

Preventing Sin

THE ETHICS OF VACCINES AGAINST SMOKING

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Advances in immunotherapy are paving the way toward vaccines that target unhealthy behaviors, such as a vaccine that blocks the action of nicotine, reducing the pleasure caused by smoking. Such a tool could prove to be an effective tool for preventing children from taking up smoking. Would it be permissible?

The alarming rates of smoking, obesity, and substance abuse pose an enormous challenge for parents and public health officials: how do we prevent children and adolescents from adopting unhealthy behaviors? Legal age limits, high taxes on nicotine products, and advertising restrictions are the primary methods used to discourage tobacco abuse by minors, but dismal statistics show that these methods are woefully inadequate. About 85 percent of current smokers in the United States began smoking before the age of twenty-one,¹ and 23 percent of high school students are current tobacco users.² Most school-based programs, as well as media and community interventions, appear to have limited effectiveness in preventing smoking and reducing prevalence rates among children and adolescents.³ There is therefore a clear need to develop additional strategies.

One new option that may soon be available is the use of nicotine vaccines. Immunological therapies to help smokers stop smoking have shown promise in phase I and II trials; similar therapies could combat smoking addiction before it starts.⁴ Nicotine vaccines are distinctive because they confer protection not against infection—the normal target for vaccines—but against enticing pleasures that lead to unhealthy behaviors. As a result, using them preventively in children would be likely to arouse some novel ethical concerns that should be addressed before the vaccines become commonly available and their off-label use as a preventive measure becomes a real option.

In this paper, we consider whether it would be ethical for parents to vaccinate their children against smoking if a nicotine vaccine were to be proven effective as a preventive intervention for children or adolescents. We begin by explaining the current state of nicotine vaccine science and suggesting some likely ethical concerns about allowing parents to have their children receive a vaccine. We then present a

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preliminary argument for making vaccination permissible, at least if nicotine vaccination substantially reduces the probability that someone subsequently becomes a smoker. We consider a series of possible ethical objections, which are useful for identifying the conditions under which it would be ethical for parents to vaccinate their children against smoking. We conclude that it would be permissible for parents to give their child a nicotine vaccine if the following conditions were met: the vaccine is expected to result in a net benefit to each individual vaccinated, the expected harms from the side effects of the vaccine are lower than the nonvoluntary harms caused by smoking, and there are no other, less manipulative methods available that are as effective at preventing smoking initiation.⁵

This paper focuses on the permissibility of parents vaccinating their children against smoking, but we close by considering what further data and conceptual analysis would be required in order to determine whether a state-mandated vaccination campaign would be legitimate, and we sketch how our framework might apply to other interventions used to prevent children from adopting unhealthy behaviors.

Our standard for parental decision-making is conservative. We assume that parents should generally act in their children's interests, unless there are pressing moral reasons to do otherwise. People who believe that parents have greater discretion in their decision-making should therefore also endorse our conclusion that vaccinating children against smoking is permissible, although they might also consider it permissible in some further circumstances where the above conditions are not met.

The Science of Nicotine Vaccines

Like vaccines against infectious diseases, such as tuberculosis or

measles, nicotine vaccines induce an immunological response. When injected into the body, the vaccine—a complex of nicotine, carrier protein, and adjuvant—triggers the production of “antinicotine” antibodies that bind to nicotine molecules in the bloodstream. If a vaccinated individual smokes, an antibody-nicotine complex forms that is too large to cross the blood-brain barrier and the nicotine molecules cannot reach stimulatory receptors in the brain. The vaccine thereby eliminates, or greatly reduces, the pleasurable sensation associated with smoking, which prevents the individual from experiencing the rewarding or reinforcing effects of nicotine that fuel addiction.⁶

Three candidate nicotine vaccines are currently being developed and tested: NicVAX (by Nabi Biopharmaceuticals, now merged with Biota), CYT002-NicQb (by CytosBiotechnology AG), and TA-NIC (by Xenova/Celtic). All three have completed phase I and II testing to show efficacy, identify side effects, and establish appropriate dosage. Phase III trials are under way for NicVAX, and two have been completed. Research has not yet been conducted to study the side effects of these vaccines in people who have never been exposed to nicotine. No testing has yet been conducted with children or adolescents.⁷

Phase II studies testing NicVAX found that 33 percent of vaccinated smoking subjects with high-level antibodies were abstinent after thirty days, compared with 9 percent of nonvaccinated smoking subjects.⁸ According to a press release, a statistically significant number of subjects treated with the NicVAX optimal dose were able to quit smoking and remain abstinent over a twelve-month period: 16 percent of NicVAX recipients achieved twelve-month continuous abstinence compared to 6 percent receiving placebo.⁹ However, the results of the completed Phase III studies were disappointing: they did not show a significant difference

between the vaccinated group and placebo on the primary endpoint.¹⁰ Phase I and II studies of NicQb found that 42 percent of vaccinated subjects who maintained sufficiently high antibody levels were able to quit smoking after twelve months, compared with 21 percent of subjects on placebo (who received only behavioral smoking cessation counseling).¹¹ A study testing the safety and efficacy of TA-NIC found that 38 percent of vaccinated subjects quit at twelve months, compared with 8 percent on placebo.¹² These results suggest that nicotine vaccines could eventually be effective antismoking tools.¹³ A randomized, controlled trial is underway to delineate the long-term efficacy of NicVAX in combination with varenicline.¹⁴

The vaccines currently being developed use the technique of active immunization as a treatment strategy for nicotine-dependent individuals, and they have been tested for their therapeutic effects in helping chronic smokers quit. However, some researchers have speculated about using a vaccine as a preventive in minors who do not smoke or who are experimenting with nicotine products.¹⁵ Children and adolescents may be engaging in smoking initiation but are generally not yet combating addiction, whereas highly addicted individuals may still find satisfaction in smoking despite the vaccine's physiological effects. Employing a vaccine for prophylactic purposes in children and adolescents who are not yet nicotine-dependent might therefore be a highly effective strategy in cutting smoking incidence at the national level.¹⁶

Ethical Concerns

Suppose that we have a vaccine with proven effectiveness. When given to children or adolescents, it predictably and substantially reduces the probability that they will smoke during their lives. Such a vaccine could yield great public health benefits.

