Contested Boundaries: Evaluating Institutional and Government Authority in Academia and Public Health

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Contested Boundaries: Evaluating Institutional and Government Authority in Academia and Public Health

A dissertation presented by

Stephanie Morain

to
The Committee on Higher Degrees in Health Policy

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Abstract

This dissertation explores tensions between individual freedom and institutional authority. Chapter one examines public perceptions of the legitimacy of "new frontier" public health measures. I present results from a national survey of 1,817 adults concerning the acceptability of public health interventions for noncommunicable diseases. We found that support for these interventions is high overall; strongly associated with race and political orientation; and tied to perceptions of democratic representation in policy making. There was much support for strategies that enable people to exercise healthful choices, but considerably less for more coercive measures. These findings suggest that the least coercive path will be the smoothest. Additionally, the findings underscore the need for policy makers to involve the public in decision making, understand the public's values, and communicate how policy decisions reflect this understanding.

Chapter two provides a normative analysis of the legitimacy of public health efforts to address noncommunicable disease. I argue that we should move away from the harm principle as the basis for assessing the legitimacy of public health measures, and introduce John Rawls's legitimacy principle as an alternative framework by which to assess the state's moral authority to enact these new measures. I suggest that the legitimacy principle better frames the relevant

liberty interests at issue in questions of public health policy, and may offer a more robust protection for individual liberty than does the Millian harm principle.

Chapter three examines institutional approaches to the oversight of faculty-industry consulting relationships within academic medical centers. I report on a Delphi study to elicit medical school administrators' views about the oversight of such relationships. We found strong support for two oversight strategies: providing educational resources to faculty regarding consulting relationships with industry, and policies that would bring consulting agreements under institutional review. Finally, respondents opposed the use of categorical prohibitions on consulting relationships with specific industries, recommending instead that agreements be evaluated based upon the specific activities of the relationship rather than upon the type of industry. We conclude with specific recommendations for medical schools for the management of faculty-industry consulting relationships.

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Introduction

[The police power is] vested in the legislature by the constitution, to make, ordain and establish all manner of wholesome and reasonable laws.., either with penalties or without...as they shall judge to be for the good and welfare of the commonwealth, and of the subjects of the same.

It is much easier to perceive and realize the existence and sources of this power, than to mark its boundaries, or prescribe limits to its exercise.
--Chief Justice Shaw[1]

In May 2012, New York City Mayor Michael Bloomberg announced his plans for a far-reaching ban on the sale of large sodas and other sugary drinks across the city. Under the measure, food service establishments would be prevented from selling sugary drinks in containers larger than 16 ounces. With this ambitious effort, New York City reinforced its status as an aggressive promoter of public health initiatives, a trend-setter whose public health initiatives have frequently become models for other cities, including calorie posting requirements, restrictions on trans fats, and bans on smoking in both indoor and outdoor public spaces.

The rationale of the city's proposal is perhaps best captured by the statement of Deputy Mayor Gibbs, who offered the following commentary in support of the proposed rule:

> Obesity is an illness that is slowly, painfully destroying health and taking lives. Over time, our environment has been increasingly working against us. People move less and eat more, portion sizes have grown, and sugary beverages—full of empty calories—have grown exponentially and nearly 6,000 New Yorkers are now dying each year of obesity related illness. The question rightly became not: how dare the government intervene, but how dare the government fail to intervene?

While the City's approach found strong resonance among public health advocates, the support was far from universal. To opponents, the measure represented yet another example of

the nanny state run amok. The ensuing debate revealed deep tensions over the balance of individualism, self-determination, and personal responsibility against countervailing themes of human interconnection and social obligation.

This tension invokes broad themes at the heart of an ongoing debate within political discourse over the proper scope of criminal law and other forms of social coercion: What is the appropriate balance between individual autonomy and institutional control? What reasons might justify the control of personal behavior that, despite having impacts for others, is commonly viewed as self-regarding? Who has the right to require individuals to modify their behavior, and under what circumstances?

In this dissertation, I examine these questions, with a search for the appropriate balance between individual authority and institutional control. Each of the three chapters in this dissertation addresses a normative or empirical question central to determining the appropriate balance between self-regulation and external control. In Chapters 1 and 2, I explore the appropriate scope of government regulation in the name of promoting public health. The central question motivating this research is that of legitimacy: how extensive is the moral authority of the government to protect and promote the health of the public? In Chapter 3, I explore the balance between self-regulation and external control in the academic setting, with a focus on institutional oversight of faculty consulting agreements.

The question of legitimacy can be examined through two different lenses. The first is as a descriptive concept, referring to people's beliefs about political authority. In this approach, first set forth by Max Weber,[2] legitimacy is understood to be a function of the willingness of members of a society to assume the benefits and burdens associated with membership. In the domain of public health, a public health activity is legitimate if the public perceives it to be an

appropriate use of government authority, and therefore feel an obligation to comply with its demands.

Descriptive legitimacy has important practical implications for public health agencies. Understanding the public's perceptions of legitimacy can inform critical policy decisions regarding both the target of interventions, as well as their scope. This understanding can support efforts to obtain and maintain legitimacy of public health departments. Obtaining and maintaining legitimacy is critically important because it affects both the public's willingness to support and comply with public health interventions; and the likelihood that public backlash will undermine their effectiveness. The question of descriptive legitimacy, therefore, strikes at the heart of the ability of public health to effectively address non-communicable disease.

The second lens through which to consider legitimacy is as a normative concept. Under this view, legitimacy is related to the justification of authority. Normative legitimacy concerns the proper extent and limit of the state's authority or legislative power. The inquiry of normative legitimacy is a search to define the acceptability of political institutions and their resultant use of political authority. In a constitutional democratic society like the United States, the state itself is generally assumed to be legitimate. The focus is therefore on the legitimacy of the state's use of coercive authority, or the types of public policies that the state may adopt.

In Chapter 1, I explore the descriptive legitimacy of public health authority. In joint work with Michelle Mello, I examine public perceptions of the legitimacy of "new frontier" public health measures, such as those targeted towards obesity, diabetes, and other noncommunicable diseases. I present results from a national survey of 1,817 adults concerning the acceptability of these "new frontier" public health interventions. We found that support for these interventions is high overall; strongly associated with race and political orientation; and

tied to perceptions of democratic representation in policy making. There was much support for strategies that enable people to exercise healthful choices—for example, menu labeling and improving access to nicotine patches—but considerably less for more coercive measures, such as insurance premium surcharges. These findings suggest that the least coercive path will be the smoothest and that support for interventions may be widespread among different social groups. In addition, the findings underscore the need for policy makers to involve the public in decision making, understand the public's values, and communicate how policy decisions reflect this understanding.

In Chapter 2, I turn to the question of normative legitimacy, examining the legitimacy of public health efforts to address noncommunicable disease. Within the field of public health ethics, the question of public health legitimacy has focused upon the Millian harm principle. I challenge the appropriateness of the harm principle to determine the legitimacy of public health policies to address noncommunicable disease. I argue that we should move away from the harm principle as the basis for assessing the legitimacy of public health measures, and introduce John Rawls's legitimacy principle as an alternative framework by which to assess the state's moral authority to enact these new measures. I suggest that the legitimacy principle better frames the relevant liberty interests at issue in questions of public health policy, and may offer a more robust protection for individual liberty than does the harm principle.

In Chapter 3, I extend this inquiry into the proper scope of authority to a new setting: academic institutions. In this chapter, I examine the scope of institutional authority over faculty in medical schools and their affiliated institutions, with a focus on institutional approaches to the oversight of faculty consulting relationships within academic medical centers.

While the ethical issues surrounding financial conflicts of interest have been well-documented, far less attention has been paid to the legal aspects of consulting activities. Of particular interest include the consulting agreements, or contracts, that govern faculty-industry interactions. I report on a Delphi study (joint work with Steve Joffe, Eric Campbell, and Michelle Mello) of medical school administrators with expertise in the management of faculty consulting agreements. Our primary purpose was to evaluate potential approaches for the oversight of such agreements so as to provide guidance for the management of faculty-industry consulting relationships by medical school faculty. Through the Delphi process, we characterize shared norms regarding the acceptability of contract provisions, best practices for the management of consulting relationships, and the permissibility of faculty relationships with specific industries. We found broad agreement among panelists regarding the importance of institutional review to protect the interests of medical schools and their broader institutions. In examining specific strategies for oversight, we found strong support for two approaches: providing educational resources to faculty regarding consulting relationships with industry, and policies that would bring consulting agreements under institutional review. While respondents supported a review mechanism for the evaluation of individual contracts, the panel was divided as to both the feasibility and desirability of mandatory as opposed to optional review. Finally, respondents opposed the use of categorical prohibitions on consulting relationships with specific industries, recommending instead that agreements be evaluated based upon the specific activities of the relationship rather than upon the type of industry. We conclude with specific recommendations for medical schools for the management of faculty-industry consulting relationships.

[1] *Commonwealth v Alger*, 61 Mass (7 Cush) 53, 85 (1851).

[2] Weber M. Economy and society. Eds. Guenther Roth and Claus Wittich. Berkeley: University of California Press; 1968.

CHAPTER 1

Legal Strategies to Prevent Noncommunicable Disease: Public Views, and Why They Matter

1.1 INTRODUCTION

The increasing burden of noncommunicable diseases is one of the greatest challenges currently facing American public health. Although infectious diseases continue to pose a threat to the nation's health, their relative burden has been dwarfed by that of noncommunicable illnesses, particularly diseases associated with modifiable risk factors such as overeating, physical inactivity, and alcohol and tobacco use. Consequently, there is increasing interest in using law and policy to influence these behavioral risk factors.

From a public health perspective, the mandate for population-level interventions is clear. In 2000 the three leading causes of death in the United States were tobacco use (contributing to 18.1 percent of all deaths), poor diet and physical inactivity (16.6 percent of deaths), and alcohol consumption (3.5 percent of deaths).[3] The economic impact of health conditions related to these risk factors is also staggering.[4,5]

Many health departments and legislative bodies in the United States have adopted policies that apply both traditional and more innovative public health tools to combat tobacco use, obesity, heart disease, diabetes, and other chronic health conditions.[6,7,8] Examples include hemoglobin A1c surveillance programs to track the level of blood sugar control in people with diabetes, bans on the use of trans fat to reduce people's intake of particularly harmful fats, increased taxation of cigarettes, and school-based body mass index screenings to identify obese

and overweight children.

These initiatives have provoked intense political and moral debates. The initiatives are part of the "new frontier" of public health law[9]—historically, relatively few legal interventions have focused on behaviors to prevent noncommunicable diseases, and new initiatives venture into new and controversial terrain. Critics assert that legal initiatives to combat obesity and other chronic health conditions unduly restrict individuals' liberties and exceed the appropriate scope of governmental authority in public health.[10,11]

The controversy calls into question the public's willingness to view as legitimate uses of the power of the state any new-frontier interventions that attempt to use the law to prevent noncommunicable disease by influencing personal health behaviors. Securing and maintaining moral and legal authority from the public for health officials to address a problem such as a noncommunicable disease and its behavioral underpinnings is critically important because that authority affects people's willingness to support and comply with public policies.[12,13] Compliance with such interventions, in turn, is a critical determinant of the extent to which the policies will achieve their objectives.

Previous studies have not examined whether there is a relationship between legitimacy and compliance concerning public health laws. In other areas, although the evidence is somewhat mixed, studies have found legitimacy to be associated with an increased likelihood of compliance government regulations,[14] taxes,[15] and enlistment,[16] as well as an increased willingness to defer to legal authorities such as the police and courts.[17]

To date, public health agencies have moved through the contested territory of noncommunicable disease control without the benefit of a solid understanding of how the public views these initiatives. Prior research suggests that factors such as public trust and perceptions of

government competence influence support for infectious disease control measures[18] and that educational attainment and sex predict a person's support for some policies to address obesity.[19] However, no studies have examined predictors of support for new-frontier public health initiatives across a range of noncommunicable health conditions.

In this article, we present results from a national survey of US adults concerning the acceptability of public health legal interventions addressing noncommunicable diseases. We found that support for new-frontier public health interventions is high overall, strongly associated with race and political orientation, and tied to perceptions of democratic representation in public health policy making. Our findings can help lawmakers as they consider what level of support they can expect for new-frontier public health initiatives, why support may be forthcoming, and from whom.

1.2 STUDY QUESTIONS

We investigated four sets of questions. First, how do Americans perceive the performance of public health officials and agencies, both generally and in specific domains?

Second, what are the public's attitudes toward new-frontier public health initiatives, and how do these attitudes compare to perceptions of traditional public health activities? Because *legitimacy* could have various meanings, our survey asked respondents how much they would support or oppose various government initiatives. We examined levels of support for government action on seven noncommunicable health conditions and fourteen specific strategies to address them.

Third, does support for new-frontier public health initiatives differ by demographic or health status characteristics? And fourth, how are attitudes toward these initiatives correlated

with broader views about government, perceptions of the public health system, and opinions on personal responsibility for health?

Our empirical approach was guided by a detailed conceptual model of legitimacy adapted from three models set forth in the political science literature. The first is based on citizens' judgments about governmental trustworthiness.[14] This model examines the extent to which a government is motivated to deliver on its promises, do right for the people it serves, and seek policies that truly benefit the public, as well how capable it is of doing so.

The second model, referred to as the procedural fairness model, assesses whether a government is structured to ensure that issues are resolved in a regular, predictable way, and that access to decisional arenas, such as legislative bodies or court systems, is open and fair.[20] The third model is based on "attitudinal consistency," or the degree to which values expressed by a government are aligned with citizens' own values.[21]

The literature on predictors of public support for public health interventions is surprisingly limited. Although influential normative scholarship has emphasized such features as public justification and transparency in decision making as indispensable conditions in maintaining public trust in various health contexts,[22, 23] empirical validation of these theoretical assertions is scarce. There is evidence that procedural justice and trust in institutions influence citizens' evaluations of the police,[24] legal systems,[25] and scientific research,[26] but there are no published analyses of predictors of legitimacy in the public health context.

Prior opinion surveys about the public health system have focused on Americans' priorities in public health and the perceived performance of public health agencies.[27] The data shed light on the questions we are asking but fail to illuminate all of the drivers of legitimacy. In addition, many surveys have asked about support for specific public health initiatives, especially

those aimed at obesity[28,29,30,31,32,33] and smoking.[34,35,36,37,38] However, surveys limited to a particular disease or risk factor are too narrowly focused to support an empirical analysis of legitimacy in new-frontier public health interventions generally. We report on predictors of legitimacy across a range of conceptual domains and intervention types.

1.3 STUDY DATA AND METHODS

1.3.1 Survey Questionnaire

We designed a twenty-five-question survey instrument with structured response categories to elicit public views about the three domains of the conceptual model (trustworthiness, procedural fairness, and attitudinal consistency) and support for new-frontier public health laws.

The survey questionnaire was developed in consultation with an advisory group of public health officials and experts, as well as psychometric experts at Knowledge Networks (now part of GfK), a professional survey organization. The draft questionnaire was initially piloted on forty-two adults, five of whom participated in cognitive debriefing interviews, and then pretested on another thirty adults.

1.3.1.1 Survey Administration

The final survey was administered online using KnowledgePanel, a standing, probability based, nationally representative sample of US adults maintained by Knowledge Networks. Panel members are recruited using random-digit dialing and address-based sampling, creating a sampling frame that covers approximately 97 percent of US households.

To support subgroup analyses, we oversampled people with diabetes and residents of the New York City metropolitan area. We anticipated that New Yorkers would be especially familiar with new-frontier public health interventions given that city's many initiatives in the area.

The survey was fielded between October 12 and October 24, 2011. Knowledge Networks processed and weighted the data using a three-step weighting process to adjust for known selection deviations during sampling, noncoverage and nonresponse bias resulting from panel recruitment methods and attrition, and the oversampling of New York City residents and people with diabetes. Knowledge Networks merged the survey data with its previously collected data on panel members' demographic characteristics, health status, and political attitudes and engagement.

1.3.1.2 Data Analysis

We divided the variables into two groups by combining responses of somewhat or strongly support and somewhat or strongly oppose. Then we used multivariate logistic regression to analyze predictors of support for government action in new-frontier public health areas and for specific public health legal interventions.

A separate model was run for each of the outcome variables. Predictor variables—which were kept consistent across models to facilitate comparisons of effect sizes across models—were demographic characteristics, health status, perceptions of public health officials, political ideological orientation and engagement, and views on responsibility for health.

Analyses were performed using the statistical analysis software Stata, version 11. Probability weights were supplied by Knowledge Networks. Missing data were rare (2.6 percent or less for any question). Collinearity checks were performed, and the final model included only moderate (rho < 0.57) correlations among the explanatory variables.

We performed two sensitivity analyses. First, we eliminated one variable that had moderate correlations with other covariates and compared the results of the full and reduced-form models. Second, we compared the results of models run with and without survey weights.

The results were robust to these changes.

1.3.1.3 Limitations

Like all surveys, our study was subject to nonsampling error, including nonresponse bias. Notwithstanding the high response rate and weighting corrections for nonresponse, it is still possible that our sample was nonrepresentative in some way for which we could not adjust.

Additionally, most survey respondents had not directly experienced most of the new-frontier public health policies about which our questionnaire asked, and their reported levels of support may not reflect how they would actually respond to these initiatives. Furthermore, although we provided respondents with definitions of public health policies and officials, we did not assess their level of knowledge of public health agencies or activities, which may have influenced their responses.

Finally, reported opposition to new-frontier public health initiatives may simply reflect a generalized suspicion of government. However, the fact that most respondents rated public health agencies' and officials' performance highly undercuts this hypothesis. Approval levels for the Centers for Disease Control and Prevention were particularly high, even though antigovernment sentiment tends to be directed at the national government.

