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Legal Strategies to Manage Obesity and Increase Physical Activity

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Executive Summary

This White Paper reviews the public health law system in the context of using legal strategies to manage obesity and encourage physical activity. There are many sample strategies in the White Paper. These are intended as templates and are not recommendations for specific courses of action. The level of specific legal detail was limited to keep the White Paper to a manageable length. There was no attempt to do a comprehensive review of the medical and scientific literature because it is expected that the primary audience for this paper will be experts in the underlying medical and research literature.

The Scope of Public Health Authority

The courts give the government broad authority to protect the public health and safety. Historically, the major limitation on the public health powers is that it can not be used as a subterfuge to deny individuals criminal due process rights or to impose racially or ethically discriminatory policies. The courts have recently expanded the First Amendment protections for free speech to include advertising and other forms of commercial speech. The commercial speech doctrine limits the government's right to control general advertising for lawful products, such as food and drugs. Advertising on federally regulated broadcast media (radio and broadcast television) can still be regulated, but Internet and print advertising can be regulated only if it is deceptive.

Within these constraints, the courts defer to the legislature and public health agencies, generally upholding all laws that have a legitimate public health purpose. The primary limits on regulation are not legal, but political and financial. Strategies that do not have public support will be difficult to enact through legislation, and will seldom prove successful. Public policy makers also have an obligation to base their recommendations on the best available scientific knowledge, because neither the legislature or the courts have the expertise to make an independent evaluation of public health regulations.

Levels of Government

Public health practice is a shared enterprise of the federal, state, and local governments. Federal law is controlling in areas of national scope and interest, such as environmental law and the regulation of goods in interstate commerce. The states and larger cities manage issues of local concern, including restaurant sanitation, communicable disease control, and life-style regulations, such as anti-smoking laws.

Legal interventions must be targeted at the right level of government to be effective. The FDA is the appropriate agency to improve nutritional labeling on packaged foods, but state and local health departments would be better able to regulate the information provided on restaurant menus and at point of sale for food. Cities and states play an important role in developing new policies because they do not have to satisfy a national constituency. Many cities banned smoking in public places before there were state level bans.

Legislative or Administrative Action?

Congress or the state legislatures are usually seen as the starting point for new legal strategies. In many situations, however, public health agencies have sufficient authority to carry out new strategies without specific new legislation, as long as the strategy does not need additional funding. For example, a state health department might require physicians to report individuals with morbid obesity as part of the existing disease reporting system. The agency can also require regulated parties to change their practices, as when the Texas Department of Agriculture directed the public school nutrition programs under its authority to control the availability of snack foods.

While legislative action is necessary for programs that require new funding, or when the proposed strategy exceeds the authority of the public health agency, in many cases it is not the most efficient way to initiate public health strategies. Legislation can take a long time to pass. The proposed legislation will be modified through compromises with other interest groups. In some cases, the final statute will be so modified as to make it difficult or impossible to accomplish the original objectives. Once a statute is passed, it is hard to change as new research becomes available because the legislators will have moved on to other, more pressing concerns. When agencies act through administrative orders or regulations, they are drafted by the expert staff of the agency and are not subject to the same legislative compromises. As new research becomes available, they can be modified to take advantage of the most effective strategies to manage obesity and encourage physical activity.

Legislation will be important where existing laws inadvertently complicate the control of obesity and physical inactivity. For example, agriculture policy encourages the production of meat and grain, rather than fruit and vegetables. Land use and transportation policy complicate the development of mixed use neighborhoods that provide opportunities for people to walk as part of their daily lives. Identifying and modifying existing laws to harmonize them with managing obesity and physical inactivity is a prerequisite to many interventions.

The Role of the Federal Government

Managing obesity will require fundamental changes in eating patterns that are rooted in ethnically and regionally diverse cultures. This will require flexible local action, supported by federal guidance and funding. Federal funding allows state and local agencies the flexibility to implement public health initiatives without requiring new state legislation and funding. Agencies such as the Centers for Disease Control and Prevention can provide expertise, guides to best practices, and funding to encourage and direct state and local action. Federal funding already supports many critical state and local public health programs, such as those providing childhood immunizations.

In areas of traditional federal regulation, such as prepared food labels, federal laws and regulations will be important to set uniform national standards. Congress may also pass laws to direct state action, as was done through the environmental laws, or to limit conflicting state action, as was done by the Cigarette Labeling Act of 1969. The Medicare and Medicaid programs have an important role in setting standards for treating obesity and its sequellae and Congress can encourage private medical insurance to follow these standards.