However, unlike vaccines for dangerous infectious diseases like measles or polio, which are generally objected to only on the grounds of side effects, a nicotine vaccine would raise wider ethical concerns. First, some people might object that smoking is not like the infectious diseases that other vaccines protect against, since it is not wholly bad. No one would choose to get polio, but many people enjoy smoking. Second, one might argue that people who start smoking are responsible for doing so and are also responsible for continuing. Again, this is unlike contracting most infectious diseases. Vaccinating children would therefore involve putting them at risk of side effects in order to prevent harms for which they would have been responsible. Finally, one might object that preventing someone from engaging in an unhealthy behavior is an unacceptable interference with her freedom.

Each of these objections merits consideration. But in each case, we argue, either the objection does not apply or the benefits to a child of receiving a nicotine vaccine are likely to be great enough to override it. Nonetheless, the objections do provide insight into the conditions that should be met in order for the administration of a nicotine vaccine to be ethically permissible.

The Health and Economic Benefits of a Nicotine Vaccine

The practice of allowing parents to vaccinate their children against smoking cannot be justified simply by showing that the total benefits to society of permitting vaccination would outweigh the costs. This would leave open the possibility that some children would predictably be made worse off by vaccination and thereby sacrificed for the greater social good. All else being equal, it is wrong to inflict a harm on someone without her permission. Children, at least when young, are unable to consent to being harmed. Hence, in order to justify vaccinating their child,

parents should be confident that she is likely to be better off vaccinated than not—that is, there should be an expected net benefit for each child.¹⁷

Each day in the United States, about 3,900 young people between the ages of twelve and seventeen years smoke their first cigarette, and an estimated 1,000 middle and high-school students become daily cigarette smokers.¹⁸ The negative health effects of smoking are well established. In the United States, tobacco dependence is the primary cause of 30 percent of all cancer deaths and nearly 80 percent of deaths from chronic obstructive pulmonary disease.¹⁹ Compared to nonsmokers, smokers are at significantly increased risk for coronary heart disease, cerebrovascular disease, depression, substance abuse, and malnutrition.²⁰

A nicotine vaccine would have a substantial positive impact on welfare, and the side effect profile seems likely to be quite mild.

Smoking is expensive, too. In 2006, U.S. consumers spent an estimated \$90 billion on tobacco products. Smoking also has significant economic repercussions through increased health care costs and lost productivity due to absenteeism. From 2000 to 2004, cigarette smoking cost the U.S. economy more than \$193 billion (\$97 billion in lost productivity plus \$96 billion in health care expenditures).²¹ According to the Milken Institute, reducing the current national rate of smoking from 22 percent to 15 percent would generate savings of \$30 billion in health care treatment costs and \$80 billion in lost productivity.²² In sum, smokers are at much greater risk for health problems compared to nonsmokers, spend a lot of money to maintain their habit, and miss more days of work due to ill health.²³

Given the serious costs of smoking, it follows that the vaccine would have a substantial positive impact on welfare. In this respect, at least,

receiving a nicotine vaccine during childhood would yield a prospect of substantial benefits to an individual, by preventing harms that she might otherwise experience.²⁴

The expected health benefits from vaccinating a child must be weighed against any negative impacts on health. The most important of these are side effects. The current nicotine vaccines have undergone phase I and II testing in adults and have been generally well tolerated in smokers. The most common side effects observed with these vaccines were short-lived “flu-like symptoms” (fever, headache, chills) and pain at the injection site.²⁵ There may also be other long-term side effects that will become apparent when a sufficiently large and varied number of people have received the vaccine (that is, in phase IV testing).

Research has not yet been conducted to study the vaccines’ side effects in children or adolescents.²⁶

Although we cannot rule out the possibility of more severe side effects, on the basis of what we know, the side effect profile of nicotine vaccines seems likely to be quite mild. The side effects noted above are no more severe than those of vaccines that are already routinely administered to children, which include low-grade fever, soreness, redness or swelling at the injection site, temporary headache, dizziness, fatigue, fussiness, and loss of appetite.²⁷ Moreover, the vaccines’ mechanism of action suggests that their side effects are likely to be relatively benign: because a nicotine vaccine targets nicotine molecules rather than biological processes in the central nervous system, fewer side effects are expected than for immunological therapies that target brain processes.²⁸

On the assumption that a nicotine vaccine substantially reduces the

probability that someone becomes a smoker, and given the current probability that a child in the United States will grow up to be a smoker, the expected harms prevented by vaccination are likely to be far greater than those that it would cause. The economic costs of smoking also weigh in favor of vaccination. These considerations provide a powerful provisional (*pro tanto*) case in favor of permitting parents to vaccinate their children against smoking.

First Objection: Smoking and Pleasure

Vaccinating one's child against smoking would provide her with expected net health and economic benefits, but these are not the only components of welfare. Smoking is associated with many subjectively valued goods, including pleasurable physiological effects (such as a smoking high, stress reduction, and appetite suppression) and nonphysiological effects (such as projecting a desired image and the sociological benefits of being part of a group unified by a characteristic behavior). One could therefore argue that the welfare of a child or the adult she becomes might be diminished if a vaccine stopped her from experiencing these goods.