1.4 STUDY RESULTS

1.4.1 Sample Characteristics

Of 2,690 American adults invited to participate, 1,817 (67.5 percent) completed the survey. Table 1.1 summarizes the sociodemographic characteristics of respondents. Forty-four percent were current or former smokers and nearly 72 percent were overweight or obese. Because of deliberate oversampling, 22 percent had diabetes, and nearly 14 percent

resided in the New York City metropolitan area. All results reported below represent national estimates derived through application of appropriate survey weights.

Table 1.1: Sample Characteristics (N=1817)

	Number of respondents	%†
DEMOGRAPHICS		
Age (years)		
18-35	387	21.3
35-64	1055	58.1
65 and over	375	20.6
Education		
High school or less	785	43.2
Some college	525	28.9
Bachelor's degree or higher	507	27.2
Race		
White	1240	68.2
Black	199	11.0
Hispanic	254	14.0
All other races	124	6.8
Sex		
Male	916	50.4
Female	901	49.6
Household income		
1st (lowest) quintile	262	14.4
2nd quintile	372	20.5
3rd quintile	295	16.2
4th quintile	415	22.8
5th (highest) quintile	473	26.0
Census region		
New England	83	4.6
Mid-Atlantic	469	25.8
excluding NYC metro	152	8.4
East-North Central	216	11.9
West-North Central	95	5.2
South Atlantic	314	17.3
East-South Central	81	4.5
West-South Central	180	9.9
Mountain	124	6.8
Pacific	255	14.0
Metro status		
NYC metropolitan area	317	13.8
Metropolitan, not NYC	1249	68.7
Rural	251	13.8
Household characteristics		
Married	1003	55.2
Children living in household	545	30.0
Employment status		
Employed	970	53.4
Disabled	177	9.7
Unemployed	670	36.9
Health insurance coverage		
Medicaid	78	4.3
Medicare	470	25.9

Table 1.1 (Continued)

Other	935	51.5
None	249	18.4
HEALTH STATUS		
Overweight (BMI≥25)	1301	71.6
Smoker	803	44.4
Diabetic	401	22.1
POLITICAL CHARACTERISTICS		
Political Ideology		
Liberal	495	27.2
Moderate	663	36.5
Conservative	632	34.8
Politically engaged	618	34.5

† Source: Authors' survey of 1817 American adults (unweighted data). Percentages may not sum to 100 due to rounding or refusals to answer. NYC=New York City. "Unemployed" includes persons not working for any reason, including retirees, except those not working due to a disability. "Smoker" was defined as having smoked at least 100 cigarettes in lifetime. "Politically engaged" was defined as reporting at least one of the following during the previous 12 months: held a publicly elected office; commented about politics on a message board or Internet site; written a letter to the editor; served on a community board; worked with others in the community to solve a problem; given money to a Presidential campaign; given money to another (non-Presidential) political campaign, issue, or cause; volunteered or worked for a Presidential campaign; volunteered or worked for another (non-Presidential) political campaign, issue, or cause; contacted a government official; or attended a political protest or rally.

1.4.2 Perceptions Of Public Health Agencies And Officials

Survey respondents had a positive view of the performance of public health agencies, although the agencies were perceived to be more effective in some areas than others. Seventy-five percent of respondents rated the Centers for Disease Control and Prevention's overall performance as excellent or good, and a majority also gave high ratings to state and local health officials (Table 1.2).

Perceptions of the fairness and representativeness of public health officials' decision making were more mixed. Only about one in three Americans perceived that public health officials "always" or "usually" make decisions in a fair way, respect people's rights, and understand the public's values. And roughly one in four had a much more negative perception, reporting that officials "rarely" or "never" demonstrated these characteristics.

Although 75 percent of respondents gave high ratings to the performance of the government's system of providing vaccines against infectious diseases, performance ratings were lower for other health threats, especially chronic diseases and obesity (Table 1.2). While perceived performance for these areas was low, the proportions of respondents who felt that the government had "a great deal" or "some" responsibility to address chronic diseases and obesity were much higher (69 percent and 61 percent; data not shown). These figures suggest that the performance ratings may reflect a view that the government has done too little, rather than too much, in those areas.

Table 1.2: Public Perceptions of Public Health Officials

	%				
PERFORMANCE OF PUBLIC HEALTH AGENCIES & OFFICIALS:[a]	Excellent	Good	Fair	Poor	
CDC	17.1	57.9	21.6	3.3	
State health department	7.4	53.2	33.0	6.4	
Public health officials in local community	7.2	47.8	36.7	8.3	
PERFORMANCE OF GOVERNMENT'S SYSTEM IN:[b]	Excellent	Good	Fair	Poor	
Providing vaccines to prevent the spread of infectious disease	22.7	52.7	19.3	5.3	
Detecting and preventing foodborne illness	7.5	43.7	34.4	14.4	
Preventing the spread of HIV/AIDS	6.7	43.1	38.0	12.2	
Reducing tobacco use	6.8	35.5	37.4	20.4	
Reducing obesity	5.1	29.7	43.2	22.1	
Preventing unintentional injuries	4.4	42.2	42.2	11.2	
Preventing chronic illnesses	4.1	33.7	45.6	16.5	
TRUST IN PUBLIC HEALTH AGENCIES & OFFICIALS[c]	A lot	Somewhat	Not too much	None at all	
CDC	40.4	44.4	11.1	4.1	
State health department	22.0	55.6	17.3	5.2	
Public health officials in local community	18.7	54.8	19.9	6.6	
PERCEPTIONS OF PUBLIC HEALTH OFFICIALS:	Always	Usually	Sometimes	Rarely	Never
Officials can be counted on to make decisions in a fair way	2.1	28.1	47.9	17.0	4.9
Officials respect people's rights	4.2	34.3	41.0	15.1	5.4
Officials understand the public's values	2.11	27.6	43.8	21.2	5.3

Source: Authors' survey of 1817 American adults (weighted data). Percentages may not sum to 100 due to rounding

[a] Question text: "How would you rate the performance of the following agencies or individuals?"

[b] Question text: "How would you rate the performance of our government's system in each of the following areas?"

[c] Question text: "How much would you trust each of the following sources to provide accurate information about health problems or issues that are important to you?"

1.4.3 Perceived Legitimacy Of New-Frontier Public Health Initiatives

1.4.3.1 Overall Levels Of Support

Respondents were asked to rate the amount of responsibility that the government had to address various health challenges, representing both new-frontier and traditional areas for public health. With the exception of preventing unintentional injuries, a majority of respondents reported that the government had either "a great deal" or "some" responsibility to address each of the challenges.

However, higher proportions of respondents reported that government had "a great deal" of responsibility to address traditional public health challenges such as detecting and preventing foodborne illness, preventing HIV/AIDS, providing vaccines for infectious diseases, and preventing unintentional injuries, in contrast to meeting new-frontier health challenges such as preventing chronic illness, reducing tobacco use, and reducing obesity by encouraging healthy lifestyles.

Although some respondents did not perceive a strong governmental responsibility to address new-frontier public health conditions, there were very high levels of support for government action in such areas. Strong majorities of respondents expressed support for government action in each of seven new-frontier areas, ranging from 70 percent for government action to reduce alcohol consumption to nearly 90 percent for government action to prevent cancer (Table 1.3).

Acceptance of specific legal strategies was inversely related to the degree that they involve coercion or otherwise intrude into personal behavior. We examined support for four legal initiatives, selected to represent a range of coercive measures, in each of the following three areas: tobacco use, "obesity and related diseases like diabetes and heart disease," and childhood

obesity. In each case, support was highest for the least restrictive policy and decreased markedly as the burdensomeness and punitiveness of the policies increased (Table 1.3).

To further explore the reasons why people oppose new-frontier public health policies, we asked respondents to rate their support for two legal initiatives. The first was a hemoglobin A1c surveillance scheme modeled after New York City's program to track blood level control in people with diabetes. The second was a legal mandate that all food manufacturers and chain restaurants substantially reduce the amount of sodium in their products.

Two-thirds of respondents supported the surveillance scheme and three-quarters supported the sodium reduction requirement. Among those who opposed the policies, in both cases, fewer than 10 percent cited skepticism of their effectiveness as the primary reason. Nearly 80 percent of those opposed to the surveillance scheme grounded their opposition in a perception that "the policy would intrude too much into individual privacy," and nearly 77 percent of those opposed to the sodium reduction mandate felt that "government should stay out of matters like what people eat."

Table 1.3 Support for New-Frontier Public Health Initiatives

	% Who Support	% Who Oppose
HOW MUCH DO YOU SUPPORT OR OPPOSE GOVERNMENT ACTION TO:		
Prevent cancer	88.9	11.2
Prevent heart disease	85.6	14.4
Help people control their diabetes	83.7	16.3
Prevent childhood obesity	81.3	18.7
Prevent and reduce tobacco use	75.9	24.1
Prevent obesity in adults	75.8	24.2
Reduce alcohol consumption	70.2	29.8
SUPPORT FOR POLICIES TO REDUCE OBESITY AND RELATED DISEASES[a]		
Increase affordability of fruits and vegetables	83.6	16.4
Require postings of calorie counts	80.8	19.2
Prevent use of food stamps for soda and other sugary beverages	75.7	24.3
$50 annual surcharge on insurance premiums of obese individuals	37.6	62.4
SUPPORT FOR POLICIES TO REDUCE CHILDHOOD OBESITY[b]		
Require more instruction in public schools about the health risks of obesity	89.2	10.8
Require public school students to participate in at least 45 minutes of daily physical activity	88.4	11.6
Require BMI screening and surveillance of schoolchildren	52.0	48.0
Make possession of soda and other junk foods a disciplinary offense	32.5	67.5
SUPPORT FOR POLICIES TO REDUCE TOBACCO USE[c]		
Provide people with free nicotine patches	72.6	27.4
Require cigarette packages to display graphic images	63.4	36.6
Make it illegal to smoke in private spaces	37.9	62.2
Permit employers to test and fire for tobacco use	20.0	80.0
SUPPORT FOR:		
Requiring food manufacturers and chain restaurants to significantly reduce sodium content of their foods	75.9	24.1
Hemoglobin A1C surveillance program	65.7	34.4

Source: authors' survey of 1817 American adults. Response categories combine somewhat and strongly support/oppose.

[a] Question text: "Thinking about government policies to reduce obesity and related diseases like diabetes and heart disease, how much would you support the following policies…"

[b] Question text: "Thinking about government policies specifically aimed to reduce *childhood* obesity, how much would you support the following policies…"

[c] Question text: "Thinking about government policies specifically designed to reduce tobacco use, how much would you support the following policies…"

1.4.3.2 Differences Across Population Subgroups:

Multivariate analyses revealed significant differences in support for government action in new-frontier public health areas across population subgroups, with African Americans, women, and people ages eighteen to thirty-five reporting higher levels of support for government action than whites, men, and older Americans (Table 1.4).

The difference across races was especially large and consistently significant for all seven new-frontier public health areas. The odds of supporting new-frontier initiatives were two to four times higher for African Americans than for whites, depending on the health condition addressed. Hispanics were also significantly more supportive than whites of government action in two areas, prevention of heart disease and control of diabetes.

The association of race and other demographic characteristics with support for specific new-frontier public health interventions was less consistent. African Americans, women, people with lower incomes and levels of educational attainment, and those ages eighteen to thirty-five were significantly more likely than others to support some of the initiatives tested, but the significance of these effects varied across initiatives (Table 1.5). Banning smoking in private spaces was significantly associated with a greater number of demographic characteristics than other initiatives were.

We hypothesized that New York City residents would be more likely than other respondents to support new-frontier public health initiatives because they were particularly familiar with them. However, such an effect was generally not in evidence (Tables 1.4 and 1.5).

We anticipated that people who were overweight, smoked, or had diabetes would disproportionately oppose new-frontier public health initiatives because, as targets of such interventions, they might perceive the policies to be especially burdensome. Such an effect was

present for smokers (Table 1.5). However, people with diabetes were significantly more likely than others to support government action in new-frontier public health areas and no less likely to support specific policies (Table 1.4). Being overweight predicted lower support only for insurance premium surcharges on obese subscribers (Table 1.5).

Table 1.4 Regression Results: Support for Government Action in New-Frontier Areas

	Odds Ratios						
	Prevent Cancer	Prevent Heart Disease	Help People Control Diabetes	Prevent Childhood Obesity	Prevent Tobacco Use	Prevent Adult Obesity	Reduce Alcohol Consumption
SOCIODEMOGRAPHICS							
Age 18-35	1.8**	1.2	2.0***	1.5	1.5*	1.6**	1.1
African American	3.9**	2.8**	4.3***	3.3**	2.1**	2.4**	2.7***
Hispanic	1.7	2.2**	2.8***	1.4	1.3	1.3	1.5
Other race	0.5**	0.9	1.2	1.0	0.8	1.1	1.5
Male	1.0	0.9	1.3	0.9	0.6***	0.8	0.5***
1st (lowest) income quintile	1.7	1.2	1.6	1.1	1.0	1.4	1.8**
2nd income quintile	1.1	1.1	1.5	1.1	1.1	1.2	1.9***
New York City resident	3.0***	1.3	1.1	1.5	1.0	1.6	0.8
HEALTH STATUS							
Smoker	1.1	1.1	0.9	0.9	0.8	0.9	0.7**
Diabetic	2.2***	1.6**	1.7**	1.4	1.4*	1.5**	1.9***
POLITICAL CHARACTERISTICS							
Liberal	1.5	1.0	1.0	1.5	1.5*	1.6**	0.9
Conservative	0.5***	0.5***	0.6***	0.5***	0.8	0.5***	0.8
Politically engaged	1.2	0.9	1.1	0.8	0.9	0.7*	0.8
BELIEFS							
Positive rating of government performance in addressing public health conditions	1.1	1.0	1.0	1.0*	1.0	1.0	1.0
Positive rating of performance of public health agencies	0.7	0.7**	0.7*	0.7	0.9	0.9	1.0
Trusts public health agencies	1.4	1.5*	1.7**	1.5*	1.2	1.4*	1.1
"People like me" can influence government priorities in public health	2.4***	2.0***	2.2***	1.9***	1.7***	1.5**	1.7***
Personal understanding of officials' decisions about public health policy	1.9**	1.8**	1.2	0.9	1.5*	1.2	1.9***
Public health officials make decisions in a fair way	0.9	1.2	1.5	2.2***	1.2	1.3	1.1
Public health officials respect people's rights	1.7*	1.4	1.4	1.8**	1.9***	1.4	1.0

Table 1.4 (Continued)

Public health officials understand the public's values	1.4	0.9	1.5	2.7***	1.1	1.9***	1.5*
Internal health locus of control	1.1***	1.1***	1.1***	1.1***	1.0	1.1***	1.0

† Source: Authors' survey of 1817 American adults. Logistic regression models predict the probability of strongly or somewhat supporting government action to address each health condition. The following respondent characteristics were included in all models, but did not achieve statistical significance in any model: educational attainment, marital status, presence of children in the household, employment status, disability, urbanicity, being overweight (BMI>25), being elderly (>64 years), household income in the 3rd or 4th quintile, and Census division. "Internal health locus of control" was defined as the degree to which an individual believes that health outcomes are a direct result of internal factors, such as one's own behavior, as measured by the Multidimensional Health Locus of Control scale. *P<0.1; **P<0.05; ***P<0.

Table 1.5 Regression Results: Support for Specific New-Frontier Policies

	Odds Ratios					
	Require Food Manufacturers and Chain Restaurants to Reduce Sodium In Foods	Hemoglobin A1c Surveillance	$50 Annual Insurance Surcharge for Obese Persons	School-based Body Mass Index Screening	Banning Smoking in Private Spaces	Graphic Labeling on Cigarette Packages
SOCIODEMOGRAPHICS						
Age 18-35	1.1	1.7***	1.7***	1.2	1.9***	1.4*
Age 65 and over	1.5*	0.9	1.2	1.0	1.7***	1.4*
Some college	0.9	0.7**	1.0	0.9	0.9	0.8
Bachelor's degree or higher	0.8	0.6***	1.2	1.1	1.1	0.7**
African American	2.3**	1.3	0.8	1.1	2.1***	1.5
Hispanic	1.2	0.8	0.9	1.1	1.8***	0.9
Other race	1.4	1.0	1.1	1.0	1.7**	1.1
Male	0.6***	1.1	1.1	1.4**	0.8*	0.9
1st (lowest) income quintile	1.1	2.3***	1.0	2.0***	1.9**	1.4
2nd income quintile	1.3	1.5*	1.0	1.4	1.8***	1.2
3rd income quintile	1.3	1.0	0.9	1.5*	1.0	0.8
Unemployed	0.8	1.1	1.0	1.0	0.9	0.7**
West North Central region	0.7	0.8	1.3	1.3	1.2	1.9*
Married	1.0	1.1	0.9	1.1	1.5**	1.0
Child in household	1.1	1.2	1.0	0.9	1.5***	1.4**
HEALTH STATUS						
Overweight (BMI>25)	1.1	1.1	0.6***	0.9	1.0	1.2
Smoker	0.8	0.9	0.8	0.7***	0.4***	0.7***
Diabetic	1.4	0.7*	0.7	1.2	1.6**	1.1
POLITICAL CHARACTERISTICS						
Liberal	0.9	1.2	0.9	0.8	0.8	1.2
Conservative	0.5***	0.7***	0.8	0.6***	0.7*	0.7**
Politically engaged	0.7	0.9	1.2	1.0	0.9	1.0
BELIEFS						
Positive rating of government performance in addressing public health conditions	1.0	1.0	1.1	1.0	1.0	1.0

Table 1.5 (Continued)

Positive rating of performance of public health agencies	0.7*	1.0	0.9	1.0	1.1	1.0
Trusts public health agencies	1.1	1.1	0.8	1.0	0.7**	1.1
"People like me" can influence government priorities in public health	1.2	1.2	1.2	1.4**	1.4**	1.4**
Personal understanding of officials' decisions about public health policy	1.2	1.1	1.4*	1.3	1.2	1.6***
Public health officials make decisions in a fair way	1.1	1.0	0.9	1.0	0.8	0.8
Public health officials respect people's rights	0.9	0.9	1.0	0.9	1.1	1.0
Public health officials understand the public's values	2.7***	1.9***	1.4*	1.5**	1.5*	1.4*
Internal health locus of control	1.0*	1.1***	1.1***	1.1***	1.0*	1.0*

† Source: Authors' survey of 1817 American adults. Logistic regression models predict the probability of strongly or somewhat supporting each policy. The following respondent characteristics were included in all models, but did not achieve statistical significance in any model: disability; urbanicity; New York City metropolitan residency; residence in other Census regions; and household income in the 4th income quintile. *P<0.1; **P<0.05; ***P<0.01.