Unique Aspects of Obesity and Physical Activity

Obesity is correlated with race, sex, and class. It may have genetic determinants and its major sequella, diabetes, has strong genetic determinants. Severe obesity, and obesity complicated by diabetes, are covered disabilities under federal and some state antidiscrimination laws. While other public health problems share one or more of these factors, obesity is unique in being the most complex problem to affect such a large number of persons. Legal strategies to manage obesity must be sensitive to these complicating factors or risk political and judicial scrutiny.

The great successes in public health were interventions such as water and waste water treatment that did not require personal behavioral changes. Interventions based on changing personal behavior, such as the control of sexually transmitted diseases or smoking, are more difficult and require much more time and education. Changing eating and physical activity patterns will require broad-based interventions carried out for a long period of time. These will be difficult to sustain because change will come slowly. Legislatures and the public will question whether the results are worth the investment because they expect to see quick results. Keeping both individuals and the government focused on the problem of obesity over the long-term will be the greatest challenge facing public health policy makers.

Legal Strategies to Manage Obesity and Increase Physical Activity

Introduction

Protecting the public's health and safety is a core function of government. The governments of the original colonies enforced public health laws before the American Revolution and their powers were retained by the states when the Constitution was ratified. In 1850, the first demographic study of deaths in the United States, the Report of the Sanitary Commission of Massachusetts (the Shattuck Report[1]), found that the average life expectancy in the United States was between 25 and 35 years. The major cause of mortality was infectious disease spread through inadequate sanitation. The Report led to a model public health law that formed the basis of a national sanitation movement. Over the next 100 years, life expectancy more than doubled. The sanitation movement, combined with vaccinations and measures to control tuberculosis and other diseases that are spread through person-to-person contact, reduced the burden of infectious diseases in the United States. Law was integral to this public health revolution.

As individuals live longer, chronic diseases such as diabetes, cardiovascular disease, and cancer displace infectious diseases as the major risk to individual health. These diseases are exacerbated by increases in the prevalence of obesity and physical inactivity. Alarmingly, the most dramatic changes in obesity and physical activity levels occur in children. There are aspects of these conditions that fit the public health model and should be subject to interventions based on well-understood public health law paradigms. Other aspects may demand a hybrid approach of behavioral change through education coupled with legal interventions, as has been required for conditions such as alcoholism.

This White Paper begins with an analysis of the legal authority and mechanisms for federal, state, and local public health law interventions. Public health law is a complex mix of federal, state, and local regulations, and there are many useful approaches beyond seeking specific legislation. It is critical to understand how the different levels of public health authority interrelate when one is planning regulatory strategies. In many cases, agencies have the flexibility to implement new strategies without new legislation. This saves time and allows a more flexible response. The White Paper concludes with a review of sample strategies targeted to different aspects of the problem. This is augmented with tables to allow a quick overview of the legal principles and strategies.

Federalism and Public Health Law (Table 1)

The Constitutional Allocation of Powers

The contemporary organization of public health law and public health services is rooted in the original allocation of powers between the state and federal governments. The American colonies

[1] L. Shattuck et al., Mass. Sanitary Comm'n, Report of a General Plan for the Promotion of Public and Personal Health (Boston, Dutton & Wentworth (state printers) 1850), *available at* http://biotech.law.lsu.edu/cphl/history/books/sr/index.htm.

carried out health and safety regulation under the authority of colonial governors. These powers were called the police powers. After the Declaration of Independence and before the ratification of the Constitution in 1789, the states exercised all governmental powers, including the police powers. While the states were associated under the Articles of Confederation, they did not cede any significant powers to a central government. In states with large cities, the public health authority was shared by city governments such as those in Boston, New York, and Philadelphia.

When the Constitution was drafted, the states recognized they needed to have a central government that could deal with foreign powers, domestic insurrections, and prevent trade wars and other interstate disputes. The federal government was given power over international affairs and interstate commerce: "To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."[2] The foreign powers include broad national security powers and the right to make treaties with other nations, which have public health implications for managing the international spread of diseases and bioterrorism incidents.[3]

Congress was also given the right to overrule (preempt) state laws in areas where the federal government has authority. The Tenth Amendment reserves to the states all powers not specifically given to the federal government.[4] In particular, domestic public health regulation was left to the states. The Eleventh Amendment prevents private litigation against a state for money damages, unless the state legislature consents. This was modified by the Fourteenth and Fifteenth Amendments, which allow Congress to provide remedies for racial and other pervasive discrimination by the states.

The State Police Powers

The primary powers reserved to the states by the Tenth Amendment are those necessary to protect the public health and safety, as exercised by the states before entering the union: the police powers. Blackstone, the preeminent codifier of British law, defined the police power as: "...the due regulation and domestic order of the kingdom, whereby the inhabitants of a state, like members of a well-governed family, are bound to conform their general behavior to the rules of propriety, good neighborhood and good manners, and to be decent, industrious and inoffensive in their respective stations."[5] (Under the King, this was an unlimited power, with breaches of quarantine being punishable by death.[6]) Legal theory in the late 1700s saw the police power as an expression of the power of the state to protect itself from threats, as well as the power to regulate domestic order. Epidemics were seen as grave threats to the state itself,[7] which they were: in one summer 10% of the population of Philadelphia, a leading American city, was killed

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[2] U.S. Const. art. I, § 8, cl. 3 (Commerce Clause).

