Review

Tobacco harm reduction: A call to address the ethical dilemmas

Brion J. Fox, Joanna E. Cohen

[Received 31 July 31, 2001; accepted 18 February 2002]

The 2001 Institute of Medicine report *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction* has helped to focus attention on the scientific basis for assessing tobacco harm reduction products. As the tobacco research and policy communities tackle the challenges of evaluating harm reduction, there are ethical issues that must also be addressed. There has, however, been very little writing on the ethics of this field. In an effort to spur research into answering these ethical questions, we present two complementary approaches. First we outline three overarching topics in tobacco harm reduction that would particularly lend themselves to study: (a) Is the pursuit of tobacco harm reduction an ethical goal? (b) What are the ethical considerations of tobacco harm reduction vis-à-vis pharmaceutical companies? and (c) What are the ethical considerations for harm reduction vis-à-vis tobacco companies? We then present one possible framework for analyzing the ethical issues that accompany particular tobacco harm reduction strategies. By considering the ethical dilemmas attendant to tobacco harm reduction in a prospective and thoughtful manner, we will be better prepared to handle the challenges that face us individually as researchers and collectively as a tobacco control community.

Introduction

In 2001, the Institute of Medicine published a report assessing the science base for tobacco harm reduction (Stratton, Shetty, Wallace, & Bondurant, 2001). In that report, the term *harm reduction* referred to strategies that lower tobacco-related mortality and morbidity even though there continues to be exposure to one or more tobacco-related toxicants. There are a wide variety of harm reduction strategies. Some of these strategies include using nicotine replacement therapies to reduce smoking, the development of ‘safer’ cigarettes, and the implementation of behavioral strategies to reduce the total number of cigarettes a person smokes. The Institute of Medicine report has helped spur the tobacco research and policy community to examine more closely the prospect of developing products and strategies for tobacco harm reduction. This effort comes bearing a myriad of challenges, including the scientific difficulties in developing and evaluating new products, the prospect that individual benefits may be outweighed by population harms, and the reality that many ideas may arise, and indeed may be encouraged to arise (Stratton et al., 2001), from the tobacco and pharmaceutical industries.

Some have argued that tobacco harm reduction strategies are inevitable because the tobacco and pharmaceutical industries are pursuing reduced risk products independently. This, however, merely abdicates responsibility for exploring whether a harm reduction approach is desirable. We in the tobacco control community have an obligation to make choices about our own behavior and to act as advisors to clinicians, consumers, policymakers, and other researchers. These roles are especially important when examining tobacco harm reduction because of the uncertain nature of the information and the possible unintended consequences of harm reduction strategies. As tobacco scientists and policymakers address these
challenges, it is imperative to confront head-on the ethical questions that they present. If we fail to examine these issues proactively, we may find ourselves reacting to potential dilemmas as individual moral actors, rather than defining as a community the standards to which we should hold research and researchers. By engaging in this dialogue early, we will be able to respond thoughtfully to many of the ethical challenges posed.

In the hope of provoking these discussions, we suggest below three topics that should be the focus of greater study as the tobacco control community evaluates the advantages and disadvantages of pursuing a harm reduction strategy: (a) Is the pursuit of tobacco harm reduction an ethical goal? (b) What are the ethical considerations of tobacco harm reduction vis-à-vis pharmaceutical companies? and (c) What are the ethical considerations for harm reduction vis-à-vis tobacco companies? Because of the overarching nature of these questions, they will not be answered quickly, nor should they be. These questions should be part of an ongoing dialogue and series of analyses that encompass the wide range of interests of the tobacco control community. Given, however, that there is an immediate need to understand some of the ethical implications of particular harm reduction strategies, we also present and discuss an ethical framework for analyzing proposed harm reduction strategies.