1.4.3.3 Beliefs About Government And Health:

As expected, support for most new-frontier public health initiatives was significantly lower among political conservatives and respondents who believed health status to be strongly controllable through individual action (Tables 1.4 and 1.5). Results concerning beliefs about public health officials were more complex.

The belief that "people like me" can influence which public health problems the government chooses to prioritize was a strong and consistent predictor of support for government action and specific initiatives, with odds ratios of 1.5 to 2.4 (Table 1.4). Respondents were also significantly more likely to support new-frontier public health initiatives if they perceived that public health officials understood the public's values (Table 1.5). However, perceptions of public health officials' and agencies' performance, trust in public health officials, perceptions that they could be counted on to make decisions in a fair way, and perceptions that they respected people's rights were generally not significant predictors of support.

1.5 POLICY IMPLICATIONS

As public health agencies seek to combat the increasing burden of chronic disease, they confront critical questions about how to set priorities and evaluate the wisdom of policy approaches. These decisions require careful weighing of the following considerations: the importance of the problem, the effectiveness and cost-effectiveness of various interventions, and the likelihood that the chosen interventions will enjoy public acceptance.

Public opinion should not be the sole determinant of public health policy agendas or policies.[39] However, if policy makers do not understand that opinion, policy choices may go seriously awry. When members of the public view a policy as legitimate, they may be more

likely to comply with the behavioral changes that public health officials are seeking to encourage, which strengthens the policy's chances for success.

Public backlash against some new-frontier public health interventions suggests that legitimacy is a major challenge facing public health officials working in this realm. Identifying predictors of public support and ways to maximize that support thus provides key building blocks for informing sound policy decision making. Our findings suggest several lessons for public health policy makers considering new-frontier public health interventions.

1.5.1 The Least Coercive Path Is The Smoothest

One key finding is that the greater the restraint a legal intervention imposes on individual liberty, the greater public opposition to the intervention is likely to be. There was much support among our respondents for strategies that enable people to exercise healthful choices—for example, menu labeling and improving access to nicotine patches—but little support for more coercive measures, such as insurance premium surcharges.

Respondents who opposed particular policies identified their effects on liberty and privacy as the primary reason for that opposition far more frequently than concerns about the policies' effectiveness. These findings suggest that continuing the current focus on using law to shape health environments, rather than exerting more direct pressure on individual behavior, is a sound strategy for maximizing the legitimacy of policies.

1.5.2 Support May Come From Surprising Quarters

Policy makers generally need not fear strong opposition from groups that feel "targeted" by a particular new-frontier public health intervention because of a health condition. Contrary to our expectations, except for the most punitive policies we examined, survey respondents were no less likely to support interventions aimed at obesity and diabetes if they had those health

conditions than if they did not. This is consistent with political science research findings that self-interest has minimal explanatory power in explaining the attitudes of the American public.

Smokers, however, were less likely than other respondents to support policies to discourage tobacco use. This result suggests that self-interest may play out differently where an intervention targets a health behavior, rather than a health condition.

Our data also suggest that unlike self-interest, concern for one's social group may influence attitudes toward public health interventions. We found higher levels of support for government action in new-frontier public health areas among African Americans and, to a lesser degree, Hispanics. A possible explanation is that the diseases targeted by such interventions disproportionately affect minority communities.

1.5.3 Pay Attention To The Public Health Policy-Making Process

Finally, and perhaps most importantly, policy makers should understand that people's beliefs about the public health policy-making process drive their perceptions of the legitimacy of new-frontier public health interventions. The strongest predictor among the belief measures we tested was the perception that "people like me" can influence government priorities in public health. Also important was the belief that public health officials understand the public's values. These constructs were strong and consistent predictors of perceived legitimacy across multiple public health policies.

These measures relate to the notion of democratic representation in public health policy making. Interestingly, this construct appears to play a larger role in driving public support for new-frontier public health interventions than the trustworthiness of public health officials, their record on respecting individual rights, or their performance generally.

Thus, of the theoretical models of legitimacy that we discussed above and tested, the procedural-fairness model appears to have the greatest applicability in the public health realm. This model emphasizes reliable processes of resolving issues and open, fair access to decisional arenas. Our data suggest that the public's conception of fairness may have less to do with how particular decisions are made than with more general considerations of access to the decision-making process and faith that decision makers know their constituents well enough to carry out their will.

1.6 CONCLUSION

How, then, can policy makers maximize support for new-frontier public health interventions? First, they should involve the public in priority-setting activities in public health. Second, they should seek to understand the values held by different segments of the population and incorporate those values into policy decisions. Third and finally, they should communicate to the public how they incorporated those values into policy decisions. Public justification for important policy decisions should be offered in every instance and should reflect an understanding of and respect for the public's values.

Public health officials are currently working within a challenging political climate that includes a strong movement toward smaller government. In this context, the high level of public support that we found for government action to address new-frontier health problems is striking. Public health officials should be heartened by this finding. In moving forward, the challenge is to respond to this demand for a public health response to noncommunicable disease in ways that allow members of the public to feel that their voices are heard, understood, and valued.

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CHAPTER 2

Mill, Rawls, and the Search for a Principle of Public Health Legitimacy

2.1 INTRODUCTION

What are the limits of government authority to protect and promote the health of the public, and how should we understand these limits in an era increasingly characterized by non-communicable disease?

A scan of any major news outlet today reveals this inquiry is far from academic. Public health proposals across the nation foster rigorous debate across the media and wider blogosphere: can a city restrict soda size to reduce obesity rates? Can bans on smoking in public places be extended to cover parks and beaches? Can companies be permitted to require employees to participate in wellness screening programs?

These proposals pose a central challenge for public health regulation: to what degree can the state restrict individual freedom in the name of reducing the burden of conditions such as diabetes, obesity, or hypertension, which, as noncommunicable diseases, pose no direct risk of physical harm to others?

Such questions obviously require empirical assessments, for the issue of the effectiveness of interventions has a central role in evaluating the appropriateness of a regulation. The question of effective interventions for the conditions at issue here is one that deserves attention, particularly given the complex disease etiology of the chronic diseases targeted by these form of interventions. However, underlying these questions of effectiveness is a deeper inquiry—even if such policies *are* effective at achieving the stated health goals, is such state intervention ethically permissible?

The fundamental question here is therefore one of legitimacy: how extensive is the moral authority of the government to protect and promote the health of the public? Does this authority extend so broadly so as to include the capacity to address noncommunicable disease prevention through the regulation of individual health behaviors?

In a liberal society, this question of the legitimacy of state action in the name of public health is one that involves a balance between the government's power to secure the communal provision of security and welfare against the constraint of preserving the liberty of its citizens. In the United States, this constraint is commonly understood as deriving from the Constitution, which creates a zone of non-interference for individuals, independent from government constraints on individual decision-making. What is less clear, however, is how extensive this zone of non-interference is to be understood: what forms of regulation are prohibited, of what forms of activities, and how strictly?

To date, much of the contemporary discourse has revolved around the "harm principle" of John Stuart Mill, arguably the most familiar proposal for a principled limit to state authority. In this chapter, I will argue that the harm principle, despite its intuitive appeal, fails to adequately frame the liberty interests at issue in public health policies and thus fails to provide adequate protection of liberties. This deficiency results from the harm principle's exclusive focus on the legitimacy of the *reasons* given for a law. I argue that we should consider not only the rationale given for a public health policy, but also the effects of that policy on individual liberty. I then suggest that the liberal principle of legitimacy of John Rawls offers an alternative means by which to determine the principled limits of public health authority, one that may have some advantages over the traditional Millian approach.

2.2 PUBLIC HEALTH LEGITIMACY IN AN ERA OF NONCOMMUNICABLE DISEASE

The twentieth century witnessed a dramatic shift in the nature of disease challenges in the United States, as morbidity and mortality from noncommunicable disease that are associated with modifiable risk factors replaced infectious diseases as the leading threats to the nation's health.[40] While the burden of infectious diseases, including tuberculosis, influenza, and HIV, continue to pose considerable challenges to population health, their overall impact on total morbidity and mortality has been dwarfed in recent decades by the burden posed by chronic diseases, particularly those associated with lifestyle behaviors such as overeating, physical inactivity, and tobacco use. By 2010, the 3 leading causes of death in the U.S. were poor diet (contributing to 25.5% of all deaths.), tobacco use (17.8% of deaths), and high body mass index (14% of deaths), with physical inactivity and alcohol consumption contributing an additional 8.8% and 3.3%, respectively.[41]

This changing pattern of disease, or "epidemiologic transition,"[42] has been accompanied by a series of new public health interventions aimed at addressing the challenges posed by non-communicable disease at the local, state, and federal level. These interventions aim to extend the familiar tools of public health, such as surveillance of disease and regulation of harmful substances—long used to combat infectious diseases and occupational exposures—towards addressing such modern health challenges as diabetes, obesity, and heart disease.

This shift in public health interventions is perhaps most evident in New York City's public health approach over the past decade. In 2002, the City's Department of Health and Mental Hygiene (DOHMH) launched a series of initiatives targeting chronic disease, including tax increases on tobacco products; comprehensive smoking bans in restaurants, parks, and other public places; a ban on the use of trans fats by food service establishments; and mandated

posting of calorie counts on menu boards in chain restaurants.[43] In 2006, the City expanded its efforts to include diabetes management, enacting regulations which mandated laboratories to report hemoglobin A1C levels to DOHMH, thereby creating the nation's first community-wide diabetes registry—and in so doing, launching the nation's first surveillance program that tracks a disease which is neither communicable nor associated with environmental or occupational exposure.[44] Most recently, the City's Board of Health moved to ban the sale of sugar-sweetened beverages over 16 ounces at all restaurants, movie theatres, sports stadiums, and food carts.[45]

While New York City has become perhaps the most visible and aggressive leader in these efforts, it has not been alone in its approach. Similar efforts have developed across the nation at both the local and state level, including mandatory body mass index screening and surveillance for schoolchildren,[46] taxes on soft drinks and obesogenic foods,[47] and bans on smoking in private spaces such as cars and homes.[48] While public health continues to be a primarily local and state issue, the federal government has increasingly exerted its authority in this arena. Recent examples of federal public health laws include those established by the Patient Protection and Affordable Care Act of 2010, which authorized new public health regulations such as excise taxes on indoor tanning services[49] and mandatory nutritional labeling at chain restaurants and vending machines.[50]

These new interventions vary in the degree to which they rely on coercion or otherwise limit individual freedoms in order to achieve their objectives. Some initiatives involve little to no restrictions on individual freedom, such as those that aim to provide information or to shape choices by changing the "default option."[51] Other initiatives, however, deliberately limit individual choice in order to reduce the prevalence of unhealthy behaviors such as smoking, poor diet, or physical inactivity.[52] Such limits on choice have provoked intense controversy,

particularly for those measures perceived as relying upon a greater degree of coercion to achieve their stated health goals.

The objections to the use of coercive state authority to control non-communicable disease have taken several forms. Across the media and blogosphere, pundits have repeatedly invoked the image of the "nanny state" to denigrate proposals they view as posing an undue intrusion into autonomy, substituting government control over matters for which individuals should be permitted to make decisions for themselves. Vociferous critiques have also been launched within academic circles, particularly among legal scholars. Among the most vehement scholarly critiques has been offered by Richard Epstein, a conservative legal scholar, who argues that newer public health regulations unduly extend public health authority beyond its purported "traditional" role of combating health threats that involve collective-action problems (such as the threat of infectious disease) into "inappropriate areas" of health regulation.[53] According to this view, public health authority should track the idea of public goods (or bads) in economics: public health action is legitimate only to address communicable disease and other collective action problems where competitive markets cannot be relied upon to secure the social optimum, such as sanitary water and sewer systems, pollution, and securing a safe food supply.[54] As obesity and related disease pose "no imminent threat to the public," they do not merit the same level of intervention as infectious diseases.

Epstein's construction of a sharp delineation between "old" and "new" public health has been criticized at various levels, including for presenting a historical portrayal that oversimplifies the trajectory of American public health,[55] and veiling his political and moral preferences behind seemingly objective claims about the economics of disease control.[56] While I'm sympathetic to these critiques, I suggest Epstein's criticisms nevertheless merit a serious consideration of the

appropriate boundaries of public health law, as they invoke themes that reflect a broader discomfort with how these newer public health measures fit within a liberal society.

This broader discomfort has been previously described by Lindsey Wiley as representing an emerging critique of the new public health that is liberal "in the classical sense."[57] This critique reflects a general discomfort with the expansion of government power to protect public health as a potential incursion on the values of liberalism, which,

by definition, holds liberty to be accorded priority over other goods and demands that limitations on liberty be carefully, narrowly, and thoroughly justified.

This liberal critique has been explored in considerable detail by The Nuffield Council, an independent body in the United Kingdom that examines and reports on ethical issues in biology and medicine. As described by in the Council's report, *Public Health: Ethical Issues*,[58] liberals emphasize autonomy, valuing the individual's ability to determine the course of his or her own life. Liberals also place emphasis on equality between citizens in both the personal and political spheres of life. Finally, while the liberal agrees with the libertarian thesis on the need to constrain the state's authority so as to protect individual freedoms, the liberal also believes that the state's power may be used to advance the welfare of its citizens. The inherent tension for public health in the liberal state is therefore how to both protect autonomy while promoting welfare.

In its report, the Nuffield Council identifies the harm principle of John Stuart Mill as one way to resolve the tension between these two values. The choice of this principle reinforces a long-standing trend in public health ethics. As observed by Powers, Faden, and Saghai,[59] numerous contributions to the public health literature, both in the United States[60,61] and in other Western nations,[58,62] have put the harm principle “front and center” in the debate over the proper

scope of government authority in public health, particularly with respect to addressing noncommunicable disease.

On its face, Mill's harm principle presents a robust defense of individual liberty. one that finds strong resonance in a liberal state. By restricting the scope of state authority to cases involving harm to others, Mill's principle seems to offer the protection against the "mission creep" the liberal critique of the new public health presents as so objectionable. However, a closer read of the principle suggests that it may not protect liberty to the extent desired by its proponents. Of even deeper concern to liberals, the harm principle may, rather than preserving individual autonomy, actually serve as the rationale for inappropriate encroachments on individual liberty.

In Section 2.3, I will offer several observations as to why Mill's harm principle is ill-suited to address questions of public health policy in a liberal state. My argument proceeds as follows. First, I argue that Mill's focus on the reasons for a law as the test of legitimacy is problematic because it makes legitimacy dependent upon assessing the legislative intent of a law, which leads us down the proverbial rabbit hole regarding the coherence of legislative intent. Second, I argue that the focus on paternalism fails to adequately frame the liberty interests invoked by public health policies, which aim not at the benefit of individuals but rather at that of populations. Finally, I argue that exclusive focus on the rationale for the law fails to give adequate consideration to the effects of law on individuals, which thereby fails to give adequate priority to liberty.

Given these limitations, I propose that we consider whether an alternative framework might be better suited to the question of legitimacy in public health practice. In Section 2.4, I begin the exploration for such an alternative by looking to a theory that has had tremendous

influence both within the broader field of political theory, and more narrowly within the field of ethics and health. Specifically, I suggest that the work of John Rawls and his liberal principle of legitimacy provides an alternative, and arguably more illuminating, lens through which to examine questions of public health authority.

2.3 RECONSIDERING THE ROLE OF THE HARM PRINCIPLE IN PUBLIC HEALTH

In the introductory section, I suggested that the harm principle of John Stuart Mill is ill-suited to determine when public health authority is—and is not—appropriate. This limitation occurs, I argue, for three distinct but interdependent reasons: the reliance on the problematic concept of legislative intent; the failure to adequately characterize the true liberty interests at issue; and its failure to give adequate priority to liberty resulting from the exclusion of considerations of the effects of a law on individual liberty.

In the remainder of this section, I will introduce Mill's harm principle and explore the challenges encountered in its application to concrete policy questions, with a focus on the implications of these challenges for public health practice. Ultimately, I suggest that these limitations should motivate us to broaden our search for other liberal frameworks that might better inform the question of when public health authority is legitimate.

2.3.1 Introducing Mill's Harm Principle

In the opening of *On Liberty*, Mill describes his subject as "social liberty," or the nature and limits of power that society can legitimately exercise over an individual. Alan Wertheimer explains this issue as resulting from the need to adjudicate two competing values.[63] First, following Kant, we believe the individual is the primary locus of moral value and thus are

committed to the priority of individual freedom. Yet we also believe that the state is justified in exercising coercive power over the individual—if it does so for the right reasons. The debate, however, is what these reasons are, or, as Mill describes, how it is that we are to make the "fitting adjustment between individual independence and social control."[64]

Mill (boldly) asserts that this adjustment can be made using one "very simple principle" to determine when the state can legitimately restrict individual liberty. The central thesis of Mill's argument can be summarized by the following passage, referred to (though not by Mill himself), as the "harm principle." According to Mill:

> … the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise or even right. There are good reasons for remonstrating with him, or reasoning with him, or persuading him, or entreating him, but not for compelling him. The only part of the conduct of anyone for which he is amenable to society is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign.[65]

Thus, if an individual's action harms others, the state has an appropriate reason to restrict his or her liberty. This claim seems fairly uncontroversial. Yet Mill goes further, and claims not only that this test provides *a* reason to justify state interference with liberty, but that it provides the *only* reason.[66] According to Mill, determining the proper limits of state action is a straightforward test: if the action harms others, the state can restrict an individual's liberty. If the action harms only the individual, the state should not interfere.