Regarding the physiological effects, we accept that a nicotine vaccine would cut a child off from access to certain pleasures. But although it might reduce the *range* of pleasures she could experience, being unable to access these would be unlikely to substantially reduce the total pleasure she experienced. First, for many sources of pleasure, there are reasonable alternative ways to attain similar pleasures. A life lacking peanuts, for example, need not be one with fewer pleasures, for the joy of cracking shells and chewing salty snacks can be obtained with pistachios. Likewise, the pleasure of satisfying an addictive craving could be satisfied through a more benign substance (like coffee), the pleasure of keeping one's mouth

actively satisfied through chewing gum, and so forth. Only if no such alternative sources of pleasure were available should we accept that a life without smoking would contain less pleasure.

Second, although the physical effects of nicotine would not be experienced by a vaccinated child, the nonphysiological goods associated with smoking could still be achieved. The child or future adult would be able to engage in the *act* of smoking, and therefore capable of maintaining the perceived image, status, or sociological benefits associated with this behavior. It just would not be as fun.

Smokers might respond that there are no alternative activities that could really substitute for the role smoking plays in their lives. An ex-smoker may still miss smoking, despite the activities he uses to try to substitute for it. However, even if such a response were successful, it would not apply to the case we are considering. For children and adolescents who are not yet smokers, smoking has not yet attained an irreplaceable position in their lives. Preventing them from experiencing the pleasure of smoking therefore would not reduce the total pleasure they experience in the same way.

Given the health and economic benefits of not smoking, and the possibility that vaccinated individuals could find alternative ways to experience many of the goods that smoking confers, we conclude that being vaccinated against smoking would still provide a substantial expected benefit to each vaccinated child.

Second Objection: Harm and Personal Responsibility

Justifying vaccinating one's child against smoking is not just a matter of weighing the expected harms and benefits to her of vaccination against those of refraining from vaccination. In the case of a nicotine vaccine, we appear to be balancing the risks of an involuntary intervention (a child being vaccinated) against the risks of a

voluntary behavior (an adult smoking). Imagine someone who was vaccinated but would never have smoked anyway. She might argue that being a nonsmoker was not a matter of luck, but a result of the sensible choices she made. Conversely, she might argue, those people who would now smoke if they had not been vaccinated would be responsible for their smoking and so for the risks to health it poses: either they could have decided against smoking when they started or they could have given it up as young adults. Vaccination against smoking, she might argue, therefore constitutes unacceptable paternalism.

We think this objection has real force: putting people at risk to prevent some of them from engaging in dangerous behaviors is not the same as putting them at risk to prevent some of them from experiencing wholly involuntary harms. There do not seem to be clear precedents for doing this, and so even though we intuitively think that it must be permissible to put people at *some* risk to save them from their later voluntary actions, we do not have an argument to convince someone who does not find this intuitive and insists on the priority of individual liberty and the inviolability of persons. Fortunately, we do not need to make such an argument. At least some children start smoking before they are fully autonomous.²⁹ Others start smoking under pressure, such that the decision to start is not fully voluntary. And some of the harms caused by smokers are the result of secondhand smoke, for which the person harmed is not responsible. As long as these nonvoluntary harms outweigh the harms caused by nicotine vaccination, vaccinating children can still be justified, whatever one's position on personal responsibility. Given the very low level of side effects, we think that this condition is easily met. If all (or very nearly all) of the harmful effects of smoking were voluntarily self-inflicted by autonomous individuals, then the case in favor of vaccination would be undermined.

Third Objection: Freedom

Thus far, we have evaluated the ethics of smoking vaccines only in terms of their impact on welfare. But the real ethical concern that people have about these vaccines is more likely to lie in the way that they would allow parents to interfere with their children's lives, especially the lives they might choose to lead as adults. This is a concern about freedom.

A nicotine vaccine might inappropriately infringe on a child's freedom if it restricted her liberty or if it disrespected her autonomy, and it might disrespect her autonomy by undermining her capacity for autonomous choice, not respecting her choices, or illegitimately controlling her choices. In our view, however, only the last is a genuine risk of a nicotine vaccine.

Liberty. Most people think that having a range of choices is valuable even though they cannot pursue every available option. It is better, for example, to have a range of career options than just one possible career, even if I end up only pursuing one. This is the value of liberty.³⁰ It might be thought that vaccinating a child against smoking is unethical because it reduces the number of life-options open to her and therefore undermines her liberty.

Two points may be made in response to this objection. First, it is not clear that being vaccinated against smoking would reduce the number of options someone has available to her. It would change her experience of those options, and thereby make one of them less appealing than it might have been, but the options would still remain. Second, suppose it were true that vaccinating a child against smoking would reduce the number of options open to her during her life. It does not follow that this reduction in liberty is ethically problematic. Imagine an Anglophone parent who is torn between sending his daughter to a French immersion school at a distance from her home or sending her to the English-speaking school nearby. If he wants to spend

more time at home with his daughter and so chooses the local school, he may make it very hard for her to become fluent in a second language. But most people would agree that he acts permissibly. If it is permissible for a parent to remove a good option (such as speaking a second language fluently), then surely it is permissible for a parent to remove a potentially bad option (to smoke, with its attendant negative health consequences).