[3] Stephen Dycus, Arthur L. Berney, William C. Banks & Peter Raven-Hansen, National Security Law (New York, Aspen Publishers 2003).

[4] U.S. Const. amend. X.

[5] 4 William Blackstone, Commentaries *162.

[6] *Id*. at *161.

[7] William H. McNeill, Plagues and Peoples 160-65 (1976).

by yellow fever.[8] It was only through heroic action that social order was preserved during the worst of the epidemic.[9] When the early courts established the reach of the police power, their decisions were based on these catastrophic threats. It is not surprising that the courts found that the state's police power was limited only by the nature of the threat and whether the state's actions were rationally related to addressing the threat.[10]

The United States Supreme Court still recognizes this broad deference to the state's need to protect its citizens from threats to the public health. Persons challenging the state's actions are not allowed to attack the underlying policy choices as long as those choices do not conflict with other Constitutional protections:

> "It is not for the courts to determine which scientific view is correct in ruling upon whether the police power has been properly exercised. The judicial function is exhausted with the discovery that the relation between means and end is not wholly vain and fanciful, an illusory pretense."[11]

The courts also defer to policy decisions made by public health agencies acting under the state's police power authority.[12]

The Federal Public Health Powers

The federal powers under the Commerce Clause are broadly construed by the courts, as are the national security powers. In some areas of public health, such as environmental pollution and sanitation laws for food shipped in interstate commerce, the federal government has been very active and has a primary legislative and enforcement role. The federal government has been much less involved in traditional public health regulations such as communicable disease control. In traditional public health areas, the federal government usually uses its spending power to direct state regulators to follow best practices developed by the CDC. It is expected that this separation of roles will continue, with the federal government regulating goods such as food and drugs in interstate commerce, and the states directly regulating behavior and local conditions such as land use, often with the urging of the federal government through the spending power.

Shared State and Federal Authority for Public Health

The Constitution's drafters saw the federal government as having a limited role in daily life. It would deal with foreign governments and stand ready to raise and direct an army in case of

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[8] J. H. Powell, Bring Out Your Dead: The Great Plague of Yellow Fever in Philadelphia in 1793 (1949).

[9] Smith v. Turner, 48 U.S. (7 How.) 283, 340-41 (1849).

[10] Edward P. Richards, *The Jurisprudence Of Prevention: The Right Of Societal Self-Defense Against Dangerous Persons*, 16 Hastings Const. L.Q. 320 (1989).

[11] Williams v. Mayor of Baltimore, 289 U.S. 36, 42 (1933).

[12] City of New York v. New St. Mark's Baths, 497 N.Y.S.2d 979, 130 Misc. 2d 911 (N. Y. Sup. Ct. 1986).

foreign attack or domestic insurrection. The federal government did have a role from the first in public health related to foreign trade. One of the first acts of Congress was to establish a system of public health service hospitals and quarantine stations to deal with potential public health threats from outside the United States. There was also an early, short-lived federal vaccine agent law to provide safe smallpox vaccine.[13] Beyond these efforts, the federal government left most public health regulation to the states for the next 100 years. The new state governments continued regulations established in the colonial period and expanded them significantly in the early and mid-1800s,[14] with major cities continuing to exercise considerable regulatory authority.

The balance of regulatory power began to shift in the 1880s, as the federal government created its first national regulatory agencies and the United States Supreme Court reined in numerous state regulations as violations of the Commerce Clause.[15] The modern FDA was born when Congress passed a law regulating food sanitation in 1905.[16] The FDA's powers were broadened in the 1930s and the federal involvement with health and public health expanded after World War II, including the development of the modern Centers for Disease Control.

In contemporary practice, the federal, state, and local governments share the legal authority for the protection of the public health and safety. State and local government rely on the police powers for direct regulation. The federal government relies on the commerce clause to regulate goods and activities that affect interstate commerce.[17] All levels of government use their powers to tax specific activities and goods to provide positive and negative incentives in areas where they either lack the authority to regulate or choose to not regulate directly for political reasons. The spending power - the government's ability to directly fund activities and goods it wants to encourage - is used in parallel with the power to tax. The CDC uses the spending power to fund specific state public health programs that target important health areas that the states might not have the funds to address themselves. Congress also uses the threat of withholding funds to persuade states to pass their public health laws using the states' own police power: when the federal government wanted to improve automobile seatbelt use, it required states to pass seatbelt laws as a condition of receiving federal highway funds.[18]

Traditional areas of public health that deal with local problems and have been carried out by the states since the colonial period - communicable disease control, drinking water sanitation, and animal control are examples – are still primarily carried out by the state and local governments. In these traditional areas, the federal government's role is exercised primarily through the spending power and the power of persuasion. In many areas, the CDC proposes best practices

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[13] Vaccine Agent Act of 1813, Law of Feb. 27, 1813, ch. 37 (repealed 1822). *Available at* (http://biotech.law.lsu.edu/cases/vaccines/vac_act_1813.pdf).