**Should the tobacco control community pursue tobacco harm reduction?**

As the Institute of Medicine report discusses, harm reduction strategies that have been adopted in fields other than tobacco control can provide analogies to possible tobacco harm reduction strategies. For example, improving the safety of automobiles is analogous to removing toxicants from tobacco smoke; providing clean needles through needle exchange programs is analogous to heating rather than burning tobacco products; and providing methadone to heroin addicts is analogous to providing long-term nicotine replacement therapy to people who are addicted to nicotine. In many cases, these harm reduction strategies were reported to be successful, although recently there has been growing criticism of a harm reduction approach (Erickson, 1999; Mangham, 2001; Mugford, 1992).

Part of the desire to pursue a tobacco harm reduction strategy is based upon the belief that we will be unable to achieve our health goals through current efforts to prevent and treat tobacco use. For example, it is believed that there remains a significant core of individuals who are unable to quit, are increasingly recalcitrant or otherwise impervious to the public health messages (e.g., Irvin & Brandon, 2000), and who would benefit from harm reduction strategies. In addition, even the most efficacious treatments or prevention programs will not reach all smokers. In fact, there is a core of smokers, often poorer, less educated, or suffering from a co-morbidity such as mental illness, that would disproportionately benefit from safer products. The difficult question, however, is whether efforts taken to reach hard core smokers will overshadow efforts that could help a larger number of smokers.

The recently published Public Health Service Clinical Practice Guideline *Treating Tobacco Use and Dependence* concluded, ‘There is insufficient evidence to support a recommendation regarding harm reduction strategies’ (Fiore et al., 2000). The Guideline describes numerous strategies and approaches for the effective treatment of tobacco dependence, and speaks of ‘optimism’ for a ‘promising era in the treatment of tobacco use and dependence’ (Fiore et al., 2000). The report identifies the failure to systematically implement the guideline recommendations as the key barrier to increasing quit rates; that is, it may be too soon to give up hope on treating the great majority of smokers. This is not because our tools are insufficient, but because we have been inadequate in adopting and applying the tools. This view was supported by the publication of a prevention priorities project that identified that adult tobacco cessation treatment was among the most effective, cost-effective, yet under-utilized prevention interventions (Coffield et al., 2001).

Similarly, the Centers for Disease Control and Prevention have identified Best Practices for states developing programs to reduce tobacco use (Centers for Disease Control and Prevention, 1999). The neglect of many states to fully fund programs to promote these best practices shows another failure to live up to the full promise of what we can accomplish in reducing tobacco use. Indeed, the U.S. Surgeon General has declared that a 50% reduction in youth and adult smoking could be achieved by applying what we already know (U.S. Department of Health and Human Services, 2000).

The concern is that if clinicians and public health professionals are encouraged to implement harm reduction strategies, it is possible that this would be done at the expense of delivering the cessation messages and developing the prevention programs that we know are effective. We fail not because current strategies are ineffective, but because of a lack of commitment to strategies that we know work. The conundrum thus posed is whether it is ethical to invest time, energy, and resources in the development and testing of new harm reduction strategies when strategies known to be effective have not been fully implemented. The challenge remains even if a private company introduces the harm reduction strategy—i.e., the tobacco control community will need to decide if it endorses or uses the product.

It is not as simple as saying that we can pursue all approaches simultaneously. One of the difficulties in persuading clinicians to provide treatment is the confounding nature of the multiple messages they receive. Similarly, it has been shown that with the advent of low tar and nicotine cigarettes, smokers used the lower-risk messages to continue their smoking behavior (National Cancer Institute, 2001). In assessing the potential value
of a harm reduction product, there must be some recognition that there will be a tradeoff for other public health efforts. On the other hand, there should also be a recognition that there is nothing foreseeable that suggests the current approaches will ‘solve’ the problem in the near future, and eventually some form of harm reduction product may be necessary.

What are the ethical considerations of harm reduction with regard to pharmaceutical companies?

Any consideration of pursuing or recognizing the legitimacy of tobacco harm reduction raises the specter of involvement with pharmaceutical companies. These companies currently market nicotine replacement products and non-nicotine therapies, such as bupropion SR. These agents have been approved for use as cessation devices in a number of countries, and have established the pharmaceutical companies as partners in the effort to promote tobacco cessation. In the future, these companies may seek to promote these or newly developed products as harm reduction products, which could put them at odds with the cessation community.