Two features are worth noting with respect to Mill's argument. First, Mill constructs the test of legitimacy as dependent upon the *reasons* for state interference. The harm principle acts to distinguish classes of reasons that are permissible grounds for state restrictions of individual liberty from impermissible classes of reasons.[67] The second feature is the *types* of reasons that Mill finds permissible. Specifically, state action is *only* permissible when undertaken for the purpose of preventing harm to others.

Both of these features, I argue, raise issues for the use of Mill's harm principle as a test of the legitimacy of government action in public health. In the remainder of this section, I will identify several of the most challenging problems facing Mill's harm principle as a test of the legitimacy of public health measures. For most of the issues discussed below, I will admittedly be rehearsing complaints made by previous critics of Mill's project. My aim in presenting these issues here is not to introduce a novel critique of Mill, but instead to suggest that these limitations point us to the need for an alternative framework, one which I will introduce in Section 2.4.

2.3.2 Liberty, Legitimacy, and Legislative Purpose

Mill's argument for the harm principle rests upon a fundamental presumption in favor of individual liberty. As presented by Mill, determining whether a law is legitimate therefore becomes a search for the types of reasons that can justify state interference with that liberty.

In framing the test in this way, Mill's harm principle becomes a test of legislative intent.[68] This framing raises (at least) two issues. First, it requires identifying the reasons motivating a legislature with respect to the public health proposal in question--in other words, what is to be

understood as the legislature's intent. However, whether any coherent notion of legislative intent can be reliably determined—or even exists—is far from a settled matter.

The central critique of legislative intent can be summarized as follows: as the legislature is not a person, but rather consists of a group of people with diverse goals and interests, it is not the form of subject to which we can attribute an intent. As argued trenchantly by Max Radin in his 1930 Harvard Law Review article,

> A legislature certainly has no intention whatever in connection with words some two or three men drafted, which a considerable number rejected, and in regard to which many of the approving majority might have had, and often demonstrably did have, different ideas and beliefs.[69]

Radin's skepticism about legislative intent raises an obvious challenge for Mill's proposal: if legislative intent does not exist (or at least, cannot reasonably be identified), how then are we to evaluate whether or not the intent is a permissible reason for state action?

One possible response to this concern is that, while legislative intent perhaps cannot be divined from the legislature as whole, it is nevertheless often possible to reduce the intention to some subset of the legislators, such as the intention shared by the majority who vote in favor of a law.[70] Yet even among the majority of legislators who vote a bill into law, there may be a large number of motivating reasons, such that no single one can be said to serve as *the* motivating reason for a law's passage.

An alternative response might be that, even if unable to restrict the motivations of various legislators to a single reason, we may nevertheless be able to identify a family of reasons held by legislators as justification for the law. While this is likely more consistent with the actual process of lawmaking as described by Radin, it is unclear that this removes the challenge for the harm principle, as the principle gives little guidance regarding the evaluation of laws that are

supported by multiple types of reasons. For example, to take an issue of particular relevance to the examination of contemporary public health policies, how are we to consider cases where the aim of improving an individual's own good is only one of several rationales offered in support of a law? Does the presence of *any* paternalistic justification count to make the law impermissible? Conversely, can the objection of paternalism be diffused if we are able to identify a non-paternalistic reason?

These issues are central to determinations of public health legitimacy, as public health laws are often supported by multiple reasons, including protection of the individual directly regulated by the law, protection of other individuals from indirect harm, as well as protection of the public from diffuse harm.[71] Consequently, public health laws often take the form of what Joel Feinberg describes as "mixed paternalistic laws,"[71] or laws that are supported by a mixed rationale, one that is only partly paternalistic.

What guidance does the harm principle provide for evaluating such cases? James Wilson suggests two potential interpretations, neither of which seems plausible.[72] At one extreme, we could read the harm principle as holding that the presence of *any* paternalistic reason is sufficient to overrule other reasons, thereby rendering the law illegitimate. Yet this seems implausible, as it would allow the rationale of a single legislator to render an otherwise permissible law as illegitimate. At the other extreme, we might hold that any non-paternalistic reason would be sufficient to make a law permissible. This seems similarly implausible, resulting in almost no policy being ruled impermissible on grounds of paternalism as there is likely always to be at least one possible non-paternalistic justification for a policy, even one which has a large paternalistic bent.

An alternative approach, suggested (and subsequently rejected) by Wilson, is that we might aim for a rule that would hold that "a policy is (impermissibly) paternalistic if *most* of the motivation behind it is paternalistic."[72] However, this returns us to the previously unresolved issue of having to determine the legislative intent of the policy, reinforcing the issues associated with making legitimacy dependent upon the intent or reasons motivating a policy.

2.3.3 Legislative Purpose, Public Health, and Paternalism

A second issue arising from making legitimacy in public health dependent upon the reasons for government policy is that it presupposes a theory of government regulation that is inconsistent with the actual practice of public health policy. As discussed previously, Mill proscribes government action that is done for the sake of preventing self-regarding harms. The challenge, however, is that public health policy, unlike clinical medicine, aims not to improve the health of a single patient, but rather that of the population. Public health policy, therefore, focuses not on restricting individual actions so as to protect defined individuals from harm, but rather aims more broadly, focusing on reducing the prevalence of risk factors at the environmental level.[60,73] When we institute water treatment programs, we don't say "we do this to protect you, Citizen X, from making the reckless decision to drink contaminated water" but rather "we treat the water to reduce the risk of water-borne diseases." Similarly, when a food manufacturer adopts a voluntary program to reduce the sodium content in its foods to reduce heart disease risk, while we may know that this will lead to fewer lives lost to heart attack or stroke, we will not be able to identify which specific individuals we will protect. The effort therefore aims not to protect defined individuals from the harm they might incur from eating too much salt, but rather to reduce the overall distribution of risk across the population. While such

policies unquestionably impact choices at the individual level, they are not motivated by a straightforward presupposition that any particular individual may otherwise not act in his or her best interest, but instead by an effort to manage population-level risks.

Given this orientation, the thrust of Mill's objection against paternalism seems misplaced. What is potentially objectionable about public health policies is not that they supplant an individual's judgments about what is best for his or her own interest, but instead that they do so based upon what is best for the interest of the population at large.

If this is true, the harm principle's orientation towards concerns of paternalism fails to appropriately characterize the true liberty interests that deserve consideration and protection in public health decision-making. The risk to liberty is not, as the Millian paradigm would suggest, from government regulation that acts to know what is best for any citizen more than he himself knows, but instead from regulation that puts the interest of population-level health over the citizen's interest in determining for himself which health risks to assume.

This mischaracterization has practical implications. Failing to adequately identify what liberty interests are at issue makes it difficult, if not impossible, to ensure that those interests are given adequate protection. Recognizing the true limitations on liberty therefore facilitates conceptual clarification of the relevant issues, enabling us to identify and weigh the trade-offs involved in decisions over how--or even whether--to regulate. The more relevant question is therefore not whether or not an individual's health poses a risk of harm to others, but instead on when, and in what circumstances we, as a society, may—and may not—do to reduce health risks at the population level, with the recognition that such actions may restrict the range of individual action.

2.3.4 Exclusive Focus on the Rationale Obscures Relevant Considerations of the Law's Effects

Finally, and perhaps most importantly, by focusing exclusively on the law's rationale, the harm principle obscures consideration of what should be a central concern for liberals, namely, the *effects* of those laws on individual liberty. While the harm principle restricts the use of coercive state authority to the cases where the aim is to prevent harm to others, it places no principled limits on the use of law once the threshold of harm to others has been reached. As described by Dripps, "[t]he harm principle operates catastrophically; conduct is either harmless and therefore immune from punishment or harmful and thus fair game."[74]

Under this framing, the extent to which the harm principle will serve as a principled limit on the use of state authority rests entirely on how "harm" is understood. However, as numerous commentators have identified, the concept of "harm" presents several liabilities that undermine its ability to serve as a constraint on state authority.

A complete address of the traditional criticisms leveled against the harm principle is beyond the scope of this paper, but a few are worth noting here. First, as noted by Dripps, the concept of harm is vague, "vague enough that proponents of morals laws could frequently point to some immediate consequence of private vice that can plausibly be characterized as harm."[i] In

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[i] This criticism is perhaps most problematic for subjective conceptions of harm, in which the existence of harm is determined by individual perception. Under this reading, "if people sincerely report that they have been 'harmed' by some occurrence, they have been." *See* Smith S. 2004. The Hallowness of The Harm Principle. University of San Diego Legal Studies Research Paper Series, No. 05-07, at 20. Harm would thus either be defined as the infliction of pain, or the frustration of one's preferences.

The challenge, however, is that under this reading, the potential scope of what constitutes harm is nearly limitless, for "[a]ny sort of conduct to which some people object *will* inflict pain of various sorts and will interfere with the satisfaction of some people's preferences." As a result, the harm principle becomes entirely incapable of serving as a limit to state action, and therefore fails to give individual liberty the priority required by liberal morality.

An alternative approach to the subjective definition of harm would be to define harm in narrower terms. Mill himself suggests this approach in his description of harm as an act that injures the interests of another, "or rather (injures) *certain interests,* which, either by express legal provision or by tacit

contemporary public health debates, this is particularly challenging for assessments of non-physical harms, such as negative financial externalities borne by third-parties. It seems implausible to hold the effects of economic burdens on others as irrelevant for the purposes of regulatory decision-making. However, if economic burdens are to be considered as harms, the distinction between the realm of private behavior and that which is open to public regulation.

Second, the harm principle invites speculations of complex causal chains that, at their extreme, stretch the limits of credulity. Among the most creative attributions in the public health literature include those pertaining to motorcycle helmet laws, which have been alleged to respond to the need to protect *other motorists* from accidents caused by helmetless cyclists who may be struck by flying rocks and lose control.[75] Such arguments are also becoming increasingly prevalent as tobacco control efforts expand to restrictions on smoking in parks and other outdoor spaces, which has been alleged to protect young children from the risk of witnessing smoking behavior that might encourage future smoking.[76]

Such arguments reveal that conduct which affects oneself and that which affects others is often not an either-or distinction, but rather a matter of degree. As Mill himself notes, ""No person is entirely an isolated being; it is impossible for a person to do anything seriously or

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understanding, ought to be considered as rights." At first blush, this seems sensible; it can't be that every injury can justify legal restrictions. It isn't the role of the state to interfere if, to take an example from Mill, my business fails because you open a more successful store across the street that drives me into bankruptcy. Certainly I'm negatively affected, perhaps even deeply so, but this impact doesn't seem to merit state action.

The challenge, however, is that by making "harm" dependent on some concept of pre-existing "rights", harm becomes a *normative* concept. *See* Gray J. 2000. Mill's Liberalism & Liberalism's Posterity. The Journal of Ethics, 4(1/2): 137-165, at 147. Therefore, rather than providing an objective criterion, the harm principle instead "hinges on assessments of the relative severity of harms that, in their dependency on disputed conceptions of the good life, are inherently controversial." This constrains the ability of policymakers to maintain neutrality between different conceptions of the good, thereby undermining a central value of the liberal state. This is a particularly devastating blow to Mill's harm principle, as it deprives it of what has been presented as the chief aim of the principle, namely, to "settl[e] issues about restraint of liberty that arise between people of different moral outlooks." *See* Gray J. at 147.

permanently hurtful to himself without mischief reaching at least to his near connections, and often far beyond them."[77] Yet, as it is framed by Mill, the harm principle's ability to distinguish between impermissible and permissible reasons for state coercion is contingent upon the presence of such a distinction. In its absence, any possible protection the harm principle might provide against impermissible intrusions upon individual liberty is eviscerated.

While the issue was present even in Mill's era, this concern for the potential for expansive attributions of causal harm is magnified by two features of contemporary society. First, individuals are dramatically more interconnected than at the time of *On Liberty's* publication in 1859. Second, the tools of modern social science have dramatically expanded our contemporary understandings of causation, increasingly revealing the mechanisms by which seemingly self-regarding behavior affects others.

This expansion, coupled with the aformentioned vague nature of harm, means we are increasingly able to demonstrate that harm can be linked to nearly every human action. Consequently, the harm principle, rather than serving as a bulwark against intrusive state coercion, may in fact provide the justification for a broad range of coercive state regulations. As described by John Gray: "the problem is that, once the trip-wire set by the [harm principle] has been crossed, even trivial harms to others could sanction substantial restrains of liberty. The protection afforded the priority of liberty by Mill's principle, though apparently stringent, is for this reason in reality slight."[78]

Given contemporary understandings of causation, therefore, the relevant question is not *whether* an action causes harm, but rather explores the nature and the extent of the harm.[79] On these issues, however, the harm principle is frustratingly silent. Further, the harm principle gives little consideration for the liberty interests attached to the regulated activity--a strange omission

for a principle purportedly directed at protecting individual liberty from government overreach. As a result, the harm principle provides little guidance for how to consider and evaluate whether liberty is better protected by state regulation or by its absence.

Given these limitations, I propose that the Millian harm principle is ill-equipped to frame the relevant liberty considerations posed by questions of public health policy, and thus fails to provide adequate protection for individual liberty. I therefore suggest that we need an alternative framework, one that better supports our ability to identify and weigh the trade-offs involved in decisions over whether--and how--to regulate in the name of protecting and promoting the public's health. In Section 2.4, I propose such an alternative.

2.4 RAWLS AND THE LIBERAL PRINCIPLE OF LEGITIMACY

In Section 2.3, I argued that Mill's framing of legitimacy as dependent upon the *reasons* given for a law fails to provide adequate consideration for the *effects* of a law upon individual liberty. In this section, I will suggest that John Rawls's liberal principle of legitimacy offers a potential alternative test of legitimacy, one which places consideration of the law's effects on liberty front and center in an analysis of the appropriate scope of government authority.

Rawls describes the test of legitimacy as follows "Political power is legitimate only when it is exercised in accordance with a constitution (written or unwritten) the essentials of which all citizens, as reasonable and rational, can endorse in the light of their common human reason."[80] This, for Rawls, is the "liberal principle of legitimacy."

According to Rawls, a legitimate law is one that, among other requirements,[ii] is exercised in accordance with a legitimation-worthy constitution. Consequently, the law must be consistent with a constitution that secures the constitutional essentials established by the first principle of justice, which demands that:[81] "Each person has the same indefeasible claim to a fully adequate scheme of equal basic liberties, which scheme is compatible with the same scheme of liberties for all."[82]

In establishing this requirement, Rawls, like Mill, aims to secure for individuals a zone of non-interference over some range of choices. Unlike Mill, however, the zone Rawls protects is delineated not by the *motivation* or *reason* given for government action, but instead by the *effect* resulting from this action upon a defined set of liberties. Specifically, the legitimacy of a law is judged by its effects on basic liberties, defined by Rawls as including the following:

a) freedom of thought
b) liberty of conscience
c) the political liberties
d) freedom of association
e) freedoms specified by the liberty and integrity of the person
f) the rights and liberties covered by the rule of law [83,iii]

[ii] Frank Michelman suggests that this formulation actually creates three distinct tests, each which must be met to ensure the requirements of legitimacy are fulfilled. The additional tests include first the *procedural component*, namely, that the law must be passed in a series of events in accordance with the rules for lawmaking that are either constitutionally prescribed or prescribed in accordance with constitutional prescriptions. Additionally, the constitution itself must be what Frank Michelman has described as "legitimation-worthy." That is, the constitution must be such that it is sufficiently acceptable to individuals who hold what may be vastly different conceptions of the good, providing them with reasons that they can be expected to endorse. While I find all three tests are likely relevant in evaluating the legitimacy of public health authority, the question of whether or not a specific regulatory act meets the "content" test seems the most pressing. I therefore restrict my analysis to this question.

[iii] In presenting the basic liberties in this way, I borrow heavily from Frank Michelman. See Michelman F. The Priority of Liberty: Rawls and 'Tiers of Scrutiny'. In: Brooks T, Nussbaum M, eds. Rawls' Political Liberalism. New York, Columbia University Press, Forthcoming. Available via SSRN: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1927292. Accessed December 5, 2013.

According to Rawls, these liberties delineate the boundaries of individual freedom which legislative majorities are obligated to respect. Further, these liberties are given what Rawls terms an "an absolute weight," or special status, one which has lexical priority over considerations of social or economic efficiency, and thus cannot be traded away in order to promote policies needed for economic efficiency or growth.[84] Following from this priority, "a basic liberty can be limited or denied only for the sake of one or more other basic liberties."[85] Individuals are thus afforded a zone of protection from interferences with negative liberty, one that gives a central role to respecting the capacity of individuals to have, to revise, and to rationally pursue a conception of the good.[86]

This priority of liberty, however, is not to be read as an all-encompassing restriction on laws restricting individual freedom of action. "No priority is assigned to liberty as such, as if the exercise of something called 'liberty' has a preeminent value and is the main if not the sole end of political and social justice."[iv] The protection of liberty afforded to individuals by Rawls is distinct from libertarian liberty. Specifically, while "there is, to be sure, a general presumption against imposing legal and other restrictions on conduct without sufficient reasons...this presumption creates no special priority for any particular liberty."[87]

Instead, the priority given to basic liberties is tightly linked to Rawls's conception of the person as reasonable and rational, alternatively described as possessing the two powers of moral personality: "the capacity for a sense of right and justice (and thus to be reasonable), and the capacity for a conception of the good (and thus to be rational)."[88] The basic liberties and their

[iv] This statement reflects Rawls's modification of the initial account of the basic liberties as presented in *A Theory of Justice*, motivated by H.L.A. Hart's critical review (Hart HLA, Rawls on Liberty and Its Priority, University of Chicago Law Review. 1973; 40(3):551-55. Among his critiques, Hart noted that Rawls's initial discussion of the priority of liberty in *Theory of Justice* at times used arguments that suggested the priority of liberty was to be understood as libertarian liberty. In *Political Liberalism,* Rawls agreed with Hart's observation, and clarified how his claims related to the priority of liberty were to be understood as applying only to the basic liberties, not liberty writ large.

priority are "to guarantee equally for all citizens the social conditions essential for the adequate development and the full and informed exercise of these powers…"[89]

It would be hard to overstate the importance of these two powers within a Rawlsian conception of justice. These powers are fundamental in securing for individuals the status as a fully cooperating member of society, comprising "the necessary and sufficient condition for being counted a full and equal member of society in questions of political justice."[90] Further, these powers (in cooperation with other features of the two principles) secure for individuals the basis for self-respect, the presence of which secures for us a "sense of our own value rooted in the conviction that we can carry out a worthwhile plan of life"[91]—and the absence of which causes individuals to doubt their own value and the value of their plan of life, as well as their capacity to pursue it.[92]

From this discussion of the priority of liberty and its rationale, we are provided with a mechanism by which to adjudicate whether a specific law conforms to the content of the constitution. Laws which restrict a basic liberty are only justified insofar as they are necessary to secure one or more other basic liberties. When two liberty interests conflict, we are to look to the significance of the liberties for the development and exercise of the two moral powers. Again, quoting Rawls, "a liberty is more or less significant dependent on whether it is more or less essentially involved in, or it is a more or less necessary institutional means to protect, the full and informed and effective exercise of the moral powers."[93] Thus, when faced with such a liberty conflict, the relevant criterion that should guide our action is that which will "allow the adequate development and the full and informed exercise of [the] moral powers."[94]

While far more could be said about Rawls's liberal principle of legitimacy, I propose that this admittedly rough summary suggests three potential advantages of Rawls's conception of

legitimacy over Mill's harm principle. First, it gives central consideration to the effects of a law on individual liberty, and clearly defines which effects on liberty merit consideration. Second, it acknowledges the reality that different liberty interests often conflict; and third, it provides a means by which to adjudicate such liberty conflicts, if and when they occur.