[14] William Novak, People's Welfare (Chapel Hill, Univ. of N.C. Press 1996).

[15] Schollenberger v. Pennsylvania, 171 U.S. 1 (1898).

[16] This was passed after the 1905 publication of The Jungle, Upton Sinclair's novel about the food processing industry.

[17] Gonzales v. Raich, 125 S. Ct. 2195 (2005) (U.S. Reporter citation not available at time of writing); U.S. v. Locke, 529 U.S. 89 (2000); Massachusetts v. Hayes, 691 F.2d 57 (1st Cir. 1982) (Mass.).

[18] 23 U.S.C. § 405 (2005).

and supports these through grants. The CDC also acts as a national resource for the collection and analysis of state data on health conditions. The greater the impact on interstate commerce or international relations, the greater the federal role will be. Thus in areas such as environmental pollution control, the regulated entities are often multinational businesses and governments themselves, as the pollution they generate can have effects beyond state and national borders. The federal government sets national standards that state laws must follow and directly enforces these standards through administrative agency practice and Department of Justice prosecutions.

This mix of state and federal regulation, with the states retaining considerable authority, leads to different enforcement strategies and priorities among the states. Such diversity of state approaches is a core value of federalism, described by the United States Supreme Court as a mechanism allowing the states to serve as laboratories for public policy innovation.[19]

Tobacco control is an example of shared state and federal regulatory authority with variations in state and local application. Some aspects of tobacco regulation are generally accepted and these have become federal standards. The federal government regulates the labeling and interstate sale of tobacco and sets a minimum age for smoking. There are other areas, such as smoking in restaurants, bars, and the workplace where there is no national consensus. These areas are left to the state and local governments. In some states there are statewide restrictions on smoking.[20] In others the state legislature has preempted any local laws that are stricter than state standards. The net benefit is positive in that communities and states willing to go beyond the national consensus on regulating smoking have the freedom to do so and thus provide models for other states.

The flexibility of state-based enforcement and the opportunity it provides for innovation will be valuable for treatment of obesity and physical inactivity, both because there is no national consensus on the best approach to these problems, and because they have pronounced regional variations. Cultural norms concerning food have dramatic variations over even short distances. New Orleans, Lafayette, and Shreveport are all in Louisiana, but they have different culinary traditions, all of which are distinct from those of San Diego, California. In cities such as New York, culinary traditions may vary by block. While national fast food franchises may be uniform across the United States, and thus amenable to uniform national regulation, they account for only a part of the culinary landscape and cannot be the only focus of food regulation. Cultural norms for physical activity and the necessary environmental support for such activity (bike paths, public parks, even crime control) also vary significantly within and across communities.

Overview of Governmental Organization and Sources of Law (Table 2)

The Constitution organizes the federal government into three branches, with overlapping powers, that act as checks and balances on each other. These three branches - legislative, executive, and judicial - carry out the functions of government and are the source of the legal rules and guidance

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[19] New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932).

[20] 32 Cal. Gov't Code § 7597 (2005) (smoking is prohibited in and around public buildings and public passenger vehicles; additional restrictions by certain public entities are authorized.).

that define the legal environment in the United States. (While the states are free to organize their governments differently, all use the same tripartite model.)

The federal government is the creation of legislation passed by Congress. The Constitution gives the President, as head of the executive branch, certain intrinsic powers such as the national security powers and the power to appoint individuals to lower offices in the executive branch. The United States Supreme Court is given the right to hear a limited number of disputes, including those where states are suing other states. Beyond these specific grants of power in the Constitution, the framework of the federal government has been created by Congress. The federal agencies that make up the executive branch, the budget that pays the President's salary, the lower federal courts, and all federal jurisdiction beyond that expressly granted to the United States Supreme Court in the Constitution, are creatures of statutes passed by Congress and signed by the President, or passed over the President's veto by a two-thirds vote of Congress.