The participation of pharmaceutical companies in the debate on harm reduction raises challenging ethical issues. Despite the positive advances that have been made by the drug industry, they are private corporations driven by a profit motive. In the pursuit of harm reduction, this business ethic may conflict with a public health ethic. There are a number of ways that this conflict could be realized. For example, the development of competitive nicotine delivery devices that would replace cigarette smoking with long-term nicotine maintenance (Warner, Slade, & Sweanor, 1997) could subject the pharmaceutical companies to the criticism that they are simply replacing one addiction with another. Moreover, if the pharmaceutical industry produces new products that reduce harm but do not promote cessation, or market existing products as a complement to smoking that will reduce overall harm, the presumed beneficence of the industry may be lost.

There may also be ethical issues with respect to having researchers collaborate with pharmaceutical companies. These companies have an economic interest in the outcomes of studies they fund that may conflict with the independence that researchers desire. There is an association between positions that are favorable to the pharmaceutical industry and financial relationships of the authors with this industry (Stelfox, Chua, O’Rourke, & Detsky, 1998). There is evidence that proceedings from pharmaceutical-sponsored symposia tend to have misleading titles, to use brand names, and to not be peer reviewed (Bero, Galbraith, & Rennie, 1992). Further, many contracts between the pharmaceutical industry and investigators have unacceptable publication clauses, and a substantial number of articles that are published include authorship lists that do not meet accepted criteria for authorship (Bodenheimer, 2000). An uncomfortable reality is that pharmaceutical companies and, potentially, tobacco researchers who receive support from the pharmaceutical industry, could have a vested interest in the types of harm reduction strategies explored.

Recent efforts have addressed the publication of data from sponsored clinical trials (e.g., Davidoff et al., 2001) and have established guidelines for industry collaboration (Centers for Disease Control and Prevention, 1997). These efforts provide guidance as to how to conduct collaborations but do not discuss whether to pursue the collaboration in the first place. Moreover, because drug companies are able to invest great resources in the development of pharmaceutical products, they may be in a position to control the tobacco harm reduction research agenda. Drug-free harm reduction strategies, such as banning smoking in workplaces (Chapman et al., 1999; Evans, Farrelly, & Montgomery, 1999; Glasgow, Cummings, & Hyland, 1997), may get left out of any serious discussion of tobacco harm reduction.

A final difficulty is that, although it is possible to get public money to study pharmaceutical products, the majority of funds for clinical drug trials in the U.S. is provided by pharmaceutical companies. Academic medical centers are now receiving a minority of those funds, with for-profit contract-research and site-management organizations the favored providers of clinical trial services (Bodenheimer, 2000); thus, researchers who choose to pursue harm reduction products may be required to work with this industry.

What are the ethical considerations of harm reduction with regard to tobacco companies?

With respect to harm reduction, the greatest incentive for creating safer products may come from the tobacco industry itself. Many of the private lawsuits have been based upon a failure of the industry to create a safer product, misleading the public into thinking that a product is safe, or, in the case of public plaintiffs, to not pursue research into safer products. The industry thus has incentives, in the form of improved public relations and the avoidance of future litigation, to create a safer product. Any company that develops a safer product is also likely to have a significant market advantage over its competitors.

Furthermore, the tobacco companies may be best situated to understand the subtleties of nicotine delivery and the development of a safer cigarette. Indeed, there are many industry products that are already being tested or discussed. As a result of these factors, it is likely that the tobacco control community will face the prospect of having to assess a tobacco-industry-produced harm reduction product. This assessment may include direct collaboration in the development or testing of such a product, or responding to the presence of such a product in the market.

There are reasons that the tobacco control community may be cautious of such a collaboration. It is well established that the tobacco industry has perverted...
science for its own purposes by creating artificial controversy, attacking the reputation of tobacco control researchers, and filtering science through lawyers (Bero, Barnes, Hanauer, Slade, & Glantz, 1995; Saloojee & Dagli, 2000). Efforts by the tobacco industry to sponsor forums to discuss scientific issues or promote collaboration have been met with scorn and have been boycotted by many in tobacco control. Similarly, efforts to enlist reputable scientists to review or support the work funded by the industry have been met with derision (Gardiner, 2001).