With these potential advantages in mind, I will explore how Rawls's account of legitimacy might guide our evaluation of the legitimacy of public health regulations. I will begin by analyzing what I believe is a fairly uncontroversial case: the use of coercive state authority through public health laws aimed at the control of infectious disease. I find that Rawls's legitimacy principle, while offering greater protection for individual liberties, is nevertheless capable of justifying the use of public health authority in a situation where the use of such authority is largely uncontested. From there, I will explore recent policy debates about two issues at the forefront of modern public health: smoking and obesity. The analysis of these cases, I will argue, demonstrates that the Rawlsian framework both offers a better framework than the harm principle for the identification and consideration of relevant liberty interests posed by new public health measures, and may even offer a more robust protection for individual liberty.

2.4.1 Rawls, Individual Rights, & Public Health Authority

To introduce the account of how Rawls's liberal principle of legitimacy might be used to evaluate the legitimacy of coercive state authority, and how that approach might differ from that of Mill, I begin with a case that is generally held as a clearly legitimate role of public health authority: epidemic disease control.

The 1905 Supreme Court case of *Jacobson v Massachusetts,*[95] arguably the most famous legal decision in public health law, offers a prime example of a case in which individual liberty

was constrained in the name of protecting public health. The case involved a mandatory vaccination requirement imposed by the City of Cambridge, MA, in response to an epidemic of smallpox. The case was challenged by Henning Jacobson, who objected to the measure as an undue violation of his liberty interests. How would the Mill and Rawls each adjudicate this case?

For Mill, an epidemic of contagious disease seems to offer a clear case in which the state can be said to be acting to prevent harm to others from contagion. As this provides a legitimate reason for government action under Mill's framework, state coercion would be permitted, including the imposition of requirements for mandatory vaccination.

For Rawls, the result would be similar, but it would rest upon a somewhat different justification. To assess the legitimacy of the measure, Rawls's legitimacy principle would require us to first examine whether it violated a basic liberty. Here, the answer is straightforward: mandatory vaccination poses an obvious restriction on the basic liberty listed above as (e), those freedoms specified by the liberty and integrity of the person. The next step, therefore, is to assess whether or not this restriction is permissible: is liberty being restricted for the sake of another basic liberty?

As the justification for mandatory vaccination is to protect the integrity of the person from the transmission of infectious disease, Rawls's framework would permit restricting this liberty, as it is being undertaken so as to secure the very same liberty for others. Such restriction is wholly consistent with the state's goal of securing the equal right of each person to a "fully adequate scheme of equal basic liberties which is compatible with a similar scheme for all."[96]

In this manner, Rawls's reasoning is remarkably similar to the actual language presented by the U.S. Supreme Court in their decision upholding the vaccination requirement. Writing for

the majority, Justice Harlan notes that while the state affords considerable protections to individual liberties,

> …the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good…'Even liberty itself, the greatest of all rights, is not unrestricted license to act according to one's own will. It is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others. It is then liberty regulated by law.' [95]

In this case, the Rawlsian approach also parallels that of Mill. When assessing conduct that can physically harm others, the two principles seem to converge. Rawls's liberal principle of legitimacy therefore seems at least as good as Mill's principle in holding as legitimate a generally uncontested case of public health authority. I will now turn to examining how the principle might address contemporary public health policies for obesity and smoking, with an eye to exploring whether Rawls's principle might have some advantages to the Millian approach.

2.4.2 Obesity, Negative Externalities, and the Case of Mandatory Exercise

In the earlier discussion of the harm principle, I suggested that the principle provides inadequate protection for individual liberty. This occurs, I suggested, as a result of two conceptual ambiguities inherent in the harm principle: the vague nature of harm, and the absence of a clear-cut distinction between conduct that affects only oneself and conduct that also affects others. The issues posed by these ambiguities are thrown into sharp relief when applied to obesity, a condition that at the center of recent policy debates over the appropriate scope of government authority.

In the past three decades, adult obesity rates have more than doubled, from 15 percent in 1976-1980[97] to over 35% by 2010.[98] Recently classified as a disease in its own right,[99] obesity is also associated with a host of both short- and long-term health conditions, including heart disease, diabetes, various cancers, respiratory disorders, arthritis, and reproductive complications.[100] Consequently, obesity is associated with a 50-100% increased risk of premature death from all causes.[100]

In addition to its extensive health burden, obesity also takes a substantial financial toll. In a widely cited 2009 study on the impact of obesity on aggregate health spending, Finkelstein et al. estimated that the direct costs of obesity may be as high as $147 billion per year, or nearly 10% of total annual medical expenditures.[101] A more recent estimate by Cawley and Meyerhoefer finds costs may actually be twice as high, accounting for 20% of health expenditures ($190 billion in 2005 dollars).[102] The economic toll of obesity is even higher when indirect effects are included, such as employee absenteeism and productivity,[103] workers compensation claims,[104] and even increased fuel costs.[105]

Proponents of obesity regulation have pointed to these financial costs as justification for various policy strategies, including taxation of sugar-sweetened beverages (SSBs),[106] restricting the portion size of SSBs,[107] and menu labeling.[108] To such proponents, the case of obesity represents a market failure, as obese individuals do not bear the full cost of their condition. In the language of economics, obesity represents a negative externality problem, in which a cost is borne by an external party--in this case, taxpayers, employers, and coworkers.[109]

Thus, as a result of this negative externality, seemingly self-regarding behaviors such as diet and physical activity levels can have widespread effects on other individuals, and upon the broader society. When these effects are aggregated across the population, they can result in

substantial costs for individuals in the form of increased taxation, insurance premiums, and suppressed wages. A recent study by Cawley and Meyerhoefer estimated the annual "third party" expenditures (in the form of increased insurance premiums and taxation) at $3,220 for an obese female and $967 for an obese male.[102]

Given the magnitude of the financial costs incurred on non-obese individuals, a reasonable case can be made that the negative externalities associated with obesity constitute a harm to others that legitimates government intervention. Nevertheless, taking this harm principle approach is not without cost. While the justification of financial harms may offer support for obesity policies desired by some public health advocates, it also risks opening the door to conclusions that many liberals would find undesirable, or even abhorrent.

These risks have not been lost on critics of the so-called "nanny state." In a Fox News segment, Ann Coulter (herself an advocate of gay rights), noted that if the justification for smoking or obesity regulation is that "we all have to pick up the tab," then a consistent approach might demand restrictions on gay bathhouses, given the societal costs of HIV/AIDS.[110] Similarly, in a scathing commentary on recent public health policy proposals, Jacob Sullum argued that, if the financial harms of obesity justify taxes on junk foods or bans on fast food restaurants, then they also could justify mandatory calisthenics in the town square.[111]

The critiques by Coulter and Sullum suggest the harm principle may prove deficient as an external constraint on government authority in public health. Once a plausible case has been made for considering such negative externalities as harms, Mill's harm principle can no longer serve as a limit on government intervention. Instead, rather than providing a protecting zone of non-interference for individual liberty, the harm principle may actually serve as the *justification*

for a broad range of intrusive government activities. Thus, "[t]he principle that was once a shield of individual liberty has been forged into a sword against it."[112]

Critics of expansive public health authority have argued that the fault lies not with the harm principle itself, but rather with arguments for public health policies that "boot-strap" a justification for further government intervention based upon existing government interference in the market. The remedy, they argue, is not to do away with the harm principle, but rather to end the government-subsidized programs such as Medicare and Medicaid which force individuals to pay the health care costs resulting from other people's unhealthy decisions. As taxpayer-funded subsidization of health care is itself objectionable, they argue, using financial harms as the justification for regulation would only exacerbate existing infringements on individual liberty resulting from a system of redistributive taxation.

This objection, however, takes too narrow a view towards the financial impacts of obesity. It is certainly true that government programs such as Medicaid, Medicare, and the insurance subsidies offered through the Affordable Care Act create a system of cross-subsidization in which one person's decision to choose fries over broccoli results in financial implications for others via taxation. However, the financial costs of obesity affect other individuals in diverse manners unrelated to these government programs, perhaps most significantly through the risk pooling in insurance that leads to increased premiums for individuals and/or their employers. While government-funded insurance programs may exacerbate the financial negative externalities associated with obesity, they are far from the sole contributor. Therefore, the issues associated with a harm principle approach are not easily explained away by ending government subsidization of health care.

In contrast, the Rawlsian principle of legitimacy seems to provide a robust defense of liberty against the "mission creep" risk that worries Coulter and Sullum. For example, Sullum's proposal of mandatory exercise would clearly infringe on the basic liberty associated with (e), the freedoms specified by the liberty and integrity of the person. As the priority of liberty prohibits basic liberties from being traded away for considerations of social or economic efficiency--including those resulting from costs associated with obesity--the Rawlsian legitimacy principle could clearly strike Sullum's proposal as an illegitimate use of government authority.

Unlike the Millian approach, however, the Rawlsian approach does not require a categorical decision on the legitimacy of obesity policies motivated by economic considerations. By focusing on the effects of the regulatory approach on individual liberties, rather than the justification, Rawls's principle still gives space for other, less intrusive obesity interventions. For example, under a Rawlsian framework, menu labeling requirements would seem to fall well within the permissible scope of government authority. While the regulation compels restaurant owners to display caloric information on menus and menu boards, requiring a factual disclosure of information parallels commonly accepted standards of disclosure, including product liability law requirements that manufacturers warn about (some of) the dangers associated with their goods, or the requirements of informed consent that health care professionals warn of the risks and benefits of medical procedures.[113] Rawls's decision here would therefore likely parallel that of the 2nd circuit, which upheld NYC's regulations, holding that the First Amendment protections of restaurants to engage in commercial speech was not violated, as the law in question mandated (only) a "simple factual disclosure of caloric information" that was "reasonably related to New York City's goals of combating obesity."[113] Further, while the policy may affect basic liberties of restaurant patrons with respect to liberties (a) and (b), freedom of thought and liberty of

conscience, it arguably acts not to *restrict* such liberties, but rather to *promote* them, for the requirement for the provision of basic, factual information brings more, not less, speech into the information marketplace. While the regulation deliberately places the information where individual consumers are apt to notice it, a placement which may admittedly—even deliberately—work to shape individual choices, individual consumers are nevertheless free to ignore the information provided.[114]

This analysis demonstrates the contrast between the two approaches of Mill and Rawls. For Mill, the inquiry turns entirely upon whether or not a harm can be said to exist. Once a harm is demonstrated, there is no means by which to distinguish the appropriate form or extent of coercive government strategies to address the harm. In contrast, by focusing on the *effects* on liberty, Rawls's liberal principle of legitimacy provides a test by which to distinguish between impermissible and permissible uses of government authority to address obesity. Calorie posting laws, posing no restriction on basic liberties, are permissible. Mandatory exercise laws, in contrast, infringe the integrity of the person (and not for the sake of any other basic liberty), and are therefore out.

2.4.3 Extending Smoking Regulation into Private Homes: The Case of Belmont City, CA

The Rawlsian approach may also offer some advantages over the Millian approach in assessing the legitimacy of a recent shift in smoking regulation. In 2007, the City of Belmont, California, citing the medical and economic toll of tobacco smoke for nonsmokers, passed an ordinance prohibiting smoking in a range of settings, including indoor and outdoor workplaces; outdoor spaces such as parks, sports fields and stadiums, and recreation trails; and multi-unit housing residences.[115]

On one hand, Belmont's action represents only the most recent in a decades-long rise in regulatory action aimed at reducing the harms of secondhand smoke. Driven by a steadily accumulating body of epidemiologic research secondhand smoke exposure to numerous health problems, including elevated risks of lung cancer, cardiovascular disease, and acute asthma episodes, legislative bodies at all levels of government have steadily moved to restrict smoking within enclosed spaces, including transportation on planes and buses, as well as in schools, restaurants, and private workplaces.

On the other hand, Belmont's actions may also be seen as a dramatic break with earlier tobacco control efforts. By banning smoking in multi-unit residences such as apartments and condominiums, Belmont's actions extend tobacco regulation into private homes—spaces long considered to be "beyond the legitimate reach of (tobacco) regulation."[48] Additionally, by drawing a distinction between multi-family and single-family homes, Belmont's actions have raised considerations of fairness. By focusing on the harm to others posed by secondhand smoke, Belmont City's policy applies a different standard of regulation to citizens based upon their housing status. As a result, the city's approach may disproportionately affect low-income and minority residents, who are more likely to live in multi-family households. Taking a different perspective on fairness, the ban might also work to remediate an existing disparity, as low-SES and minority populations are also disproportionately affected by secondhand smoke.[116,117]

With respect to each of these considerations, Mill's principle seems to offer little guidance, as neither privacy nor fairness are considerations that are easily incorporated into a Millian evaluation of legitimacy. From the perspective of the harm principle, the issue of legitimacy is decided solely upon the basis of whether a harm to others exists. On this issue, the

harm principle seems to offer clear guidance. While "harm" is a contested concept, there is generally little dispute that the negative health effects of secondhand smoke are legitimate grounds for government intervention. Further, there seems to be sufficient evidence that secondhand smoke can pose a risk to health in multifamily homes. The epidemiological literature is replete with studies documenting the associations between exposure to secondhand smoke and numerous health problems, including elevated risks of lung cancer, cardiovascular disease, and acute asthma episodes. Evidence also exists that tobacco smoke can move so as to affect other units in a multiunit residential building beyond that of the smoker, via such conduits as air ducts, cracks in walls or floors, elevator shafts, or even plumbing and power lines.[48,118]

In light of both the known effects of secondhand smoke, as well as the potential for secondhand smoke to travel into other residential units within a multiunit building, this regulation seems to sit squarely within the bounds set by the harm principle. As the health effects of secondhand smoke within enclosed spaces can be clearly demonstrated, a legitimate motivation exists to justify state regulation that restricts individual liberty.

While this rationale can provide justification for a law that advances a public health goal, it is nevertheless silent about the two complaints at the center of recent debates over the measure. To be fair, nothing about the harm principle says the state *must* regulate (harm is a necessary, not sufficient condition). The harm principle would certainly leave open the possibility to weigh considerations of fairness against the potential health gains and make a determination of whether the policy should be implemented. Nevertheless, the fact remains that there is nothing within the harm principle that allows such considerations to be evaluated as matters of *legitimacy*--they would only be included as matters of pragmatism.

To these limitations, I suggest, the Rawlsian principle of legitimacy may offer at least a partial remedy. First, while privacy is not listed among the basic liberties, the principle might still provide some guidance for how it should be included in considerations of legitimacy. Further, the demand for *equal* basic liberties builds in consideration for the differential effects of regulation on different population subgroups. In the remainder of this section, I will discuss each of these considerations.

At first blush, there is little in the legitimacy principle that would seem to demand considerations of privacy. No explicit protection for privacy is included in the equal basic liberties. Furthermore, there is nothing in the legitimacy principle that would suggest that the home is somehow to be considered off-limits from either government regulation or the demands of justice. On the contrary, Rawls is quite explicit to refute such claims broad claims for privacy, claiming "If the so-called private sphere is alleged to be a space exempt from justice, then there is no such thing."[119] Any value attached to private space exists only insofar as the home works to secure for individuals the conditions necessary for the protection of the basic liberties and the development and exercise of the two moral powers.

Nevertheless, the Rawlsian framework might be seen as providing a contextual argument for privacy.[120] Specifically, privacy might be seen as demanding protection because it creates the contextual conditions necessary for the exercise of other activities deemed essential. For example, privacy enables development of individuality by allowing individuals the space to differentiate between their own thoughts and feelings and those of others[120]—a clear requirement for the development of the capacity for an independent conception of the good. Further, by restricting physical access to an individual, privacy insulates the individual from distraction, a freedom "essential for all human activities that require concentration,"[120] especially, it might be

argued, the development of moral judgment associated with the capacity of reasonableness, or the willingness to accept fair terms of cooperation, provided others are willing to do likewise. Consequently, privacy might be seen as implicating (at least) three basic liberties: freedom of thought, freedom of association, and liberty of conscience.