Autonomy. To be autonomous is to have the capacity to reason about one's values and to make decisions on the basis of one's reasoning.³¹ Everyone has a duty to respect the autonomy of others, which primarily involves not interfering with its exercise. Parents also have a duty to nurture the development of auton-

By affecting a child's future desires without appealing to her reason, a nicotine vaccine would allow her parents to manipulate her behavior far into the future.

omy in their children.³² Autonomy is violated when an individual's capacity to reason about her options is undermined, when the choices she makes are not respected, or when someone illegitimately controls which choices she makes.³³

A nicotine vaccine would not interfere with someone's capacity to reason about her options, nor would it mean that her future choices about smoking would be disregarded. The vaccinated individual would retain the ability to choose whether to smoke; she would simply weigh her options differently, since the experience of smoking would be different for her than for an unvaccinated person. Likewise, there is no reason to think that changing the way she experienced smoking would affect her ability to reason.³⁴

Indeed, a nicotine vaccine might enhance autonomy in certain ways. The extent to which addicted smokers have control over their smoking behavior is disputed. But the fact that

addicts continue to smoke against their better judgment certainly suggests that addiction may undermine autonomy.³⁵ A nicotine vaccine would allow people to more easily follow through with decisions about whether to smoke that were consistent with their values.

Self-determination. Even if a person has a sufficient number of good options open to her and she is autonomous—is capable, that is, of reasoning and making decisions on the basis of her values—her freedom will still be inappropriately infringed upon if she does not actually get to make choices for herself because she is coerced or manipulated.

Roughly speaking, coercion occurs when one person controls the actions of another through physical force or

by threatening to make her worse off if she does not comply with the demands of the coercive agent.³⁶ Manipulation occurs when one person noncoercively controls the action of another in a way that undermines her ability to make an autonomous decision about what to do.³⁷ The manipulator accomplishes this by engineering a situation—through deception, direct modification of the manipulated person's options, or by playing on features of her psychology—to make it more difficult for her *not* to do as the manipulator wishes. Manipulation may be contrasted with persuasion—*influence that has its effect solely by appealing to reasons for action that are believed to be genuine.*³⁸ Persuasion is ethically unproblematic.

There is an obvious sense in which coercing or manipulating someone into receiving a vaccination is ethically problematic. However, a nicotine vaccine is not significantly different in this respect from any other vaccination or medical procedure that a

child may undergo. Because the nicotine vaccine targets *behavior*, however, there is likely to be ethical concern not just about the administration of the vaccine but also about its effects. By affecting a child's future desires without appealing to her reason, a nicotine vaccine would allow her parents to manipulate her behavior far into the future.

Manipulation is morally problematic insofar as it violates respect for autonomy. By controlling the individual's choice situation to achieve her own end, the manipulator fails to treat the person manipulated as a rational being who is able to choose for herself what ends to pursue and how to pursue them.³⁹ Other strategies to influence behavior or beliefs, such as persuasion or transparent offers (that is, offers whose terms are known to all parties involved), are morally permissible because they respect the agent's freedom to set her own ends and to determine for herself how to achieve those ends. All else being equal, manipulation becomes more problematic in proportion to the extent to which it controls the manipulee. Thus, for example, influencing a single choice through manipulation is less disrespectful of autonomy than changing the values that a person uses to make her choices.

It is possible to wrong someone through manipulation only if she is capable of acting on reasons, since the wrong derives from the value of autonomy. It might therefore be thought that a nicotine vaccine could not be manipulative, since children are not autonomous.⁴⁰ However, autonomy (and so the ability to act on reasons) develops over time. Research into the cognitive development of adolescents, for example, suggests that many are capable of autonomous decision-making in at least some contexts. Between the ages of twelve and fifteen, adolescents develop key formal cognitive structures that enable them "to reason hypothetically and independently on concrete states of affairs."⁴¹ In addition to developing the cognitive capacity

to make decisions and exercise control, adolescents construct a personal identity and develop a sense of individuation.⁴² These facts suggest that there is at least some duty to respect the developing autonomy of older children and adolescents, even if it is not as stringent as the duty to respect the autonomy of competent adults.

The fact that an act is manipulative does not entail that it is impermissible. Parents frequently manipulate their children in order to encourage them to act as they ought. Trying to make healthy behaviors seem "cool," for example, is usually an attempt at manipulation (albeit one that frequently backfires). This suggests that manipulation of one's children in the service of good ends is often permissible, all things considered, even if manipulation is wrong when we consider it in and of itself.

A balance must therefore be struck. The benefits of vaccination must be sufficiently great that they outweigh the wrong of manipulation. Since the manipulation of one's children is often permissible, even when the manipulation attempts to change the palette with which a child makes her decisions, the benefit required to outweigh the wrong of manipulation is not so large; it is likely that the benefit of preventing one's child from smoking will meet this threshold. But if manipulation can be avoided, then it should be. First, it would be better to use alternative behavioral modification strategies that appeal to reason, such as educational campaigns, if they are sufficiently effective. The statistics on the prevention of smoking cited at the beginning of this paper suggest that there is currently no sufficiently effective alternative. Though, for example, some educational strategies may have some effect, their widespread use would still not render the provision of a nicotine vaccine otiose. Second, since younger children generally have less developed autonomy, they are less at risk of being manipulated. This suggests that it is also preferable to vaccinate children young rather than as adolescents, all

else being equal.⁴³ Finally, some older children will be capable of participating in decision-making about medical treatment. Parents who are willing to countenance an informed refusal of vaccination could avoid the manipulation involved by including their children in discussions about whether to be vaccinated against smoking.

The Duration of Immunity

Recent research suggests that the efficacy of nicotine vaccines is strongly correlated with the level of antibodies available to sequester nicotine.⁴⁴ This suggests that booster shots may be necessary to maintain high enough levels of antibodies to effectively curb the pleasurable effects of nicotine and prevent smoking initiation.