Congress passes statutes that the executive branch enforces through administrative agencies. The President can make treaties with other countries with the advice and consent of the Senate. Such treaties can preempt state and congressional action, including state police powers. The President can issue executive orders to carry out policy in areas consistent with the powers given to the executive branch by Congress, and can issue some national security orders using the unilateral national security powers granted to the President directly by the Constitution. Administrative agencies in the executive branch, if so authorized by Congress, can issue regulations (rules) that have the same force as statutes, but these must be within the authority granted by Congress. Such agencies can also issue non-binding guidelines to act either as guidance on how laws or regulations should be interpreted, or as recommended practices, for example, the CDC's communicable disease control guidelines.

The courts review legislation, regulations, and executive actions to assure that they are consistent with constitutional norms and treaties and also to resolve conflicts between state and federal legislation. These decisions provide guidance on the interpretation of laws, and are often the only statement of meaning for ambiguous statutory or constitutional provisions. They are binding on lower courts in the same jurisdiction, and United States Supreme Court decisions are binding on all courts.[21] Administrative agencies also decide cases, but the decisions in these adjudications are not binding in other agency cases. They are important guidance, however, because they represent agency interpretation of law and because the agency must at least explain why it does not follow them in similar cases.

Federal court decisions, state appeals court decisions, federal and state legislation, and federal regulations have always been published for public access. State administrative regulations and decisions, state and federal guidance documents, and most executive orders were not generally available until the last decade with the advent of the Internet. Now most federal documents are published electronically and many more state documents are published electronically than were previously available on paper.

[21] Louisiana follows the civil law tradition that court decisions are not binding precedent, but they are nonetheless considered very strong indications of the way courts are to rule.

Administrative Agencies

When the Constitution was drafted, it was assumed that the federal government would be small, dealing with foreign governments and standing ready to raise an army and defend the country from invasion or insurrection. The Constitution is largely silent on the organization of government beyond the three branches or the day-to-day operation of the government. Administrative agencies and the administrative law which governs them are creations of Congress and the United States Supreme Court, with relatively little constitutional direction. While the legal evolution of administrative government has had controversial periods, basic federal administrative law has been relatively stable since the New Deal. The most significant change has been in state-federal relations secondary to the United States Supreme Court's ruling that the Eleventh Amendment limits the right of Congress to allow individuals to sue states.[22]

The Political Control of Agencies

Under state and federal constitutional principles, agencies that enforce laws must be in the executive branch. Except for the independent agencies discussed below, agencies are intended to carry out the policy of the President as elected head of the executive branch, within the constraints imposed by the legislature in the laws establishing and funding the agency. Agencies that do not do enforcement can be part of the legislature or the courts. For example, the Congressional Budget Office can be part of Congress because it only does investigations, research, and publication. Most agencies, even if they do not do enforcement, are part of the executive branch. Congress controls federal agencies through the laws that give them their powers and their budgets. The President controls the day-to-day operation of an agency through the appointment of the director and other agency officials. The highest federal appointments, called officers of the United States, have to be made by the President and confirmed by the Senate. Subordinate appointments, called inferior officers, can be made by the directors of agencies or judges, as determined by Congress. For example, the President appoints the Secretary of the Department of Health and Human Services, who then appoints the director of the CDC. The President can also issue executive orders to the agency to direct it to take specific actions, as long as these are within the authority given the agency by Congress. Since Congress sets the budget for the agency, executive orders must also use existing agency resources. The governor or other executive head of a state agency may also issue orders to direct agency action. Thus a governor could direct the state Department of Agriculture to revise rules on school lunches without needing special legislation, if the Department had the general authority over school nutrition standards.

When Congress or a state legislature wants to create an agency with some political independence, it limits the President's or governor's authority to remove the head of the agency, and it may also set qualifications for the agency head.[23] These independent agencies are run by commissions or boards - a group of appointed directors who share power and who serve for fixed terms of office. These terms are usually staggered so that a president or governor will appoint a

[22] Seminole Tribe of Florida v. Florida, 517 U.S. 44 (1996).

[23] Humphrey's Executor v. United States, 295 U.S. 602 (1935).

minority of the members during any single term. While the President or governor may issue orders to an independent agency, the agency directors may ignore these orders without losing their jobs.

At the federal level, independent agencies are usually used to create and monitor economic regulations that must be seen as impartially promulgated, such as the Securities and Exchange Commission, but there are no limitations on the role of independent agencies. The Consumer Product Safety Commission is an independent agency that has an important role in accident prevention. In contrast, the CDC, FDA, and OSHA are subordinate agencies to the Department of Health and Human Services and headed by appointees who answer to the President. Independent boards are much more common in public health at the state and local level, with many state and local health agencies headed by boards that may hire and fire the health director.[24] Such a board, if properly constituted, can provide important political protection for a health director who must take unpopular actions.