In this way, Rawls's principle offers at least a framework by which we might consider privacy-based arguments. For example, it might suggest the need for consideration as to the privacy implications associated with the law's enforcement, as permitting state intrusion into the home for purposes of ascertaining smoking behaviors might undermine the protections necessary to secure basic liberties implicated in an individual's development and exercise of the two moral powers. If enforcement had this effect, it would suggest that Belmont's law presents an example of a case in which liberty interests might be said to conflict. Faced with this conflict, we would then look to the significance of the liberties for the development and exercise of the two moral powers.

Admittedly, these considerations do not offer a straightforward answer on the issue of whether privacy-based claims might be sufficient to render Belmont's actions as impermissible. Nevertheless, the liberty principle offers at least the means by which to acknowledge that liberty interests might be in tension, while providing some guidance as to how to weigh the competing liberty interests.

Finally, we turn to how the Rawlsian approach might inform considerations of fairness. Here, the guidance from Rawls seems more straightforward. Rawls make clear that compliance with the principle of justice demands that individuals have "an equal right to a fully adequate scheme of equal basic liberties which is compatible with the same scheme of liberties for all."[121] Thus, in evaluating the effects of the smoking ban, we are directed to weigh not only the effect of

the law on basic liberties, but also how the distribution of those liberties works to affirm the status of individuals as free and equal persons. Rawls's principle therefore goes beyond Mill, demanding not only considerations of the risks associated with secondhand smoke, but also considerations of how the burdens of both smoking and its regulation are distributed. Again, while a Rawlsian analysis might get us to the same place as Mill in holding the ban as permissible, it seems better able to acknowledge and consider considerations of particular importance to liberalism.

Therefore, the case of smoking in private homes provides an example of a case where the Rawlsian legitimacy approach may provide a justifiable objection to a policy for which Mill could offer no objection. While the test of legitimacy ends, for Mill, with a determination of harm, the Rawlsian approach provides a framework for consideration of other morally relevant features, including the impact of the regulation on privacy and fairness.

2.5 POTENTIAL OBJECTIONS TO THE RAWLSIAN APPROACH

While the Rawlsian principle seems to offer advantages over the Millian approach in aforementioned cases of epidemic smallpox control, obesity, and smoking, it may admittedly face other limitations. One potential criticism of the Rawlsian approach is that provides no general doctrine of a class of aims or concerns that are simply off-limits to government regulation. Therefore, while the principle can strike down an intervention for excessive infringing upon individual rights, it excludes arguments that a law is illegitimate for extending the state's authority into an area that is altogether inappropriate for state action.

In excluding such claims, Rawls's principle may be limited in its ability to protect activities traditionally defended by liberals as areas inappropriate for government regulation. Thus, as noted by H.L.A. Hart:

> …it seems obvious that there are important forms of liberty —sexual freedom and the liberty to use alcohol or drugs among them—which apparently do not fall within any of the roughly described basic liberties; yet it would be very surprising if principles of justice were silent about them.[122]

If the legitimacy principle were to be silent on these issues, the Rawlsian approach might seem unable to defend against various illiberal uses of the law, including the use of the law to enforce morality. On this point, Mill seems to have a clear advantage. The harm principle, in no uncertain terms, holds that it is not a legitimate function of the state to punish conduct simply on the grounds that it is immoral. In contrast, Rawls cannot set such laws as simply outside the legitimate scope of government authority.

This may pose a real limitation of the Rawlsian approach with respect to certain laws that some liberals might find objectionable. Nevertheless, I suggest the scope of this risk is narrower than it might first appear. Specifically, I believe the basic liberties do offer robust protection for many such laws. Take, for instance, laws restricting sodomy or fornication. While Rawls cannot categorically exclude such restrictions, his approach nevertheless offers substantial protections for liberty of conscience that would greatly limit the permissible scope of such liberty-limiting restrictions. For, as Frank Michelman has previously argued with respect to Rawls's basic liberties, liberty of conscience is must be understood as protecting:

> not just the allowance of being internally in touch with one's conscientious deliberations and occasion-specific deliberative outcomes, but the allowance *to live out* one's conscientious convictions and decisions—to give them, in that way, expression and endorsement…claiming them as one's own in the only way that can be fully and finally credible to oneself and others.[123]

At minimum, the protection of liberty of conscience therefore offers substantial protection for sexual freedoms, which can be viewed as central to an individual's conception of the good. Therefore, while Rawls does not expressly prohibit the entire class of such objectionable laws, his principle may nevertheless offer protection against at least the most egregious forms.

An additional response to Hart's concern is suggested by Michelman's observation that Rawls's statement of the two principles of justice (and the associated discussion of the liberal principle of legitimacy) "does not exhaust the normative content of the political conception of justice as fairness."[124] The normative content of Rawls's conception of justice also includes an expectation about how those constitutionally protected liberties will have their meanings filled out in application. This application includes, among other things, Rawls's conception of public reason, which governs the way in which citizens should "deliberate together about the fundamental questions of their political life."[125] When engaged in political deliberation, citizens should reason from premises which they all can acknowledge. Substantive views of what the good life is, or what makes for a good life are therefore excluded from debate over what is and is not a basic right.

To explain how the requirement of public reason can further inform contested debates over the extent of liberty, Michelman offers the case of same sex marriage. If the debate over same sex marriage is restricted within the bounds of Rawlsian public reason, the most common objections to same-sex relationships would be excluded. Opposition to same-sex relationships, according to Rawls, can only reflect some religious or otherwise sectarian comprehensive moral doctrine, reasons that fall outside the scope of public reason.[126]

Incorporating the demands of public reason therefore seems to offer additional protections for at least some forms of liberty identified by Hart. For questions of constitutional essentials

and basic justice, Rawlsian public reason will serve to substantially restrict, if not outright exclude, many controversial restrictions on liberty not explicitly addressed by the basic liberties, including such issues as contraception, same-sex partnerships, and abortion. It is less clear, however, what response Rawls might offer to Hart regarding day-to-day legislative deliberations, to which the demands of public reason do not apply.

One possible response would be to bite the bullet and concede that Rawls's principle would not hold as illegitimate many of the restrictions on liberty to which Hart refers, including regulations pertaining to the use of alcohol or drugs. We might therefore understand Rawls's principle as setting up a system akin to the two-tier model of scrutiny applied by U.S. courts in judicial review.[123] Under this reading, only those regulations affecting basic liberties would merit the heightened review demanded by the liberal principle of legitimacy. All other regulations would be required only to meet a lesser standard, akin to the rational basis test in U.S. constitutional law, demanding only that the government's goal be a legitimate public interest, and the means selected be reasonable to meeting that (public health) goal.

Thus, while I have proposed the scope of Hart's concern is narrower than initially supposed, I concede that further work need to be done to identify whether and how a more complete response might be offered from within Rawlsian theory.

2.6 CONCLUSION

The traditional framing of Mill's harm principle as the test for legitimacy in public health is plagued with numerous shortcomings. Given these shortcomings, an alternative mechanism is needed by which to determine when public health authority is permissible—and when it is not. In this essay, I have suggested that Rawls's liberal principle of legitimacy provides one such

potential alternative. To support this proposal, I have provided a sketch of how the Rawlsian approach might frame our evaluations of policies in three areas: epidemic smallpox control, obesity regulation, and bans on smoking in private homes. These cases suggest that the Rawlsian approach might be least as good as Mill's in evaluating well-accepted public health measures such as infectious disease control, while potentially offering advantages in the evaluation of newer measures such as those targeting noncommunicable disease.

From this sketch, I cannot claim that the legitimacy principle will prove superior to the harm principle in all domains of public health regulation. My proposal for the legitimacy principle as an alternative to Mill is, admittedly, a work in progress. I have, however, proposed where further work is needed, including additional testing of the principle across various legal strategies targeting noncommunicable disease; and Hart's objection regarding the apparent limitations of Rawlsian basic liberties to respond to restrictions of such non-basic liberties such as sexual freedom.

I also leave open the possibility that other liberal approaches to legitimacy, beyond those offered by Mill or Rawls, may ultimately prove more defensible. The search for alternative principles of legitimacy demands considerable analysis beyond the limited scope possible in this chapter. At the very least, this paper should encourage further exploration of such alternatives.

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CHAPTER 3

Institutional Oversight of Faculty-Industry Consulting Relationships in U.S. Medical Schools: A Delphi Study

3.1 BACKGROUND

Consulting relationships between medical school faculty and the biopharmaceutical and medical device industries offer the potential to advance research and promote the translation of academic discoveries into applied technologies that can benefit the health of individuals and populations. Such relationships are common,[127,128] and studies suggest that faculty with industry relationships are more productive than their peers without such relationships, achieving higher rates of publication and conducting more service activities within their institutions or disciplines.[127] Yet while interactions between faculty and industry can be beneficial in promoting innovation and improvement within our health care system, academic inquiries,[129,130] government hearings,[131,132,133,134] and related litigation[135,136] have called attention to the potential risks associated with these relationships.

Consulting relationships include a broad range of activities in which a faculty member provides advice or services to companies whose activities, products, or services relate to his/her area of professional expertise, typically in exchange for payment. Consultants may act as individual contractors or as members of a board (e.g., scientific advisory board, board of directors, or data and safety monitoring board).

Prior research on consulting relationships has primarily focused on the ethical issues surrounding financial conflicts of interest. According to an Institute of Medicine committee

report, a conflict of interest is "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."[137] From this perspective, industry ties raise concerns that faculty members may be financially incentivized to act in a manner that is inconsistent with their primary duties to universities, patients, research participants, trainees, and scholarly collaborators. As prior observers have noted, these incentives may lead to various forms of problematic behavior. Within clinical trials, financial incentives may lead investigators to inappropriately enroll patients in clinical trials,[138,139] bias trials' design, conduct or analysis,[140] or withhold results that are inconsistent with the economic objectives of the industry partner.[141,142,143] In addition, financial relationships may adversely affect the broader academic environment. They may discourage open dissemination of research information and collaboration among academic colleagues or lead researchers to prioritize projects directed at specific industry goals.[144] As a result, commentators have raised the concern that financial relationships with industry may undermine the quality and trustworthiness of academic research, which may in turn jeopardize the public's trust in both medicine and scientific inquiry.[145,146,147]

While financial conflicts of interest are well-studied, less attention has been paid to legal aspects of consulting activities. Of particular interest include the terms of contracts that govern faculty-industry interactions. Prior studies of a related topic, the terms of contracts for industry-sponsored clinical trials, have raised concerns that companies may use such agreements as a vehicle to exert inappropriate control over academic researchers.[148,149] One recent study indicates that medical schools and schools of public health generally do not exercise oversight to prevent similar problems in the context of consulting agreements.[150]

In this article, we report on a Delphi study of medical school administrators with expertise in the management of faculty consulting agreements. Our primary purpose was to evaluate potential approaches for the oversight of such agreements so as to provide guidance for the management of faculty-industry consulting relationships.

Consulting agreements may contain a wide range of provisions that restrict the freedom of faculty members in ways that may adversely affect their academic responsibilities and the interests of their universities. These "restrictive provisions" might include limitations on the ability of faculty members to publish or disseminate information, make public statements that may be detrimental to the company's interests, or participate in future professional activities, such as receiving grants or research contracts within a certain subfield. These restrictions have the potential to curb academic and intellectual freedoms. Although the prevalence of such provisions has not been measured, prior reports by faculty and research administrators on consulting agreements suggest they are far from infrequent.[150,151]

These restrictive provisions affect not only the interests of the faculty member, but also those of the university with which they are affiliated. This is clearly evident in the case of contract terms pertaining to intellectual property interests, which may conflict with other agreements the faculty member has entered into with the university concerning ownership of inventions.[152] Other contractual provisions also may reach beyond the interests of the faculty member to affect those of his/her institution and other parties, including research collaborators, trainees, and students. Such provisions include confidentiality restrictions that extend to the dissemination rights of the faculty member's students or trainees, or company assertions of intellectual property interests in the work of students or trainees.

The issues raised by financial conflicts of interest have inspired efforts to mitigate the effects of these conflicts. These include guidelines from the National Institutes of Health,[153] and the Association of American Medical Colleges,[154] recommendations from the Institute of Medicine,[155] uniform requirements for manuscripts submitted to biomedical journals,[156] and more recently, federal requirements for disclosure of relationships under the Physician Payment Sunshine Act.[157] However, aside from "conflicts of commitment" policies, which focus narrowly on ensuring that faculty do not devote excessive time to outside activities, neither legal rules, nor professional guidelines, nor expert consensus statements have emerged to guide medical schools in managing the non-financial aspects of consulting relationships. Several organizations, including the Association of American Universities, in collaboration with the Business–Higher Education Forum,[158] and the Association of American Medical Colleges (AAMC)[159] have recommended general safeguards and institutional procedures for the management of academic–industry ties. These recommendations have drawn special attention to the need to avoid conflicts of interest that may compromise the integrity of clinical trials and the welfare of trial participants. However, they do not generally address nonclinical research, including in vitro tests of drugs and devices or other studies that do not utilize human subjects, or non-research activities that faculty pursue as consultants, including the provision of advice on marketing or business development and expert witness testimony.

In the absence of external guidance on the oversight of consulting agreements, academic medical centers vary considerably in the stance they have taken towards these relationships,[150] and have adopted a wide range of oversight mechanisms. Examples include school-level policies restricting the percentage of time faculty may devote to outside activities (e.g., limiting to 1 day in a 5 or 7 day week) or the amount of outside income allowed as a proportion of annual salary.

While some institutions have banned selected activities, such as speakers' bureaus or ghostwriting, most exercise little or no oversight that extends beyond conflict-of-commitment and financial conflict of interest concerns.[160]

Of particular interest is the level of scrutiny that medical schools give to the terms of consulting agreements between faculty members and industry. Research suggests that there is significant variation within the academic community in both the nature and scope of oversight. In a study of 127 medical schools and schools of public health, less than 20% of institutions reported that they required review of all consulting agreements, 15% required review of some types of agreements, 34% offered some form of optional review, and 30% had no review available.[150] Among institutions that review faculty consulting agreements, wide variation exists in both the types of issues reviewed and the responses to problematic provisions. In reviewing consulting agreements, many institutions focus solely on the institution's intellectual property rights, with only a minority taking a broader perspective that incorporates such considerations as academic freedom. Institutional responses to troubling provisions also vary considerably; approximately a third may prevent the faculty member from signing the contract, while the majority merely bring the issue to the faculty member's attention and permit him/her discretion in how to proceed.[150]

In the present study, we enlisted a panel of experienced medical school administrators to evaluate a range of potential approaches for oversight of faculty-industry consulting agreements. We sought to use these insights to develop recommendations for the improved management of consulting relationships. Our findings highlight the types of contractual provisions that merit oversight, identify strategies for managing consulting agreements to protect important interests, and suggest key considerations for implementing these strategies.

3.2 METHODS

We used modified Delphi methods to elicit administrators' views about the oversight of faculty-industry consulting relationships. The Delphi process, developed by RAND, is a method of structuring group communication to facilitate problem solving and synthesize expert opinion.[161,162] The technique has been used widely in health research, addressing ethical questions posed by conflicts of interest,[163] research and health priorities,[164,165] methodological criteria for randomized controlled trials,[166] and the development of nursing and clinical practice guidelines.[167,168,169, 170] Typically, a panel of experts, usually 7-15 individuals, is selected for participation. This size is large enough to permit diversity of representation while being small enough to allow everyone adequate voice in the process.[171] A survey is conducted in 2 or more rounds, using questionnaires designed to elicit and develop individual responses to the research question so as to enable the expert panel to refine its views.

Following each round, the research team aggregates the responses and disseminates the data to the panelists, asking them to consider others' responses in answering the same questions again in subsequent rounds. This feedback enables clarification of issues, identification of areas of agreement and disagreement, and understanding of priorities. This iterative process of feedback and review proceeds until the group reaches convergence on their perspectives of the issues examined, or until a predetermined number of survey rounds have been completed.

Although aggregate responses are provided to all participants, opinions are not attributed to specific panel members. This anonymity fosters expression of opinions and supports evaluation based upon the merit of the viewpoint rather than the status of the individual expressing it. Anonymity also may minimize the need to "save face," enabling individuals to change their views between rounds in response to the insights of their peers.

Four characteristics of the current study make it particularly appropriate for exploration using the Delphi process. First, developing an understanding of the problems, opportunities, and solutions presented by institutional oversight of faculty consulting agreements is a challenge that can benefit from analysis of subjective judgments from multiple perspectives.[162,172] Second, developing "best practices" requires the exploration and assessment of numerous options for oversight mechanisms, which can benefit from the pooled judgment of relevant experts.[162,172] Third, the anonymity provided by the Delphi method's structure reduces the influence of certain psychological factors, including the bandwagon effect of majority opinion and domination of the communication process by one vested interest or strong personality.[173] Finally, experts in this field have substantial time constraints and are widely dispersed geographically, making face-to-face meetings infeasible. The flexibility of the Delphi method enables participants to contribute according to their own schedules, minimizing burdens that might otherwise limit response rates.

3.2.1 Participant Selection

Selection of the expert panelists in a Delphi study is a critical step, as their judgments form the basis of the study's conclusions. For this study, we recruited institutional administrators with responsibility for, or extensive knowledge of, institutional oversight of faculty consulting relationships at U.S. medical schools. We selected this population because administrative officials are highly knowledgeable about relevant institutional policies and practices and the rationale for the approach the institution has taken to oversight of faculty consulting agreements.

Our initial sampling frame was derived from a prior study in which we identified institutional officials within 127 accredited allopathic medical schools and schools of public health in the U.S. who had responsibility for institutional oversight of faculty consulting relationships.[150] Because our earlier research suggested considerable heterogeneity across

schools in their approaches to oversight, with some institutions reportedly having devoted little thought or attention to the issue, we aimed to recruit participants from those institutions that had given serious consideration to whether and how the school or university should attempt to manage the nonfinancial aspects of consulting relationships.