Our previous arguments indicate that giving nicotine vaccines to some children is morally fraught because of the problem of manipulation. Consequently, even if vaccinating them were permissible, all things considered, an alternative that involved a less manipulative intervention would be preferable. A vaccine requiring booster shots might provide such an alternative. The vaccine could be given to a child when she was not fully autonomous. However, once she reached an age at which she was competent to make decisions for herself, she could decide whether to continue to receive the booster shots. This arrangement would give her more control over her life than a permanent vaccine.

Two potential downsides would also have to be addressed. First, each time a child got vaccinated, there would be a risk of harmful side effects. More vaccinations will tend to lead to more side effects. Second, the behavioral effects of receiving a temporary vaccine against smoking are unknown. It is at least possible that people who were initially vaccinated as children but then declined the booster shots would be more likely to take up smoking. The specific features of the nicotine vaccine

in question would need to be known in order to draw detailed conclusions about the ethics of its delivery. However, this discussion does suggest the interesting conclusion that a temporary vaccine might be ethically more desirable than a permanent one.

May We Vaccinate Our Children against Smoking?

Our responses to the objections we have canvassed against allowing parents to vaccinate their children against smoking imply that vaccinating one's child would be permissible under certain conditions. First, the vaccine would need to be sufficiently effective. Only if it was expected to result in a net benefit (or reduction in harm) to each individual vaccinated could we avoid the charge that it might unjustifiably harm some children. Second, the side effects of the vaccine should be low enough that they would be outweighed even by the nonvoluntary harms of smoking. Third, there should be no alternative, less manipulative interventions that would have the same effect. For example, if there were educational strategies that were equally effective, then they ought to be used instead of a vaccine.

These are conservative conditions; people who have more permissive views about risking harm to children for the sake of a gain in public health, or who believe that it is permissible to impose a risk of harm on someone in order to prevent her from harming herself, would probably endorse weaker constraints. However, if the vaccines now being developed turn out to be effective in preventing smoking initiation, and if they have a side effect profile like the one we described, we believe they would meet even the strong conditions we have laid out.

The argument so far also highlights two other ethically relevant considerations, although neither of them is a constraint on the permissibility of administering nicotine vaccines. First, there is a balance to

be struck between minimizing manipulation and involving children in decision-making. Younger children are less vulnerable to being manipulated because their autonomy is not as developed. This is a reason to vaccinate children while younger. Older children have more developed autonomy, and so if parents are willing to countenance refusal of vaccination, they can involve them in the decision about vaccination. Second, if there is a choice between a permanent and a temporary vaccine, it will respect

Since the manipulation of one's children is often permissible, the benefit required to outweigh the wrong of manipulation is not so large.

people's right to self-determination more if children are given a temporary vaccine. This does not mean that a permanent vaccine would be impermissible, however, and there might be other considerations that favor such a vaccine of which we are currently unaware.

A State-Mandated Vaccination Campaign

We have argued that it would be permissible for parents to vaccinate their children against smoking if certain conditions were met. We have so far said nothing about whether it would be permissible for the state to do the same. But if it were permissible for parents, one might ask, why wouldn't it be permissible for the state? State mandates for vaccinations against infectious diseases, such as diphtheria, polio, and measles, are widely accepted. In the United States, all states mandate certain vaccinations for children as a condition of school entry. Moreover, such a program for smoking vaccination would be likely to reach many children who are at risk of beginning to smoke, but whose parents would not otherwise vaccinate them.

However, the fact that it would be permissible to vaccinate one's own child does not entail that it would be permissible for the state to require it; further conditions would have to be met. Space does not permit a comprehensive ethical analysis of a state-mandated smoking vaccination program in this paper. Here we just indicate some of the additional considerations that are relevant to the ethics of a state mandate and identify areas where more normative analysis is required.

One of the key differences between justifying parental action in the interests of their child and justifying state action is the degree of discretion that each is allowed. We accord considerable freedom to parents to decide how they will spend their money, once basic duties like meeting their child's needs have been fulfilled. It may therefore be permissible for individual parents to decide whether they want to spend their money on vaccinating their child against smoking or to spend it on something else. They may have the option to obtain the vaccine even if it is very expensive. However, the same does not apply to government decisions. If the government is paying for vaccinations, then it must show that they are cost-effective relative to other measures that it might take to reduce the prevalence of smoking or alternative social goals on which to spend tax revenue.⁴⁵ If the government requires other parties, like parents or insurance companies, to pay for vaccination, then it must still justify imposing that cost on others in terms of its relative benefit to public health.⁴⁶

State interference in the decisions of individuals or families is generally held to a high standard of justification. In their discussion of

human papillomavirus vaccination mandates, Gail Javitt and colleagues analyze two legal conditions that must be met before a vaccine may be mandated by a state, and which they believe HPV vaccination fails to meet.⁴⁷ These conditions are instructive for the case of smoking vaccines. First, vaccination must be a “public health necessity,” which means that the condition prevented must be “associated with significant morbidity and mortality occurring *shortly after* exposure.”⁴⁸ Second, there must be a “reasonable relationship” between the government’s intervention and the public health objective.⁴⁹ Significant argument would be needed to show that a particular smoking vaccine fitted these conditions.

In terms of necessity, the dangers to a child are not pressing in the same way as the serious diseases of childhood that other compulsory vaccinations target. The harms to a child of her smoking are distant and mediated by many opportunities to reduce or prevent them. Likewise, despite the harms of secondhand smoke and the “contagious” nature of the habit, smoking does not pose an imminent and pressing risk to others. A proponent of governmental intervention would also have to show that there were no alternative effective strategies that would have an equally powerful effect on smoking prevalence but would be less intrusive. Whereas parents are generally unable to affect social determinants of smoking, such as how cigarettes are advertised or priced, this is not true of the state. Similarly, parents will not be able to stop their child from injuring others through secondhand smoke, but the state, through legislation restricting smoking in public places, can. Given the correlation between socioeconomic status and smoking behaviors in developed countries, one might argue that the state should focus on the root causes of unhealthy behaviors rather than on their effects.⁵⁰ Again, this is not a choice that parents have to face.