State administrative law follows the same model as the federal government, with some variation among the states. There are two fundamental differences between state and federal administrative law. First, many state constitutions do not require the same strict separation between the branches as the federal Constitution. Second, states do not have a single executive equivalent to the President. All states have other elected state-wide offices, and in many states these elected officials are not under the direction of the governor. In some states this has a significant impact on public health enforcement because the attorney general's office controls all legal services for the state, while the health department is under the governor's control. Thus the health department cannot bring legal actions without the permission of the attorney general, and the attorney general can bring legal actions in public health matters that do not reflect the views of the governor or state health officials.

Establishing the Agency and its Powers

The legislature creates an agency by passing a law commonly called the enabling act. This act specifies the purpose of the agency, its basic organization, and its initial budget. Future legislation can add to the agency's purpose, expand its budget, fundamentally alter its organization, or even abolish it. Such changes can only be challenged through the political process, not the courts.

When the legislature passes a law enabling the creation of an agency, or any subsequent legislation affecting the agency's power, the legislature may give the agency a broad grant of power, leaving the details to the agency, or a narrow grant of power, directing the agency as specifically as the legislature wants. For example, the original laws establishing health departments in most states used very general grants of power, such as granting the agency the power to protect the citizens of the state from all threats to the public health. A broad grant of power has four advantages:

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[24] *See, e.g.* Charter of the City of New York, ch. 22 § 553 (establishing city Board of Health).

1) the legislature does not have to anticipate the exact threats that the agency must deal with;

2) the legislature can delegate the development of specific technical standards and policies, such food sanitation codes, that are beyond its expertise;

3) the agency has the flexibility to change its strategies in the face of new threats or changing conditions, without having to go back to the legislature for new legislation; and

4) the legislature can delegate sensitive political decisions to the expert staff of the agency so that the legislature itself does not have to take a position on them.

While the delegation of broad powers to agencies was controversial in the 19th century, it is accepted by all modern courts.[25] The courts allow agencies to use these broad grants of power to address new threats to the public health, such as obesity, without waiting for specific legislation.

If the legislature wants to limit the agency's (and thus the executive branch's) discretion, it can pass a very specific law that directs the agency actions in detail. This is often done when the legislature wants to change established government practices. For example, several sections of the Americans with Disabilities Act are very detailed and specific, giving the agencies charged with enforcing the Act very little discretion. This was done because the ADA made major changes in how the government and private business had to treat the disabled, and Congress wanted to make sure that the agencies would carry out its intent.

Rulemaking

The legislature can delegate its own legislative power to an agency, allowing the agency to make rules that have the force of statutes passed by the legislature. These administrative rules (also called regulations) fill in the details when the legislature gives the agency broad powers. Rulemaking can also be used to adopt nationally recognized standards such as a food sanitation code. Administrative rules are generally made through a public participation process called notice and comment rulemaking. The agency begins the process by publishing a notice of a proposed rule and the legal and scientific justification for the rule. The public then has a period of time, usually no less than 30 days and generally no more than six months, to send written comments to the agency. Federal agencies may have public hearings to take testimony if required by Congress, and many states require agencies to have hearings on rules and take oral testimony if a group of people asks the agency to do so. The agency must consider the comments and address them in general terms. The rule may also be revised based on the comments. The responses and any proposed revisions must be published before the rule goes into effect. (There are provisions for emergency rules to deal with unexpected threats, which allow rules to go into effect during the comment process and be revised later as necessary.)

This rulemaking has three benefits for the agency. First, it gives guidance to the regulated parties, making it easier for them to comply with the law. Second, it increases public buy-in

[25] Whitman v. Am. Trucking Ass'ns, Inc., 531 U.S. 457 (2001).

through the participation in the notice and comment process. Third, once the rules have been through the notice and comment process, they have the same legal effect as laws passed by the legislature. This means that as long as the agency has not exceeded the authority it was given by the legislature and it has acted within constitutional constraints, the rules cannot be challenged in subsequent litigation.[26] For example, a state board of education, under a grant of power from the legislature to address obesity in schools, could pass a rule that defined a child as obese if the child's BMI is 27 or greater. Once established by a properly promulgated notice and comment rule, the courts would not allow challenges to the standard based on differences of opinion over the scientific definition of obesity.[27] Agencies can also issue guidelines, such as the CDC standards for immunization practice, which do not go through the notice and comment process. These are only recommendations and are not legally binding in themselves.

Limitations on Public Health Authority

There are limits on public health authority that are relevant to obesity and physical inactivity:

1) First Amendment limits on the regulation of speech;

2) Constitutional limits on using public health powers for punishment;

3) Commerce Clause limits on state laws that affect interstate commerce; and

4) Constitutional equal protection issues and state and federal disability laws;

Of these, the free speech protections are the strongest and admit of few public health exceptions. The other limits are more flexible in cases of significant and imminent public risk such as a dangerous pandemic, however, obesity and physical activity do not pose the type of risk that would trigger such exceptions. Political and financial limitations are much more common than constitutional limitations, and are expected to be the most significant limitations on public health strategies to manage obesity and physical inactivity.