We selected experts using a two-stage process. First, we developed an initial list of medical schools using the following screening criteria, based upon findings from our prior research:

(1) An institutional representative completed our earlier interview study of institutional consulting policies and agreed to be contacted for further research inquiries, *and;*

(2) based on interview responses, the institution met *any* of the following conditions:

   (a) It had a required or optional review mechanism in place for consulting agreement oversight;
   (b) It had previously given serious consideration to the oversight of consulting agreements;
   (c) It was contemplating changes to its oversight of or approach to consulting agreements;
   (d) It had recently altered its procedures for oversight of or approach to consulting agreements; or
   (e) Its representative in our earlier interview study had offered detailed comments as to the relative merits or limitations of at least one oversight mechanism.

Through application of these criteria, we arrived at an initial list of 29 candidate schools.

Second, to prioritize participation by those institutions likely to have a high concentration of faculty consulting relationships, we ranked eligible institutions based upon their receipt of National Institute of Health grant funds as a proxy for research intensity, which we expected would be correlated with faculty being sought out as consultants. We recruited individuals from

the list until reaching our target number of 12 experts.

We recruited participants via email and offered a $450 incentive for their estimated 4.5 hours of participation. Participants' informed consent was obtained and the study was approved by the Institutional Review Board of the Harvard School of Public Health, which also reviewed the study on behalf of the Dana Farber Cancer Institute and Partners HealthCare.

3.2.2 Delphi Process

We conducted this study in three stages: a first round survey, a second round survey incorporating summary results from the initial round, and a final panel teleconference.

3.2.2.1 Survey Structure

Guided by the findings of our prior interview study of research administrators,[150] we designed a 48-item survey instrument with structured response categories to elicit feedback on how institutions should approach three issues: the types of contractual provisions that may merit oversight; the oversight mechanisms schools may consider to manage consulting relationships; and whether medical schools should prohibit consulting for specific industries. Participants were also asked to provide comments to explain their ratings.

To elicit feedback on the types of contractual provisions that may merit oversight, we developed a typology of restrictive provisions, based upon our earlier interview study.[150] Participants rated the importance of oversight for 14 restrictive provisions using a 9-point scale. A rating of 9 indicated that oversight of the provision was extremely important, whereas a rating of 1 indicated oversight was extremely unimportant. To interpret importance, we divided the scale into three-point ranges, using the following definitions modified from the RAND/UCLA appropriateness method: *important:* panel mean of 7-9, without disagreement; *uncertain*: panel

mean of 4-6, or any mean with disagreement; *unimportant:* panel mean of 1-3, without disagreement. Agreement and disagreement were determined by a modified classification structure established by the BIOMED Concerted Action on Appropriateness for panel sizes from 11-13, where *agreement* is achieved when no more than 3 panelists provide ratings outside the 3-point region containing the mean (1-3; 4-6; 7-9). Participants also rated whether or not each provision was permissible, based upon a three-point categorical scale developed for this study (should generally be permitted and requires no institutional oversight; may be permissible, but only with institutional review and/or modification; and should generally be prohibited).

Participants also rated 6 oversight mechanisms that schools might consider for the oversight of consulting agreements, based upon current practices as identified in our interview study: 1) mandatory review, 2) optional review, 3) required standard provisions, 4) negotiation assistance, 5) educational training, and 6) inclusion of the school as a party to the agreement. For each provision, participants were asked to rate the oversight mechanisms along 3 dimensions aimed to capture both their theoretical appeal and their practicality. A 9-point scale was used for each dimension. Participants first rated the *logistical feasibility*, a measure of the logistical burdens for implementation of the mechanism, including resource availability, legal barriers, and necessary expertise. Participants then rated the level of *faculty support*, or how easy or difficult it would be to attract the necessary level of support from medical school faculty to enable implementation. Finally, participants rated the *overall advisability* of each mechanism, to provide an overall indication of the extent to which they would advise for or against adoption of the proposed mechanism.

Finally, participants considered whether faculty members' consulting relationships with any industries, from a prespecified list of 10 industries, should generally be prohibited.

3.2.2.2 Round 1

We conducted the first round survey using REDCap Survey, a secure, web-based application. Participants completed Round 1 between November 2012 and January 2013. After all responses were collected, the research team generated descriptive statistics to identify the mean scores and distribution of responses to each question. For each question, one member of the research team (SM) reviewed respondents' qualitative comments and synthesized them into a list of explanations for high and low ratings.

3.2.2.3 Round 2

The second survey was fielded in February 2013. During Round 2, we provided participants with the distribution of responses to each question from Round 1, as well as a reminder of their own scores from the earlier round. We presented quantitative ratings using histograms and provided the lists summarizing the free-text explanations given for high and low ratings. We then asked participants to reconsider each question in light of the ratings and comments of their peers, and then again to provide ratings for each. As with the first round, we provided space for participants to explain their ratings. Because of the limited formatting capabilities available in REDCap Survey, we conducted Round 2 by emailing questionnaires to participants as Microsoft Word documents. Participants returned their completed surveys via email or regular mail.

3.2.2.4 Final Teleconference

We drafted a report summarizing the results of the second round survey, including preliminary analyses of the study's implications for institutional policies governing faculty-industry consulting relationships. This report was circulated to all participants. We then

convened a 90-minute panel meeting with all respondents via teleconference. During this meeting, respondents were asked questions about their reactions to the report. They were also asked to suggest recommendations about oversight strategies, and to provide recommendations as to how the study results might inform policies regarding management of consulting activities. One investigator took detailed notes during the call, which were used to develop the recommendations presented at the conclusion of this paper.

3.3 RESULTS

Of 13 persons invited, 12 agreed to participate and 11 completed all aspects of the study. Table 3.1 summarizes the characteristics of the expert panelists. Although most had at least one graduate degree, educational backgrounds varied considerably. Almost half of participants (45%) were lawyers. The majority of participants were from the Northeast (55%), but each of the four census regions was represented by at least one participant. Eight of the 11 schools were private medical schools, while the remaining three were public institutions.

The participants' job titles were diverse, reflecting the heterogeneity of administrative and organizational structures across U.S. medical schools. Typical titles included senior roles within offices of research compliance, technology transfer, industry relations, conflicts of interest, and general counsel.

TABLE 3.1: Demographic Characteristics of the Expert Panel (N=11)

Participant Characteristic	#
Gender	
Female	6
Male	5
Educational Training	
JD	5
Medicine	1
PhD	1
Other	4
Years of Experience[†]	
1-5 years	0
6-10 years	7
11+ years	4
Institution Type	
Private	8
Public	3
Census Region	
Northeast	6
Midwest	3
South	1
West	1

[†]Years of experience was defined as number of years overseeing faculty research and outside activities.

3.3.1 Need for Oversight of Restrictive Provisions within Consulting Agreements

The panel rated the importance of oversight and permissibility of 14 restrictive provisions that may be found in faculty consulting agreements (Table 3.2). We grouped the provisions into 4 broad categories: provisions related to publication and dissemination, provisions related to intellectual property, provisions related to confidentiality, and other. The other provisions addressed a range of issues, including future research-related activities, liability, and scope of work.

The panel reached agreement (based on the prespecified threshold for "agreement" described above) that 6 provisions should generally be prohibited: restrictions on publication or dissemination that do not specifically reference the scope of consulting services, provisions that grant the industry partner ownership of the work of the faculty member's collaborators or trainees, provisions that grant ownership rights to products that "relate to" materials or information obtained in the consulting relationship, provisions that require signed confidentiality agreements from students or trainees, restrictions on future research-related activities, and "supremacy clauses" asserting that the faculty member's legal obligations to the company trump his/her obligations to the university or affiliated hospital employer.

For an additional 6 provisions, panelists agreed that oversight is *important*, but did not necessarily agree that these provisions should be prohibited. For 2 of these provisions—a statement granting company ownership of intellectual property rights generated within the scope of consulting services (Mean Importance=7.8), and a statement defining the scope of work so broadly as to potentially encompass some of the faculty member's academic work (Mean Importance=8.5)—panelists agreed that such provisions "may be permissible, but only with institutional approval and/or modification."

The panel disagreed as to their permissibility of the remaining 4 provisions; a

requirement that the faculty member disclose to the company the results of research prior to public dissemination; a restriction on public statements that could be detrimental to the company's interests; a statement granting the company ownership of intellectual property not limited to that generated within the scope of consulting services; and a statement defining "confidential information" that may be sufficiently broad to encompass information held by the faculty member before the start of the consulting relationship, or acquired after the relationship ended. For these provisions, the panelists' comments reflected the perceived importance of review (and perhaps modification) of the relevant contract language to ensure institutional interests were protected, but nevertheless held that such provisions might be permissible if appropriately worded. For example, panelists offered comments explaining that it may be permissible for a company to require a faculty member to disclose the results of scholarly research to the company before public dissemination. However, such disclosure should be limited solely to research related to the consulting activities. Further, it should only be permitted for the purposes of protecting pre-determined proprietary or confidential information, and not to modify or restrict the dissemination of unfavorable results.

Notably, the panel agreed it was important for medical schools to have an oversight mechanism for all but 2 of the provisions, suggesting broad agreement regarding the need for review to protect the interests of medical schools and their broader institutions (Mean Importance: 7.8-9). Several panelists expressed concern with any publication restrictions in consulting contracts, finding them to be contrary to the "heart of the academic mission," while others held that restrictions might be permissible if there was no overlap between the consulting activities and a faculty member's academic work. Notably, several participants who viewed such a provision as permissible explained this belief in reference to a broader commitment that

faculty members should not engage in *research* as consultants. From this perspective, publication restrictions would be less problematic, as consulting activities would be unlikely to generate generalizable findings of potential public importance.

Finally, panelists judged oversight of a statement pertaining to the faculty member's acceptance of legal liability as least important (mean=5.1). The panel was divided as to the importance of review for this provision (range: 1-9), and was similarly divided as to its permissibility. While most experts recognized the potential risks to the faculty member from accepting such a provision, a majority of the panel nevertheless rated this as "permissible," noting that it did not affect university interests and therefore should be left to the discretion of the individual faculty member.

TABLE 3.2: Evaluation of the Importance of Oversight for & Permissibility of Restrictive Provisions

Provision Type	Provision	Importance of Oversight† (Mean)	Permissibility‡		
			Prohibit	May be permiss-ible	Permit
Publication and dissemination	A statement restricting the faculty member's ability to publish or disseminate information that does not specifically reference the scope of his/her consulting services	9.0*	10	1	0
	A statement requiring the faculty member to disclose the results of scholarly research to the company before public dissemination	8.8*	6	5	0
	A statement restricting the faculty member's ability to make public statements that may be detrimental to the company's interests	7.9*	5	5	1
	A statement restricting the faculty member's ability to publish or disseminate information generated within the scope of his/her consulting services	6.7	2	7	2
Intellectual Property	A statement granting the company ownership rights to the work of the faculty member's academic collaborators, students, or trainees	9.0*	11	0	0
	A statement granting the company ownership of work products and inventions not limited to those generated within the scope of the consulting services	9.0*	8	3	0
	A statement granting the company ownership of work products and inventions generated in the the future that "relate to" materials or information obtained in the consulting relationship	8.8*	4	7	0
	A statement granting the company ownership of work products & inventions generated by the the faculty member within the scope of consulting services	7.8*	0	11	0
Confidentiality	A statement requiring the faculty member to obtained signed confidentiality agreements from students or trainees	7.9*	11	0	0
	A statement defining "confidential information" that seems broad enough to potentially encompass information that the faculty member possessed before the consulting relationship started or acquires after the relationship ends	8.5*	6	5	0
Other	A statement restricting the faculty member's ability to engage in future research-related activities	9.0*	10	1	0
	A statement that the faculty member's legal obligations to the company trump any conflicting commitments to the employer	9.0*	8	3	0
	A statement defining the scope of work for the consulting relationship that seems broad enough to potentially encompass some of the faculty member's academic work	8.5*	1	10	0
	A statement that the faculty member accepts legal liability for harms to the company that may arise from his/her consulting work	5.1	1	4	6

Table 3.2 (Continued)

† Question text read: "How important is it, in your view, that medical schools have an oversight mechanism for such a provision?"

‡. Question text read: (Please tell us…) "Whether such a provision should be permitted in a consulting agreement between a faculty member and a company". Options included: Should not be permitted under any circumstances (Prohibit); May be permissible, but only with institutional approval and/or modification; and "Should be permitted and requires no institutional oversight."

*: Indicates ratings which achieved agreement in the second round, where "agreement" was defined by ≤3 panelists providing ratings outside the 3-point region containing the mean (1-3; 4-6; 7-9).

3.3.2 Strategies for Managing Consulting Relationships

The panel evaluated 6 different approaches to management of consulting relationships within medical schools (Table 3.3). Each provision was rated independently, and the answers are therefore not mutually exclusive.

Providing educational resources to faculty received the highest mean rating for overall advisability for avoiding problems with faculty members' consulting agreements with industry. Participants' comments emphasized education and training about consulting policies, with the goals of correcting commonly held misconceptions, enhancing understanding of the reasoning behind policies, and promoting faculty "buy-in" regarding the importance of university oversight of consulting activities.

Although education was universally viewed as necessary, panelists' comments during the teleconference indicated that most believed education alone was insufficient to ensure adequate protection of universities' interests. Reflecting their unanimous agreement that it was unacceptable for a consulting agreement to prohibit disclosure of the terms of the agreement to the faculty member's medical school, most participants supported policies that would bring consulting agreements under institutional review. Next to educating faculty, requiring institutional review of all consulting agreements to ensure compliance with institutional policies was the highest rated management strategy (mean rating: 7.5). Nine experts rated mandatory review as "advisable," commenting that this approach offered the strongest protection for institutional interests, such as protection of intellectual property rights, academic freedom, protection of trainees and collaborators, and continued access to diverse funding opportunities. However, mandatory review was perceived as likely to face moderate logistical barriers (mean logistical feasibility: 4.4) and moderate resistance from faculty members (mean faculty support: 4.9), leading even some panelists who favored this approach to stop short of recommending

mandatory review for all schools.

Optional review was perceived as facing lower barriers than mandatory review, yet it received a lower score for overall advisability (mean: 5.9), reflecting a belief by several respondents that it offers less robust protections than mandatory review, since it would allow faculty with potentially concerning agreements to opt out of review. However, participants noted that in circumstances where mandatory review is not feasible, optional review may provide some protection of institutional interests.

Questions asked during the teleconference yielded insights regarding the anticipated time required for review and strategies to reduce the associated administrative burden. In those institutions currently conducting review on a mandatory or optional basis, experts reported that an average of 2-4 hours of staff time per agreement was required. Time for review reportedly varied based on the nature of the agreement, including the length of expected commitment, the activities involved, and whether any intellectual property might be generated by the relationships. In most cases, institutions reported being able to review agreements within one week, although agreements that raised questions related to intellectual property often required more time. Schools varied considerably in the number of agreements they reported reviewing each year, ranging from a low of 50 to a high of 1000 per year.

There was considerable heterogeneity in participants' ratings of approaches to managing consulting agreements that do not involve institutional review. For example, participants disagreed as to the advisability of requiring faculty to ensure that a specified set of standard provisions is included in their contracts. This approach could take the form of a required addendum to all consulting agreements, including clauses that reinforce that the faculty member's primary employment responsibility is to his/her medical school, that the faculty

member agrees not to use institutional resources during consulting activities, and that consulting activities may not interfere with current or future research activities undertaken by the faculty member in his/her capacity as an employee of the medical school. While 7 panelists supported this approach, 4 advised against it or were neutral (mean overall advisability: 6.1). Those in favor characterized standard provisions as protecting the main interests of the institution at modest cost, while those opposed raised concerns that it would provide incomplete protection of university interests or impede the flexibility to reflect the specifics of each arrangement.

The panel was also divided regarding the advisability of providing faculty members with assistance in negotiating terms of consulting agreements, with 5 experts advising against the mechanism, 4 advising for, and 2 giving a neutral rating (mean overall advisability: 4.5). While some participants believed that this process could help ensure compliance with university policies and alert faculty members to potential pitfalls, others were wary that negotiating terms risked creating a conflict of interest, as the interests of the faculty member and those of the university may diverge. Based on panelists' comments, concern seemed to be particularly salient among attorneys, who perceived that they could not represent a faculty member because the university was their client.

Finally, the panel rejected the strategy of making the school a party to the consulting agreement (mean overall advisability: 1.8), based upon a range of concerns, including that such a policy might require tremendous investment of institutional resources, inappropriately imply permission to use institutional resources, and involve the school in for-profit activities that are external to the academic mission and that might jeopardize the institution's tax-exempt status. Panelists were also concerned about liability issues associated with this approach, citing that schools would risk assuming responsibility and liability for consulting activities, yet still be

unable to control the risk associated with the actions of faculty members engaged in consulting activities.

Overall, these ratings suggest that education is a necessary but not sufficient component for the management of consulting agreements. While no additional policy received universal endorsement, there was strong support for policies to mandate review of all agreements.

TABLE 3.3: Evaluation of Approaches for Managing Consulting Relationships (Round 2)

	Overall Advisability		Considerations	
Approach	**Mean**	**Range**	**Logistical Feasibility† Mean (Range)**	**Faculty Support‡ Mean (Range)**
Provide educational resources	8.6*	8-9	7.5 (7-9)	8.1 (5-9)
Require review and approval of consulting agreements	7.5*	3-9	4.4 (3-9)	4.9 (2-9)
Require defined set of standard provisions	6.1	2-8	5.5 (2-8)	4.9 (7-9)
Provide review of consulting agreements on optional basis	5.9	1-9	6.4 (4-9)	6.9 (5-9)
Provide faculty members help in negotiating terms of consulting agreements	4.5	1-9	4.2 (1-9)	6.5 (3-9)
Include school as party to the agreement	1.8*	1-5	2.9 (1-5)	3.7 (1-9)

†. Logistical feasibility was rated on a 9-point scale. A rating of 1 indicated prohibitive logistical barriers would exist. A 9 rating indicated no barriers would exist. A 5 indicated moderate logistical barriers.

‡. Faculty support was rated on a 9-point scale. A rating of 1 indicated faculty opposition would definitely prevent implementation. A rating of 9 indicated faculty support would definitely promote implementation. A rating of 5 was ambivalent, indicated faculty would neither promote nor prevent implementation.