Distrust of the industry runs so deep that many have argued that relationships with the tobacco industry are unacceptable (Shield, 2001), that universities should refuse money from the tobacco industry (Chapman & Shatenstein, 2001; Cohen, Ashley, Goldstein, Ferrence, & Brewster, 1999) and that journal editors should refuse to publish articles based on research sponsored by the tobacco industry (King, Yamey, & Smith, 2000). Even analyses of legal settlements with the industry have been described as ‘dealing with the Devil’ (Annas, 1997). One would be hard-pressed to find anything positive about the past behavior of the tobacco industry that would warrant faith in moving forward in collaboration with this industry, and many organizations have specific policies against collaboration with the tobacco industry (Cohen, 2001). It is feared that collaboration, complicity, or acquiescence of the public health community in tobacco industry efforts could result in increased credibility of the tobacco industry, making it harder to oppose industry efforts that are genuinely detrimental to the public health.

Given the innate distrust of the tobacco industry, researchers are likely to want to test independently any products developed by this industry. In addition, there will be an innate skepticism of industry motives; for example, is the industry using harm reduction as a means to increase the number of smokers, or to decrease the number of smokers who quit? This skepticism will also lead researchers to critically examine the broader implications of the proposed product. This independent testing may simply delay rather than answer certain ethical questions, because independent testing could result in confirming that the products meet the claims of the industry.

There are risks to rejecting potential future relationships with the tobacco industry. As the pharmaceutical companies bear the cost of testing their products, there is an argument that tobacco companies should bear the cost of testing their products. In addition, if science is built upon open discourse, censorship of the industry could marginalize the tobacco control community. To reject all future collaborations assumes that the industry is beyond redemption, which may be a faulty and risky assumption. For example, the industry’s reputation is extraordinarily low in the eyes of the public. The result of this has been a drive for regulation and litigation. If the industry changes and the tobacco control community is not prepared to deal with an industry that is not easily demonized, the tobacco control community may lose its own credibility.

Before initiating any collaboration with tobacco companies on harm reduction strategies or tools, thoughtful analyses will be needed to define the appropriate scope and nature of the associations. Ethical considerations will vary depending on the proximity of the funds to the tobacco industry and the level of restrictions on the use of the funds. For example, there seems to be a spectrum of funding risks from clearly inappropriate to acceptable that includes: the sponsorship of a researcher or student, the direct funding of a research project, the unrestricted funding to an institution, and the use of litigation settlement funds for research. Similarly, significant ethical consideration should be given to determine how the public health community should react to industry efforts even if there is no collaboration. Over time, these reactions may prove to be what changes the most, should the industry actually reform, even if, for the immediate future, skepticism is warranted.

A framework for analyzing tobacco harm reduction strategies

If the tobacco control community can answer the questions laid out above in a way that supports pursuing tobacco harm reduction, there will still be a need to examine the ethics of individual tobacco harm reduction strategies. We propose an ethical framework under which such strategies could be analyzed similar to frameworks produced in other contexts (see for example Kass, 2001). An ethical framework will not predetermine answers to all ethical questions, nor will it guarantee that any two parties using the framework will arrive at the same outcome. What it can assist with is a rigorous analysis of the relevant questions that can then lead to an increased understanding of the principles at stake. Such a framework could also assist in the development of analyses and standards for scientific conduct, and the development of future research questions.

Ethicists have generally agreed upon a series of cross-cutting principles that can serve as the basis for a framework for analysis. Among these principles are: beneficence – the principle of doing good; nonmaleficence – the principle of not doing harm; self-determination – the principle of allowing individuals to make their own decisions; and justice – the principle of fairness (Beauchamp & Steinbock, 1999). These principles also serve as the basis for many of the ethical theories, including utilitarian, Kantian, and communitarian theories (Beauchamp & Steinbock, 1999). For our framework we have chosen to use a utilitarian approach, which evaluates and balances the likely benefits and burdens of the proposed strategy. This balancing should be done in such a manner that it takes into account the cross-cutting ethical principles as they come to bear on the underlying question. The framework that follows will account for many of the ethical questions raised earlier in this paper.
What are the proposed benefits?