Finally, there are a number of important and unresolved questions about the relationship between children, parents, and the state that would be relevant to working out the details of a vaccine mandate. Parents are generally granted some liberty to make health care decisions on their child’s behalf. This liberty has limits—for example, it is generally agreed that parents may not refuse a lifesaving blood transfusion on their child’s behalf—but the contours of those limits in less extreme cases have not been well articulated. In the United States, all states mandate certain vaccines for children as a condition of school entry, but all except Mississippi and West Virginia permit parents to exempt their children from this requirement on the basis of religious or personal beliefs.⁵¹ Even if some sort of vaccination requirement were justified, it would be necessary to work out what the legitimate penalties would be for parents who refused to comply, as well as whether and under what conditions they would be permitted to opt out.

Thus, in order to justify a state-mandated smoking vaccination program, it is not sufficient to show that parents would be permitted to vaccinate children with a particular vaccine. First, more data would be needed in order to show that the vaccine was cost-effective. Second, several other conditions would have to be met, including showing that there are not less intrusive government actions that would meet the same objective. Third, a number of disputed questions concerning the relationship between children, parents, and the state would need to be resolved in order to determine the conditions of any mandate.

Lessons for Other Behavioral Interventions

Smoking is not the only unhealthy habit our children may develop. Poor diet, alcohol abuse, and the misuse of legal and illegal drugs are all serious public health problems rooted

in behavior. Attempts to address these problems frequently target children; for example, U.S. states have tried numerous strategies to combat poor eating habits and drug use among children, including educational campaigns, local “wellness” policies, randomized drug screenings, and bans on junk food in schools.⁵² Chemical interventions against some unhealthy behaviors are possible, too. For example, there have been a number of attempts to develop long-lasting implants of drugs such as Disulfiram (Antabuse) and naltrexone that are used to treat alcoholism,⁵³ and vaccines against cocaine are in development.⁵⁴ Aspects of our analysis could also apply to these interventions. For each it would be necessary to assess the expected harm reduction to each individual from the intervention, weigh this against the benefits that the intervention might cause someone to forgo, ensure that the side effects of the intervention were low enough that they were outweighed by the nonvoluntary harms of the behavior, minimize manipulation, and show that there were no alternative, morally preferable prevention strategies.

Consider, as an illustration, a fictional vaccine against alcohol use. Suppose that inoculating one’s child substantially reduces the probability of her developing alcoholism because it induces nausea and vomiting when an individual consumes alcoholic beverages. Would it be permissible for parents to vaccinate their children against alcohol use?

Approximately 79,000 deaths are attributable to excessive alcohol use each year in the United States, making it the third leading lifestyle-related cause of death for the country. Immediate risks associated with excessive alcohol use include unintentional injuries such as automobile accidents, violence, child abuse or neglect, risky sexual behaviors, physical and mental birth defects, and alcohol poisoning. The long-term risks associated with excessive alcohol use include liver disease (alcoholic hepatitis, cirrhosis),

neurological impairments, cardiovascular problems, psychiatric problems (depression, anxiety, and suicide), and social problems (unemployment, lost productivity, and family problems).⁵⁵ Alcohol is also the most commonly used and abused drug among American youth, more so than tobacco and illicit drugs. Adolescents and young adults between the ages of twelve and twenty drink 11 percent of all alcohol consumed in the United States.⁵⁶ In 2008, there were approximately 190,000 emergency room visits by underage drinkers for injuries and other conditions linked to alcohol. In children and adolescents, alcohol consumption is associated with poor performance in school, social and legal problems, unplanned and unprotected sexual activity, physical and sexual assault, increased risk for suicide, poor brain development, and unintentional injuries.⁵⁷ Vaccination would be expected to reduce these negative consequences.

Let us assume, for the sake of argument, that the side effects of the vaccine are as low as the side effects of other routine childhood immunizations, and that children are vaccinated at an age that minimizes their manipulation while still getting the preventive effect. Given the extent of alcoholism and alcohol abuse even in countries with extensive educational campaigns, legal restrictions on alcohol purchasing and consumption, and high alcohol taxes, it would appear that there may not be alternative, morally preferable prevention strategies for parents to use.

However, the costs of alcohol consumption are not as great as those of smoking, and the benefits are much higher. First, the majority of people who drink are not alcoholics, and the net health risks and benefits of moderate drinking are difficult to calculate: while alcohol consumption is linked with increased risk of various cancers and other health problems, it may reduce the probability of heart disease and stroke.⁵⁸ Unlike cigarette smoking, drinking in moderation therefore may not pose absolute risks

to health. Thus, for most people, an alcohol vaccine would risk interfering with freely chosen pleasurable activities without providing clear net health benefits.

