000). On current epidemiological evidence, these products appear to reduce risk in comparison with cigarettes by close to 100% (Kozlowski, Strasser, Giovino et al., 2001). They have been demonstrated to carry little to no excess cardiovascular risk (Kimmel et al., 2001; Benowitz, & Gourlay, 1997), even in heart patients (Rennard, Daughton, & Windle, 1998), and no risks of oral cancer, lung cancer, or respiratory disease (Greenland et al., 1998). As much as five years use of medicinal nicotine in the Lung Health Study (Murray & Daniels, 1998) was unrelated to cardiovascular disease or other serious health effects. While greater, longer-term use of medicinal nicotine might reveal some increased to risk to health, it is not plausible to expect that such risks would ever come close to the dangers of cigarettes.

The Institute of Medicine report itself shows guarded support for this position: 'The committee also concludes that for persons addicted to nicotine, a nicotine-containing drug product is preferable to a cigarette or other tobacco-containing product as a chronic source of nicotine' (p. 227). The very next sentence in the report goes on, not to encourage such use, but rather to encourage that the Food and Drug Administration look into the matter: 'The FDA should therefore be prepared to consider the chronic administration of nicotine products as a reasonable exposure reduction strategy, again, if supported by valid clinical data' (p. 227).

Snus and medicinal nicotine are not safe or completely without risk. Both snus and medicinal nicotine may cause reproductive health problems and should be avoided during pregnancy, but these problems should still likely be less than for cigarettes (Benowitz, 1998; Stratton et al., 2001). Medicinal nicotine probably is somewhat less dangerous than snus, because medicinal nicotine lacks some of the tobacco toxins still present in snus, and because medicinal nicotine gives clearer evidence of low cardiovascular risk. However, for the present argument, it is not important to compare snus with medicinal nicotine, but it is critical to establish each as significantly less dangerous than cigarettes.

There are supposed harm reduction products that have been proved to not reduce harm to individuals. The lower-tar cigarette appears to not reduce toxic smoke delivered to smokers (Jarvis et al., 2001; Kozlowski & O'Connor, 2000; Kozlowski & O'Connor, 2001; National Cancer Institute, 1996; Benowitz et al. 1983) or mortality (Burns, Major, Shanks, & Thun, 2001). Newer cigarette-like products (Eclipse and Accord) at best make smaller changes in the product (smaller than snus or medicinal nicotine in comparison to cigarettes), and likely make concomitantly small changes, if any, in risk. Careful testing such as prescribed by the Institute of Medicine report would be needed to establish the magnitude, if any, of risk reduction from the products.

The human right to health-relevant information rises out of the principle of autonomy

Several ethical traditions (legal, medical, and public health) lead to a view that there is a human right to fair information relevant to health care. All traditions depend upon the principle of individual autonomy. Beauchamp and Childress (1994) argue that both Emmanuel Kant and John Stuart Mill helped establish the philosophical basis for valuing an individual's self worth and the individual's rights to determine goals. The Nuremberg Code (1949) and the United Nations Universal Declaration of Human Rights (1948) acknowledge a basic human right of autonomy. Legal traditions have also helped shape expectations about patient autonomy and patient rights to be informed of and consent to medical treatment (Wear, 1998). McCullough and Wear (1985) described a 'new ethos of patient autonomy' that has arisen in the face of benevolent but paternalistic ('doctor knows best') practices. Increasing governmental regulations on formal informed consent procedures and research have influenced the modern context in which patients deal with health care (Wear, 1998).

Public health ethics overlap with biomedical ethics but also have some distinctive emphases (Mann, 1999). Working in the public health field of family planning information, which can involve both one-on-one clinical encounters as well as diverse social sources of information, Freedman (1999) argued that censorship of information about reproductive and sexual health violates individual human rights. Freedman wrote: 'Women need and want reproductive health services because they want – and have – a fundamental human right to live lives that are free from unnecessary physical and mental suffering, and that permit the exercise of fundamental freedoms' (p. 147). Similarly, censoring information on genuine risk reductions to individual smokers restricts the ability of smokers to exercise their fundamental freedoms to make choices that can have dramatic effects on individual health risks.