A proposed tobacco harm reduction strategy should be analyzed for its probable real world benefits and should be examined for efficacy and for effectiveness. Furthermore, care should be taken to understand the true penetration of the proposed strategy into the market. For example, promoting nicotine replacement products as a part of a harm reduction strategy could fail if the products are not used or are used incorrectly. Similarly, new products will have limited effect if they are not purchased and used by consumers because of inadequate taste or nicotine delivery. Where evidence is suggestive of a strong potential benefit, one should not necessarily withhold the strategy in favor of scientific certainty, but it should be coupled with specific research questions to be able to promote the long-term analysis of the proposed strategy.

A primary difficulty in assessing effectiveness is that the time for scientific discovery is lengthy, and the net epidemiologic effects of new products cannot be known for years. On the one hand, too cautious a stance may discourage the development of new products that are potentially effective in reducing at least some of the risks of smoking. On the other hand, proposed tobacco harm reduction strategies should result in more good than harm, and not simply substitute harms. For example, much has been written about the failure of low tar cigarettes as a harm reduction approach. Initially these products were seen as potentially beneficial for health because they were supposed to deliver lower levels of tar. In the end, however, these products were determined to be no better than conventional products because of the innate hazards of tobacco products and how smokers actually used the product, which offset much of the benefit that could have been realized. Although an ethical analysis of low tar cigarettes may not have prevented the mistakes which occurred, a thorough ethical discussion could have identified the risks and tradeoffs that were being made, and promoted research to assist in evaluating the potential risks versus the potential benefits.

What are the possible harms?

Even if a particular harm reduction strategy suggests great promise, it must be scrutinized for the potential burdens that accompany it. These burdens could be inherent in the product or the result of replacing one risk with another. An historical example of this kind of burden would be the original Kent micronite filter, which was found to have high levels of crocidolite asbestos fibers (Longo, Rigler, & Slade, 1995).

Burdens could also arise from secondary consequences accompanying the harm reduction product. For example, by creating a safer product there could be a reduced incentive to quit smoking or avoid initiation. Therefore, a presumed-safer product could have the perverse effect of creating a greater population-wide harm if prevalence is increased. The overarching issues related to opportunity costs discussed above are especially appropriate to this part of the framework. Similarly, certain types of products may remove other motivations to quit or maintain abstinence. For example, a product that reduces or eliminates second-hand smoke could remove the incentive for individuals to quit in order to protect those around them. It could also serve to remove incentives for employers, home-owners, or policymakers to promote smoke-free environments.

Other burdens may be more regulatory in nature. If a product is developed that escapes definition as a cigarette, it may avoid taxation, advertising restrictions, and so forth. Although the solution could be regulatory, such an outcome should be considered in an ethical analysis.

Just as the proposed benefits are to some degree speculative, the proposed burdens will also be a matter of some prognostication; nevertheless, efforts should be made to understand the likely harms as well as the gaps in research that need to be filled to explain the true nature of the burden. For example, a better understanding of how individuals process risk messages is important to understanding the probable impact a reduced risk product may have on prevalence rates. In addition, research such as that published recently by Kozlowski and colleagues (Kozlowski, Strasser, Giovino, Erickson, & Terza, 2001), which provides a model for how one can balance the reduction in risk of a harm-reducing product against the increased use of that product, can assist in the calculation of the scope of the burden.

Would the possible benefits and harms be distributed across the population equitably?

Even if a product appears on balance to be beneficial, with the probable risks outweighing the burdens, the proposed product should be analyzed for its implications for social justice. If there exists a truly beneficial product that significantly reduces the risk of disease related to smoking, but that product is expensive, there arises a social justice question. What mechanisms are in place, or need to be put in place, to make a safer product accessible to all who might need it? This opens an additional set of problems, however. If no mechanism exists, should the product be abandoned even if such an action would prohibit benefit to those who could afford it? Conversely, it would be awkward at best for the tobacco control community to argue for increased availability of a tobacco product, albeit a reduced-risk one.