First Amendment

The First Amendment protections of free speech limit the government's right to regulate speech. This protection is very strong for books and other publications that represent the author's ideas or opinions. There have been books that recommended diets that are deficient in key nutrients such as B-vitamins. Following such diets can lead to dangerous vitamin deficiency diseases such as Wernicke-Korsakov syndrome from thiamine deficiency, especially in young children. Despite such risks, the government cannot remove such books from the market and persons injured by the diets cannot sue the authors because this would be indirect government censorship. This protection extends to publications that recommend specific products, as long as they are not advertisements by the manufacturers of the products. For example, a pamphlet advocating the

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[26] Heckler v. Campbell, 461 U.S. 458 (1983).

[27] City of New York v New St. Mark's Baths, 497 N.Y.S.2d 979, 130 Misc. 2d 911 (N.Y. Sup. Ct. 1986).

use of a food supplement as a weight loss drug would be protected by the First Amendment as long as it is not an advertisement by the manufacturer. The courts can be expected to extend the same protections to Internet publications, which will greatly complicate the process of getting accurate health information to the public.

Historically, the First Amendment protection of speech was not applied to commercial speech such as product advertising. Recently, however, the United States Supreme Court has broadened First Amendment protections for advertising and other forms of commercial speech.[28] If the ads are truthful, the government has less authority to limit them than in the past.[29] An example is the growth of direct-to-consumer advertising of prescription drugs for weight loss. The government has much broader authority to regulate the labels on products and to require the addition of information such as the fat content of foods, but the state has limited authority to ban truthful information on a label. Thus the Court rejected laws preventing brewers from advertising the alcohol content of their beer, despite evidence that the information encouraged the consumption of beer with more alcohol.[30] The FDA may regulate food descriptions such as "low fat" and health claims such as "reduces cholesterol" when they are deceptive, but may not be able to prevent their use when they are accurate.

Commercial speech protections are reduced for broadcast television and radio advertising. The courts have viewed the airwaves used by licensed broadcasters as a public utility, and allowed greater regulation of content than was allowed in print media. These exceptions to First Amendment protections have not been extended to the Internet or cable (non-broadcast) television. This will limit the effectiveness of government regulations on food advertising, since these regulations can only reach traditional broadcast media.

Punishment without Criminal Due Process

The courts have rejected laws that attempt to achieve public health goals by punishing persons for their health conditions. As one court said many years ago: "No self-inflicted wrong is recognized as a crime by laws governing temporal courts."[31] While this is not likely to be an issue with obesity and physical activity, the courts have generally prohibited using public health laws in place of criminal laws to punish persons without providing criminal due process protections.[32] The courts have rejected laws that punish drunkenness or being a drug addict, as opposed to possessing or selling illegal drugs.[33] Laws that impose government penalties on

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[28] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001).

Greater New Orleans Broadcasting Ass'n v. United States, 527 U.S. 173 (1999)[29]; Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60 (1983); Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980).

[30] Rubin v. Coors Brewing Co., 514 U.S. 476 (1995).

[31] Landis v. Taylor, 5 Ohio N.P. 216 (Ct. Com. Pl. 1898), *available at* 1898 WL 1445.

[32] Edward P. Richards, *The Jurisprudence Of Prevention: The Right Of Societal Self-Defense Against Dangerous Persons*, 16 Hastings Const. L.Q. 320 (1989).

[33] Robinson v. California 370 U.S. 660 (1962).

obese persons to provide incentives for them to lose weight might be found to be impermissible punishments for the status of being obese.

Commerce Clause Limits on State Action

Congress can pass laws under its Commerce Clause power that preempt state regulations if they interfere with interstate commerce. For example, the Cigarette Labeling Act limits the right of the states to regulate the advertising and warning requirements for tobacco products,[34] and the federal law regulating medical devices preempts states from putting additional requirements on medical devices sold within their borders. The United States Supreme Court has read the Commerce Clause to limit the right of states to interfere with interstate commerce even in the absence of any specific federal law regulating the commerce. This is called the Dormant Commerce Clause doctrine and it is frequently used to challenge public health regulations that affect goods in interstate commerce. The clearest application is to a state regulation that affects out of state and instate business differently, even if, on the face of the regulation, it applies uniformly to both. For example, a regulation that prohibited the sale of ice cream in Baltimore unless the cream used was produced within 50 miles of Baltimore and inspected by the City of Baltimore, was found to interfere with interstate commerce.[35] The state was not able to convince the court that there was a sound public health rationale for the differential treatment.