In public health, benefit to the many can override the rights of the individual. Public health interests should prevail when there is low cost to the individual and high benefit to society (Annas, 1999). For an individual smoker who will not give up nicotine use, the benefits of snus or medicinal nicotine could be profound to the individual (and possibly to society), while the costs to society are far from clear and convincing.

Clear and convincing evidence needed to favor public health over individual health

In law there are three standards of evidence, in order of increasing stringency: (1) the *preponderance* of the evidence, where a conclusion is 'more likely than not' to be true; (2) *clear and convincing* evidence, producing firm belief or conviction; and (3) evidence *beyond a reasonable doubt*. Clear and convincing evidence has been required in court cases involving issues like quarantine, where an individual's rights are suspended to protect the public from the risk of spreading a serious disease (Annas, 1999).

Two principles have been emphasized in determining whether public health interests should override individual health interests: proportionality and probability. The limitation of rights 'must be proportional to the public health interest and its objective.' (International Federation of Red Cross and Red Crescent Societies and François-Xavier Bagnoud Center for Health and Human Rights 1999, p. 48); and 'The risks to the public must be probable, not merely speculative or remote.' (Gostin & Mann, 1999, p. 67).

The language of the prospects for adverse public health effects is decidedly tentative with little indication of adverse public health effects being either probable or proportional. The Institute of Medicine report (Stratton et al., 2001) notes: 'Both Pauly & colleagues (1995) and Hughes (1998) *raise the possibility* that the introduction

of PREPs and their promotion as less harmful ways to smoke *could* lead to increased initiation.' (Stratton et al., 2001, p. 73); and 'The major concern for public health is that tobacco users who might have otherwise quit will use PREPs instead, or others may initiate smoking, feeling that PREPs are safe. That will lead to less harm reduction for a population (as well as less risk reduction for that individual) than would occur without the PREP, and *possibly* to an adverse effect on the population' (Stratton et al., 2001, pp. 8–4; italics added.)

When risks from a product are relatively small, the level of increased use needed to maintain a public health equilibrium (no changes in population-level problems) becomes very high (Kozlowski, Strasser, Giovino, et al., 2001). The risk to individuals from medicinal nicotine seems to be so low that it is not possible for use to increase enough to cause a net public health loss: If risks from these often over-the-counter products are less than 0.1% (1 per 1000), then use would have to increase over 1000 times to cause an equal public health problem (Kozlowski, Strasser, Giovino, et al., 2001). For a product like snus, if the risk is even 1% that of cigarettes, use would have to increase 100 times to equal the problems from cigarettes. If the risk from snus were as much as 5% that of cigarettes, use would still have to increase an unlikely 20 times for the public health problems to equal those from cigarettes.

Other issues that might prevent public health advice

Are addicts in a position to freely choose?

To hold that adult nicotine addicts are too impaired by their addiction to give informed choice is not in keeping with prevailing legal traditions on competency. Nearly every individual is assumed to be competent to choose, unless proved otherwise (Wear, 1998).

Are any harm reduction products warranted?

At least one distinguished public health scientist has raised doubts about whether harm reduction products are needed at all (Pierce, 2000, p. 227). He stated that prevention and cessation programs should possibly be the sole focus of controlling smoking-caused disease. This position can be seen as an extreme form of neglecting the right of smokers to make informed choices. If complete abstinence is *not* the only way for an individual smoker to significantly reduce health risks from nicotine addiction, then the rights of smokers to be informed of this is still in opposition to an exclusive emphasis on prevention and cessation.

Should we provide advice in the absence of proper governmental regulation?