There also could be cultural or other barriers to products that may create a social disparity. For example, smokeless tobacco, which may be considered a reduced-harm product, is almost exclusively used by males. The answers to these and comparable social justice questions lie outside the scope of this paper; nevertheless, at a minimum an examination of these questions should be made prior to the endorsement of a particular tobacco harm reduction strategy.
What additional benefits and risks accompany the proposed strategy because of the involvement of private industry?

A further level of scrutiny that a proposed harm reduction product or strategy should undergo is whether the development or promotion of the product involves the pharmaceutical or tobacco industries. In addition to the industry analyses proposed above, one must make transparent any biases or conflicts of interest that could arise due to industry involvement.

The mere existence of a bias may not be deleterious, but the proposed analysis would require the disclosure of all potential biases. Financial disclosures are clearly the most apparent and have found their way into the requirements for peer review publications and general researcher behavior. However, biases can also be experientially based. For example, as discussed above, the inherent mistrust of the tobacco industry and its motives runs deep, which itself may cause one to prejudge a product from the industry. These biases should also be disclosed when endorsing or criticizing a tobacco harm reduction strategy.

An example of how industry involvement could create an ethical dilemma can be seen in the following hypothetical situation. How should the tobacco control community react if essentially identical reduced-risk products arise out of both the pharmaceutical and tobacco industries? If the products otherwise pass ethical muster, the tobacco control community may choose to support the pharmaceutical company product because of the historical burdens that are associated with the tobacco industry. Alternatively, the tobacco control community may shy away from endorsing the pharmaceutical company product because of an appearance of impropriety if this company had funded tobacco control programs or researchers. Silence could result in a slowing of the dissemination of the proposed product. Whichever solution individuals choose to follow, their biases should be disclosed.

Discussion

One potential interpretation of this commentary is that the tobacco control community should operate under a single set of ethics. We are not advocating either for or against this proposition, and we believe this idea should be thoughtfully examined prior to any recommendation. One of the strengths of tobacco-related research is that it represents the coming together of a range of disciplines and perspectives. It is possible that the forced homogeneity of a single set of ethics could eliminate some of the diversity we currently enjoy.

If we examine the most basic sources of principle that exist in our discipline, we can see how the issues conflict as much as they overlap. Clinicians who operate under the medical model, treating disease one patient at a time, could value a harm reduction strategy that benefits an individual much more than do public health professionals who are trying to address population-based problems. Indeed, one could argue that a failure to prescribe a harm reduction product to a particular patient who could benefit from its use could be seen as a violation of a biomedical ethic. Alternatively, one could see that public health workers could consider it unethical to support a harm reduction product that had a negative effect on the overall population. Similarly, non-profit organizations may be driven by a mission to improve health of all people, whereas for profit corporations are, by definition, responsible for maximizing profits for their shareholders. If a commercially viable and individually-beneficial harm reduction product was available but nevertheless had a negative net population-based effect, one could not expect private corporations to shy away from that product, nor is it ethically clear that they should.

Our position is simply stated: Individuals should, prior to adopting a stance on a particular harm reduction strategy, conduct a rigorous ethical analysis such as that presented in this paper. Moreover, to best protect the interests of researchers and policymakers, we urge that ethical studies be embraced as a necessary part of any larger commitment to pursue harm reduction. These studies should involve thoughtful analyses of the issues from a variety of perspectives, including biomedical, public health, corporate, legal, and policy. We have presented but one approach for determining the appropriateness of harm reduction strategies. We hope that it stimulates discussion and encourages others to improve upon the framework.

Acknowledgments and disclosures

Preparation of this manuscript by the first author was supported, in part, by the Robert Wood Johnson Foundation program Developing Leadership in Reducing Substance Abuse. Dr. Cohen received funding from the Canadian Institute of Health Research. The authors would like to thank Stella Aguinaga Bialous, Mary Jane Ashley, Roberta Ferrence, Pam Kaufman, and Kenneth Warner for their helpful comments on earlier drafts of this manuscript.

References