Second, the consumption of alcoholic drinks is an integral part of several cultural practices in Western countries. Consider the traditional glass of wine drunk on the Jewish Sabbath or the sip of wine taken in a Catholic Mass. In a nonreligious setting, bars are considered a traditional place for socializing. There are a number of distinctive pleasures commonly associated with drinking, communal activities that involve it, and a sense of inclusion for those who partake. In some communities, the benefits associated with alcohol consumption may be difficult to replace. The very fact that many Western parents introduce their children to alcoholic drinks but very few introduce them to smoking indicates that they consider drinking an acceptable choice for their children, but not smoking. These considerations suggest that an alcohol vaccine would likely not result in an expected net benefit to each individual vaccinated. Moreover, since most of the harms to self caused by alcohol are the result of voluntary actions, the expected harms from the side effects of the vaccine might not be lower than the expected nonvoluntary harms of alcohol use. Consequently, given our conservative views about what parents may permissibly do to their children, we would judge it unethical for parents to inoculate their children with an alcohol vaccine with permanent effects.⁵⁹

Of necessity, this is only a sketch. It indicates how our ethical framework could be applied to a different chemical intervention to prevent children from developing an unhealthy behavior, and how the resulting ethical analysis is sensitive to the details of the intervention and the behavior in question. The conclusion that parents could permissibly give their child an effective, low-risk smoking vaccine does not imply that all and any preventive interventions can be justified

on the basis of possible future harms to the child.

Disclaimer

The opinions expressed are the authors' own. They do not reflect any position or policy of the National Institutes of Health, U.S. Public Health Service, or Department of Health and Human Services.

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4. R.A. Bevins, J.L. Wilkinson, and S.D. Sanderson, "Vaccines to Combat Smoking," *Expert Opinion Biological Therapies* 8, no. 4 (2008): 379–83; W.D. Hall, "Will Nicotine Genetics and a Nicotine Vaccine Prevent Cigarette Smoking and Smoking-Related Disease?" *PLoS Medicine* 2, no. 9 (2005): e266.
5. In their brief treatment of the ethics of vaccinating children against smoking, Andreas Hasman and Søren Holm are ambivalent. They conclude: "It is therefore arguable that active nicotine vaccination is at the cusp of infringing the right to an open future, and that vaccination of

children is not ethically unproblematic"; A. Hasman and S. Holm, "Nicotine Conjugate Vaccine: Is There a Right To a Smoking Future?" *Journal of Medical Ethics* 30 (2004): 344-45. The framework we develop here allows a much more precise conclusion to be drawn concerning whether and when vaccination would be permissible.

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7. Bevins, Wilkinson, and Sanderson, "Vaccines to Combat Smoking."

8. High antinicotinic response was defined as the response found in the top 30 percent of antibody responders (61 of the 201 subjects receiving the drug). See D.K. Hatsukami et al., "Safety and Immunogenicity of a Nicotine Conjugate Vaccine in Current Smokers," *Clinical Pharmacology and Therapeutics* 78, no. 5 (2005): 456-67.

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12. C. McNeil, "Nicotine Vaccines Move toward Pivotal Trials," *Journal of the National Cancer Institute* 98, no. 5 (2006): 301.

13. Tobias Raupach and colleagues summarize the state of nicotine vaccine research and conclude that "these vaccines could one day become part of a multifaceted approach to treating tobacco-addiction that includes counselling and pharmacotherapy"; T. Raupach, P.H.J. Hoogsteder, and C.P. van Schayk, "Nicotine Vaccines to Assist with Smoking Cessation: Current Status of Research," *Drugs* 72, no. 4 (2012): e1-e16.

14. P. Hoogsteder et al., "The Efficacy and Safety of a Nicotine Conjugate Vaccine (NicVAX) or Placebo Co-Administered with Varnicline (Champix) for Smoking Cessation: Study Protocol of a Phase IIb,

Double Blind, Randomized, Placebo controlled Trial," *BMC Public Health* 12 (2012): 1052.

15. Bevins, Wilkinson, and Sanderson, "Vaccines to Combat Smoking," 382.

16. Vacci and Chiang, "Vaccines against Nicotine," 512.

17. Sometimes, harming someone or putting her at risk of harm without her permission may be acceptable. This may be true when the harm is very low and the benefit very great. It would also be true according to utilitarian views that reject the moderate deontological assumptions of this paper and guide decisions strictly by the net benefits or harms of an action or policy. Here, we set such cases aside. We think that the use of a smoking vaccine can be justified without considering exceptions to the prohibition on harm, and we are interested in whether vaccinating children against smoking can be permissible even on our conservative standard for parental decision-making.

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21. U.S. Department of Agriculture Economic Research Service, "Table 21: Expenditures for Tobacco Products and Disposable Personal Income, 1989–2006," January 2008, <http://www.ers.usda.gov/Briefing/Archive/tobacco/>.

22. R. DeVol and A. Bedroussian, *An Unhealthy America: The Economic Burden of Chronic Disease* (Santa Monica, Calif.: Milken Institute, 2007), http://www.milkeninstitute.org/pdf/chronic_disease_report.pdf.

23. Centers for Disease Control and Prevention, "Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000–2004," *Morbidity and Mortality Weekly Report* 57, no. 45 (2008): 1226-28.

24. A vaccinated child is not the only individual who would benefit from an effective vaccine. A vaccine against smoking also confers health and economic benefits to others who are involuntarily exposed to the harmful effects of smoking. The negative health effects of secondhand smoke are well established (U.S. Department of Health and Human Services, "How Tobacco Smoke Causes Disease," 363). A nicotine vaccine that would help to prevent the spread of smoking in certain populations could reduce the harm of secondhand smoke to others. Aside from secondhand smoke, preventing individuals from smoking would confer benefits to others within the same social network since smoking behavior is socially transmitted; N.A. Christakis and J.H. Fowler, "The Collective Dynamics of Smoking in a Large Social Network," *New England Journal of Medicine* 358 (2008): 2249-58.

25. Cornuz et al., "A Vaccine against Nicotine for Smoking Cessation"; Maurer et al., "A Therapeutic Vaccine for Nicotine Dependence."