The failure of governments to establish any effective regulation of tobacco products can be seen as arguably the greatest failure of public health policy for the past 100 years. I have recently been in a meeting with several distinguished scientists and opinion leaders interested in smoking-related public policy and regulation. The majority of these individuals expressed an unwillingness to express any public opinion about would-be harm reduction products for tobacco, until such time as proper regulatory/evaluation systems were in place to unequivocally judge the degree of harm reduction afforded by the products as used by society. (This might be viewed as in keeping with the position of the Institute of Medicine report.) Clearly the best of all possible research has not yet been done on snus or medicinal nicotine, but, equally clearly, it is wrong to assume that we lack practical scientific bases for estimating that there will be harm reduction to individual smokers from these products. Though it is important to attain proper regulation over tobacco and harm reduction products, this goal is logically and ethically independent of the need to provide smokers today with what information we do have about the risks of various products.

Shouldn't manufacturers do their own promotion?

I have also heard colleagues say that manufacturers of these products don't need our help to promote their products. But that should not be justification for avoiding any positive comment or support for information that might reduce for individual smokers the harm from smoking. Note that the public health community has not similarly left all advice or encouragement about products–vaccines or seat belts or condoms (another harm reduction product) – to the manufacturers.

Public health approaches to informing smokers of harm reduction options

I am not primarily calling on the medical profession to talk with their noncompliant smoking patients about harm reduction. A broad-based model for public health interventions can be found in work on reproductive health. In the area of reproductive health and the right to information, it is argued that *comprehensive programming is needed to inform individuals* (Cohen, 1994). Such programs should include mass media advertising, message placements in TV programs, and systematic training of health professionals to discuss the needed information (Freedman, 1995).

Public health policies should be assessed for their affect on human rights

The late Jonathan Mann was a leader in calling for formal assessments of the impact of public health policies on human rights (Gostin & Mann, 1999; Mann et al., 1999). Figure 1 is derived from some of his work (Mann et al., 1999). The best policies are those that protect human rights as well as promote public health. Mann noted that it was a violation of human rights on the

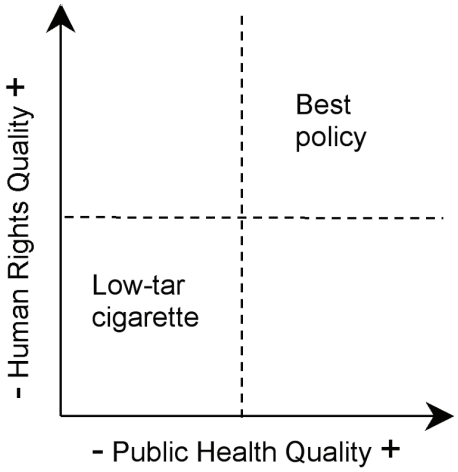

Figure 1. Schematic showing the interactive relationship between public health policy and human rights. The best policies are those that are consistent with human rights. Low-tar cigarettes are both poor public health policy and in violation of human rights to information.

part of governments to not provide honest information about the dangers of cigarettes (Mann et al., 1999). Low-tar cigarettes are designed to reassure smokers and keep them smoking (Kozlowski & Sweeney, 1997) but do not reduce health risks to smokers (Burns et al., 2001). This is both a violation of the human right to know and a counterproductive public health measure.

Cigarettes kill about half of those who smoke them (English et al., 1995; Peto et al., 1994; U.S. Department of Health and Human Services., 1989). It is urgent to inform smokers about options they have to reduce risk. This needs to be done in ways that inform smokers as fully as possible that never starting and complete quitting as soon as possible are the best choices to promote health, while also indicating that snus or medicinal nicotine (the latter more than the former) would be preferable to continued smoking. Also, complete substitution of these products should be encouraged over mixing them with continued smoking. The harm reduction message will be complex. There will be many ways to give it. Some will misinterpret even the most artfully framed message. Notwithstanding, public health policy in this instance lacks compelling justification to override the human rights of the individual. Individuals have the right to such health relevant information.

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