*: Indicates ratings which achieved agreement in the second round, where "agreement" was defined by ≤3 panelists providing ratings outside the 3-point region containing the mean (1-3; 4-6; 7-9).

3.3.3 Prohibiting Consulting by Industry Type

The expert panel did not recommend that universities categorically prohibit consulting relationships with specific industries. Of the 10 industries examined, none were rated by a majority of the panel as industries for which consulting relationships should ordinarily be prohibited (Table 3.4). Tobacco was the industry reported as most problematic, with 3 of 11 experts suggesting that prohibition is appropriate. Fewer recommended that relationships with manufacturers of alcohol (2 respondents), and firearms (1 respondent) be prohibited. Additionally, although no participants reported that relationships with insurance and financial service companies should be prohibited, several participants recommended that faculty members be cautioned regarding the risks associated with these relationships. No participants recommended prohibiting consulting relationships between faculty members and the soft drink, fast food, insurance, financial services, pharmaceutical, medical device, or biotechnology industries.

Participants' qualitative comments illuminate why they did not advocate banning consulting relationships with specific industries. Participants emphasized the beneficial aspects of consulting relationships in enhancing both scholarship and research. While participants recognized the potential risks associated with some relationships, they expressed a preference for assessing each potential relationship based upon the specifics of the arrangement, rather than relying on broad judgments based upon the industry type. In addition, some participants expressed reluctance to interfere with the outside activities of faculty members by proscribing entire classes of industry relationships.

TABLE 3.4: Considering Prohibition of Consulting by Industry Type (Round 2)

Industry Type	Should Schools Prohibit Consulting?* (Yes)
Tobacco	3
Alcohol	2
Firearms	1
Soft Drinks	0
Fast Food	0
Insurance	0
Financial Services	0
Pharmaceuticals	0
Medical Devices	0
Biotechnology	0

*Question text read: "Should consulting relationships between medical school faculty members and companies within any of the following industries ordinarily be prohibited? Yes/No"

3.4 DISCUSSION

To our knowledge, this study is the first to describe administrators' opinion on how medical schools should manage contractual and other non-financial aspects of consulting relationships between faculty and industry. Through the Delphi process, we characterize shared norms regarding the acceptability of contract provisions, best practices for management of consulting relationships, and the permissibility of faculty relationships with specific industries.

Providing education and training for faculty members on consulting activities was viewed as necessary but not sufficient for effective management of consulting relationships. Respondents supported a review mechanism for the evaluation of individual contracts, although the panel was divided as to both the feasibility and desirability of mandatory as opposed to optional review. Additionally, respondents opposed the use of categorical prohibitions on consulting relationships with specific industries, recommending instead that agreements be evaluated based upon the specific activities of the relationship rather than upon the type of industry. While consensus was not reached in all areas, this process nevertheless served to

characterize the strengths and limitations of various approaches to institutional oversight as well as the reasons that may influence the permissibility of specific contract terms.

3.4.1 Implications for Policy and Practice

Based on the results of this Delphi panel exercise, we offer the following recommendations for medical schools regarding the management of faculty-industry consulting relationships.

3.4.1.1 Educational Training on Consulting Relationships

Our findings strongly suggest a need for medical schools to provide training and educational resources for faculty regarding consulting activities. Relevant educational components include institutional policies and procedures governing consulting relationships, acceptable and problematic terms within consulting agreements, university and faculty interests that may be at risk, and the potential value of obtaining one's own lawyer to review consulting agreements. Education can serve as a vital component in managing consulting relationships, raising awareness regarding the challenges posed by certain forms of relationships and offering an opportunity to correct misconceptions regarding consulting policies.

Education of faculty members about consulting relationships should be offered in a range of formats to maximize its reach. The expert panel recommended seminar-style trainings, including new faculty orientation sessions and department-level seminars, as well as one-on-one meetings between potential faculty consultants and school administrators and/or attorneys skilled in the management of external activities. Institutions should also make various web-based resources easily available to faculty members, including the complete text of all related policies,

sample or template language, contact information for questions related to compliance with institutional policies, and contact information for private attorneys experienced in reviewing faculty consulting agreements.

When implementing these educational strategies, schools should work to secure buy-in from faculty and department chairs regarding the importance of careful review of consulting agreements and the reasons the university is getting involved in this area. Particularly where institutional review of consulting agreements is not mandatory, ensuring faculty members' compliance with institutional policies and their cooperation in pursuing the university's goals will be difficult if faculty do not perceive the institution's involvement as legitimate. Peer-to-peer education (for example, messaging from department chairs) may serve an important role in securing this buy-in, helping to build shared norms around appropriate conduct.

3.4.1.2 Institutional Oversight of Consulting Activities

According to the expert panel, medical schools should have the right to review the terms of consulting agreements made between faculty members and industry. Done well, institutional review by trained specialists (including attorneys or others skilled in the review of such agreements) offers the potential for securing the highest level of protection of institutional interests and academic freedoms, including ownership rights to intellectual property, preservation of the right to pursue research and subsequent publication and dissemination, and protection of trainees and collaborators whose interests could be compromised by faculty members' consulting agreements.

While optional policies may secure at least partial protection, several panelists expressed concern that a voluntary approach may fail to capture those agreements most in need of review

and those faculty members most naïve to the potential pitfalls of consulting relationships. Institutions should weigh the relative advantages of mandatory versus optional review in light of the level of difficulty they are likely to encounter implementing a mandatory approach, in terms of both the administrative resources required for review and potential faculty resistance to a strong assertion of oversight of these "private" arrangements.

In the face of such controversy, how might schools proceed? The recent national trend of tightening financial conflict of interest policies within academic medical centers may prove illustrative.[174] In response to the AAMC's 2008 release of new recommendations on conflicts of interest, numerous medical centers and health care delivery organizations established stricter conflict-of-interest policies that limited, among other interactions, the provision of gifts and meals by pharmaceutical companies. While the initial reaction within many schools was heated, reports suggest that the new policies quickly lost their controversial character.[175] A similar pattern may hold when establishing new oversight policies for consulting agreements. In describing the experience implementing a mandatory policy, one panelist reported faculty have come to appreciate the review process as valuable, identifying contract language faculty members themselves had not understood. However, it remains possible that at least some faculty members would perceive mandatory review as an imposition and therefore strongly resist this approach. Such resistance could undermine the oversight structure, particularly in cases where self-reporting by faculty is required to notify schools of outside relationships.

For schools considering instituting a review policy, the panelists offered several strategies to assist in the review process. Checklists and guidelines concerning common provisions, such as what should or should not constitute "confidential information," can facilitate review. Additionally, when consulting activities are unlikely to generate new intellectual property,

schools may consider the use of intellectual property waivers, through which the medical school can agree to waive its claim to intellectual property rights pertaining to the specific consulting activities. As intellectual property is often the most contentious area of negotiation, the use of such waivers—where appropriate—may streamline the agreement process.

Finally, institutions should be explicit about the purpose of review, including whether the review will be conducted solely for the purpose of protecting institutional interests or will also consider the interests of the faculty member. This may help the faculty member judge whether retaining outside counsel to safeguard his or her own interests is advisable. In some cases, institutions may determine that a university employee cannot review on behalf of both the faculty member and the university without creating a conflict of interest. According to the American Bar Association's Model Rules of Professional Conduct, a conflict of interest may exist for an attorney-reviewer if (1) representation of one party (e.g., the university) would be directly adverse to another client (e.g., the faculty member), or if there is a significant risk that the representation of one client would be materially limited by the lawyer's responsibilities to the other.[176] When such conflicts are present (e.g., because the reviewer is an attorney or institutional policy declares that a conflict exists in a broader set of circumstances), institutions should take care to clarify the purpose of review to the faculty member, emphasizing in particular that the review is to protect institutional interests and that the faculty member should consider retaining private counsel to protect his/her own interests.

Some medical schools may not find it feasible to implement mandatory review policies in the near future. In such cases, schools should consider alternative mechanisms to protect institutional interests—such as optional review, standard contract addenda, or audits of randomly selected consulting agreements, identified on the basis of faculty members' annual reports of

their outside financial relationships—to support compliance with institutional policies on consulting activities.

3.4.1.3 Contract Language

Panelists' ratings and comments suggest a number of recommendations regarding the management and permissibility of various restrictive provisions within consulting agreements. These recommendations, which are summarized in Table 3.5, fall into three broad categories: general recommendations, intellectual property considerations, and considerations relating to publication and dissemination.

With respect to general recommendations on contract language, the panelists' ratings suggest that so-called "supremacy clauses," which specify that the faculty member's legal obligations to the company trump any conflicting commitments to his/her medical school employer, should be prohibited. Such statements conflict with the primary and pre-existing commitments of faculty members to their universities. However, as one participant observed, these provisions may be permissible "under a very limited number of circumstances," such as in the rare cases where the medical school has reviewed the agreement and subsequently determined that the terms do not conflict with the obligations of the faculty member as an employee of the medical school.

The panelists' ratings and associated comments also suggest that consulting agreements should not include "noncompete clauses" that create limits on the faculty member's ability to engage in future research-related activities, such as obtaining grants or research contracts, in a certain area. As described by one panelist, such a provision "begins to impact the faculty member's terms of employment within the institution (medical school) and should not be

permitted." Finally, to effectuate institutional review, panelists made clear that consulting agreements must not be permitted to contain a provision making the contract itself confidential.

With respect to intellectual property provisions, we identified 3 recommendations from the ratings and comments of the panelists. These recommendations reflect a general concern that poorly managed consulting agreements could enable a company to "reach in" to a faculty member's academic work or that of his/her collaborators or trainees. First, contract language granting intellectual property rights for work products and inventions made by the faculty member should be assigned to the company only for those inventions made as a *sole and direct result* of providing the consulting services. Second, consulting agreements should specify that any assignment of intellectual property to the company is subject to any prior or superior rights of the academic institution. Third, consulting agreements should not grant a company ownership of work products produced by the consulting faculty member's collaborators, students, or trainees.

Finally, we identified 4 recommendations related to contract language associated with publication and dissemination rights. These recommendations reflect an underlying commitment to research and dissemination as an integral component of the academic mission. First, consulting agreements should not restrict the ability of the faculty member to publish or otherwise disseminate information outside the scope of consulting services, particularly information or research results related to the faculty member's academic work. Second, recognizing that a company may have a legitimate interest in protecting confidential commercial information, some restrictions on a faculty member's ability to publish or otherwise disseminate information associated with consulting activities may be permissible. However, such restrictions should be limited to the protection of confidential proprietary information obtained as a direct

result of the consulting activity.

Third, consulting agreements should not restrict a faculty member's freedom to make public statements that may be detrimental to the company's interests. Two panelists felt that companies might have a legitimate interest in ensuring that faculty consultants did not make disparaging remarks about the company or its products, and that this interest could be balanced against the university's interest in free discourse—for example, by ensuring that contracts at least enable faculty to speak freely on matters of public interest such as unfavorable research results. However, in general, panelists' comments conveyed heavy skepticism toward any restriction on public statements.

Fourth, given the potential challenges in distinguishing information generated through consulting from information gleaned outside consulting relationships, agreements should include a clear, narrow definition or other mechanism for the identification of what constitutes "confidential information". For instance, medical schools, using checklists, could ensure that agreements contain a standard definition of confidential information, or that a company's proffered definition does not reach the consultant's academic work. An example of categories that should be excluded from information protected as confidential might include the following:

(a) information that the faculty member possessed *before* receipt from the company;
(b) information that is or becomes a matter of public knowledge through no action by the faculty member;
(c) information that the faculty member rightfully receives from a third party not owing a duty of confidentiality to the company;
(d) information that is disclosed without a duty of confidentiality to a third party by, or with the authorization of, the company; and
(e) information that is independently developed by the faculty member and falls outside the work for hire in the consulting relationship.

3.4.1.4 The Role of Students and Trainees in Consulting Activities

Although we did not specifically inquire about whether it was ethically acceptable for

faculty members to include students and trainees in their consulting activities, several panelists offered comments flagging this as an important issue for institutional oversight. Some might argue that opportunities to participate in faculty members' consultancies could greatly enrich a student's educational experience—for instance, by providing a window into how biomedical discoveries travel from bench to bedside. However, in comments offered in response to related questions on the Delphi survey, most participants stated that student and trainee participation in faculty consulting should be prohibited, as it would constitute an inappropriate use of university resources and might exploit students and jeopardize their academic progress. However, in clarifying comments offered during the teleconference, these panelists seemed open to students and trainees independently participating in consulting activities. Such students should execute their own consulting agreements with the company, with institutional oversight. Additional measures may be necessary to manage potential conflicts in cases where a student and faculty member are both engaged in consulting relationships with the same company, such as ensuring that the faculty member does not have a supervisory role over the student in both academic and non-academic contexts.

TABLE 3.5: Recommendations for Consulting Agreement Oversight and Guidance on Contract Language

Recommendation Type	
General Recommendations	• The faculty member's primary obligation is to the university; consulting agreements may not include "supremacy clauses" or other language granting the company superior rights. • Consulting agreements may not include "noncompete clauses" that place limits on the faculty member's ability to engage in future research-related activities in the field related to the consulting activities. • Consulting agreements may not include language making the terms of the agreement nondisclosable to the faculty member's academic institution and academic collaborators.
Intellectual Property	• Work products and inventions made by the faculty member should be assigned to the company only where the work product or invention was made solely and directly because of the consulting activities. • Any assignment of intellectual property rights to the company is subject to any prior or superior rights of the academic institution. • Consulting agreements may not grant a company ownership of work products or inventions made wholly or in part by the consulting faculty member's academic collaborators, students, or trainees.
Publication & Dissemination	• Restrictions on a faculty member's ability to publish or disseminate "confidential" and "proprietary" commercial information may be permissible, but consulting agreements may not restrict a faculty member's ability to publish or otherwise disseminate information that is outside the scope of consulting services, particularly research results, data, and other information arising from the faculty member's academic work. • Consulting agreements should not restrict a faculty member's ability to make public statements that may be detrimental to the company's business interests. • Consulting agreements should include a clear definition or other mechanism for determining what does and does not constitute "confidential information". The definition must not be so broad as to potentially encompass information obtained outside of the consulting relationship.

3.4.2 Limitations

This study did not examine the full range of provisions that may be included in consulting agreements, nor did we exhaust the possible oversight approaches for management of consulting relationships. While our question domains did reflect the findings of our earlier interview study, it is possible we excluded other important considerations, such as the use of retrospective audits to monitor compliance with school-level policies in the absence of a structure for prior review.

Additionally, like all Delphi studies, our outcome is dependent upon the composition of the expert panel. Our study design aimed to minimize the effect of panel composition through several mechanisms, including the use of detailed recruitment criteria to ensure selection of participants based upon subject matter expertise. If important perspectives were nevertheless overlooked in the recruitment process, then the results of the process may not be representative of the universe of administrators.

Three aspects of the panel composition are worth noting. First, lawyers comprised the largest educational category of our panelists. While this may reflect a general trend within medical schools, it nevertheless suggests that our panel may have approached the topic with a risk-management perspective, which may not reflect the full range of considerations relevant to the evaluation of faculty-industry consulting relationships. Second, it is also possible that our selection criteria, by emphasizing schools that had either implemented or considered a mechanism for the review of faculty consulting agreements, may have favored the inclusion of panelists who supported a more active, interventionist approach. Third, while public institutions account for approximately 60% of U.S. medical schools, they comprised only 30% of our panel.

To the extent that public and private institutions differ with respect to their governance structures or administrative or legal environments, our results may not fully reflect the experiences of public institutions.

A more fundamental issue for the Delphi method concerns the appropriateness of the method to addressing governance questions. First, unlike technological forecasting or even clinical appropriateness, for which there are defined standards by which we can assess its accuracy, it is often more difficult to identify a single, independent criterion by which to assess the results of a Delphi study involving questions of governance, or even to identify the dimension we aim to improve. Whereas clinical appropriateness assessments aim to improve health outcomes, it is less clear what independent standard might be used to assess the results of a Delphi study examining best practices for the management of consulting relationships. There may be criteria by which to measure some aspects of these relationships, such as the success of various policy approaches for risk-management considerations, including limiting the number of legal challenges over intellectual property rights. However, it is less clear what standard would exist for assessing other relevant considerations, such as the appropriate level of faculty autonomy, or whether a medical school has an obligation to protect the interests of its faculty members in their external relationships.

Finally, we acknowledge the likelihood that the policies that our experts recommend likely reflect their own current and prior experiences with managing consulting relationships within their respective institutions. Our aim was not to provide a representative view of all attitudes, but rather to elicit a realistic discussion of the policy alternatives available for the management of faculty-industry consulting relationships and the likely obstacles facing various strategies to address them among individuals who had devoted substantial thought to these

issues.

3.5 CONCLUSION

The issue of contractual and other non-financial conflicts raised by faculty consulting relationships has sat is the shadow of the attention given to financial conflicts of interest, but merits consideration and action. While consulting relationships offer many benefits, they may also compromise the interests of medical schools as well as those of faculty members themselves. Despite growing awareness of the potential risks associated with these relationships, there remains considerable variation across schools in the management of faculty-industry consulting activities, suggesting a need for consensus-building activities.

This study is the first to identify areas of agreement across experts as to the management of consulting relationships, including identification of those provisions that should not be permitted within consulting agreements. In addition, our study offers recommendations for how agreements should be worded to protect institutional interests, and characterizes the strengths and limitations of different oversight mechanisms. Our findings suggest that medical schools should develop a variety of educational resources, both to raise awareness of concerns associated with faculty consulting and to support faculty members' compliance with school policies on consulting. In addition to education, medical schools should also consider mandatory review of consulting agreements to ensure compliance with school policies. The strategies we identify can allow medical schools to facilitate consulting relationships and their potential benefits for individual and population-level health, while minimizing the risks that such relationships pose to the academic and clinical missions of the institutions.

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