26. Bevins, Wilkinson, and Sanderson, "Vaccines to Combat Smoking," 382.

27. U.S. Department of Health and Human Services, "Parents' Guide to Childhood Vaccinations," March 2012, <http://www.cdc.gov/vaccines/pubs/parents-guide/default.htm>.

28. Bevins, Wilkinson, and Sanderson, "Vaccines to Combat Smoking," 380.

29. In a 2010 nationwide survey of U.S. high school students, 6.2 percent of eighth graders reported having tried their first cigarette by fifth grade; L.D. Johnston et al., *Monitoring the Future: National Survey Results on Drug Use, 1975–2010*, vol. 1, *Secondary School Students* (Ann Arbor, Mich.: Institute for Social Research, University of Michigan, 2011), 279.

30. Exactly how to specify this value is controversial. One must decide whether the number of options is important or whether, after a certain number, additional options do not add to the value of liberty, and one must decide whether all types of options are valuable, or only good or desirable options. Our argument does not require that we commit to a view on exactly how to specify the value of liberty.

31. Gerald Dworkin defines autonomy as follows: "autonomy is conceived of as a second-order capacity of persons to reflect critically upon their first-order preferences, desires, wishes, and so forth and the capacity to accept or attempt to change these in light of higher-order preferences and values. By exercising such a capacity, persons define their nature, give meaning and coherence to their lives, and take responsibility for the kind of person they are." G. Dworkin, *The Theory and Practice of Autonomy*

(Cambridge, U.K.: Cambridge University Press, 1988), 20.

32. T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics*, 6th ed., (New York: Oxford University Press, 2009), 99; M.J. Zimmer-Gembeck and W.A. Collins, "Autonomy Development During Adolescence," in *Blackwell Handbook of Adolescence*, ed. G.R. Adams and M.D. Berzonsky (Malden, Mass.: Blackwell Publishing, 2008), 174-204; V.F. Reyna and F. Farley, "Risk and Rationality in Adolescent Decision Making: Implications for Theory, Practice, and Public Policy," *Psychological Science in the Public Interest* 7, no. 1 (2006): 1-44.

33. S. Buss, "Valuing Autonomy and Respecting Persons: Manipulation, Seduction, and the Basis of Moral Constraints," *Ethics* 115 (2005): 195-235.

34. Another sense of autonomy is also sometimes found in the bioethics literature. Someone is autonomous in this sense insofar as she is the author of her own life, rather than being the creation of someone else. As a result, shaping someone's values and preferences without her permission may be regarded as ethically troubling. However, parents shape the values and preferences of their children in all sorts of ways, both deliberately and accidentally, through the behavior they model, their communication with their children, and the experiences to which they expose them. As long as this influence does not harm the children, prevent them from pursuing a satisfying life, or inhibit the development of their capacity for self-reflection (autonomy in our first sense), it is generally accepted. Changing one's child's future preferences regarding smoking does not seem to have any of these effects, and it is, in any case, a relatively small influence on a child's character in comparison to the effects parents may have on their child's religious or political views, for example. See J. Feinberg, "The Child's Right to an Open Future," in *Whose Child?* ed. W. Aiken and H. LaFollette (Totowa, N.J.: Rowman and Littlefield, 1980), pp. 124-53.

35. R. Scragg et al., "Diminished Autonomy over Tobacco Can Appear with the First Cigarettes," *Addictive Behaviors* 33, no. 5 (2008): 689-98; J.A. Savageau, P.D. Mowery, and J.R. DiFranza, "Symptoms of Diminished Autonomy over Cigarettes with Non-Daily Use," *International Journal of Environmental Research and Public Health* 6, no. 1 (2009): 25-35; C.A. Doubeni, G. Reed, and J.R. DiFranza, "Early Course of Nicotine Dependence in Adolescent Smokers," *Pediatrics* 125, no. 6 (2010): 1127-33.

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440-72. An alternative account defines it in terms of a threat to violate someone's rights; A. Wertheimer, *Coercion* (Princeton, N.J.: Princeton University Press, 1987).

37. For an analysis of manipulation, see A. Mandava and J. Millum, "Manipulation in the Enrollment of Research Participants," *Hastings Center Report* 43, no. 2 (2013): 38-47.

38. R.R. Faden and T.L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), 259.

39. P. Greenspan, "The Problem with Manipulation," *American Philosophical Quarterly* 40 (2003): 155-64.

40. J. Rudinow, "Manipulation," *Ethics* 88 (1978): 338-47, at 339.

41. J. Piaget, "Intellectual Evolution from Adolescence to Adulthood," *Human Development* 51 (2008): 40-47.

42. C.C. Helwig, "The Development of Personal Autonomy throughout Cultures," *Cognitive Development* 21 (2006): 458-73.

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44. Vocci and Chiang, "Vaccines against Nicotine," 510; Cornuz, "A Vaccine against Nicotine for Smoking Cessation."

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47. *Ibid.*, 388-90, citing *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905).

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58. M.A. Collins et al., "Alcohol in Moderation, Cardioprotection, and Neuroprotection: Epidemiological Considerations and Mechanistic Studies," *Alcoholism: Clinical and Experimental Research* 33 (2009): 206-219; L.R. Harriss et al., "Alcohol Consumption and Cardiovascular Mortality Accounting for Possible Misclassification of Intake: 11-Year Follow-up of the Melbourne Collaborative Cohort Study," *Addiction* 102, no. 10 (2007): 1574-85.

59. There would remain the interesting question whether parents should be permitted to use a temporary chemical intervention to prevent their children from drinking while underage. A temporary intervention would involve less manipulation, but would also have much lower benefits to the child, since many of the dangers of alcohol use occur later in life.