The courts may limit states' authority to regulate areas such as food labeling, which is already regulated by the FDA, if the court sees the state regulation as burdening interstate commerce or conflicting with the FDA requirements. Congress may pass laws prohibiting certain state regulations - the House of Representatives has already passed a bill that would ban obesity lawsuits against fast food providers.[36] State laws targeting national franchise restaurants could be attacked for interfering with interstate commerce.

Constitutional Equal Protection Issues and State and Federal Disability Laws

Obesity is a complex disease with genetic and behavioral components. The risk of diabetes, the most important sequella of obesity, is strongly determined by genetic factors. These genetic and behavioral factors are correlated with race, being more common in blacks and Native Americans. They are also correlated with class, especially for women, with poor women being heavier than wealthier women. The United States Constitution prohibits individuals from being treated differently because of race, and many states extend that guarantee of equal protection to distinctions based on social class. Since legal interventions that target obese individuals, such as "fat taxes," insurance surcharges, and requirements to participate in weight loss programs, will affect blacks more frequently than whites, these interventions will be constitutionally suspect.

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[34] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001); Cipollone v Liggett Group, Inc. 505 U.S. 504 (1992).

[35] Miller v. Williams, 12 F. Supp. 236 (D. Md. 1935).

[36] H.R. 554, 109th Cong. (1st Sess. 2005) (An Act to Prevent Legislative and Regulatory Functions From Being Usurped By Civil Liability Actions Brought Or Continued Against Food Manufacturers, Marketers, Distributors, Advertisers, Sellers, and Trade Associations For Claims Of Injury Relating To a Person's Weight Gain, Obesity, Or Any Health Condition Associated With Weight Gain Or Obesity).

The state will have to convince the court that the programs are racially neutral and that they are narrowly tailored to minimize racial impact.

Legal strategies that target obese individuals may also violate federal and state disability discrimination laws. While the courts have not traditionally treated obesity as a protected disability,[37] these rulings were based on the assumptions that obesity was a voluntary condition and that individuals could escape their condition by just losing weight.[38] While the United States Supreme Court has not addressed whether obesity is a disability under the Americans with Disabilities Act (ADA), it has interpreted the ADA's requirement that a condition affect a major life activity as including conditions that have not yet resulted in secondary illness. In that case, the court found that the extra risks of pregnancy in an HIV-infected woman would affect the choice to have children, which is a major life activity. Thus, otherwise asymptomatic HIV was classified as an ADA disability.[39] As medical evidence accumulates that obesity is a disease with complex social and genetic antecedents that can have a significant impact on major life activities,[40] the courts are beginning to classify obesity as a protected disability.[41]

To the extent that obesity is an ADA protected disability, employers and government agencies that penalize obese workers or treat them differently from other workers may be violating the ADA. While the ADA does not affect group health insurance practices, special conditions on health insurance for obese individuals might violate the ADA. These could include surcharges for obese individuals that are not applied to other persons with elevated health risks, such as persons with heart disease. The ADA can also affect access to government benefits. In at least one case, a federal court has allowed women seeking obesity-related treatments under Medicaid to sue their state for failing to provide the treatment.[42]

Some large employers are changing job descriptions to make it more difficult for obese workers to meet the physical requirements for jobs. For example, grocery store checkers can also be required to retrieve shopping carts from the parking lot or stock shelves, changing a sedentary job into one that will be difficult to do for an obese worker. This is legal under the Americans with Disabilities Act as long as the employer can show that the job qualifications are not a sham. Limiting the employment opportunities of obese workers can condemn them to lives of poverty, which limits their ability to make healthy choices and exacerbates their obesity.

The genetic basis for diabetes also raises issues for individuals who are not genetically pre-disposed to diabetes. This will become a more pressing question as genetic testing makes it

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[37] Torcasio v. Murray, 57 F.3d 1340 (4th Cir. 1995) (Va.); Hazeldine v. Beverage Media, Ltd., 954 F. Supp. 697 (S.D.N.Y. 1997); Morrison v. Pinkerton Inc., 7 S.W.3d 851 (Tex. App. 1999).

[38] Coleman v. Georgia Power Co., 81 F. Supp.2d 1365 (N.D. Ga. 2000).

[39] Bragdon v. Abbott, 524 U.S. 624 (1998).

[40] Funk v. Purdue Employees Fed. Credit Union, 334 F. Supp.2d 1102 (N.D. Ind. 2004).

[41] Cook v. State of Rhode Island Dep't of Mental Health, Retardation, & Hosp., 10 F.3d 17 (1st Cir. 1993) (R.I.); Branson v. Ethan Allen, Inc. (E.D.N.Y. 2004), *available at* 2004 WL 2468610; Warner v. Asplundh Tree Expert Co. (D.Conn. Dec 10, 2003), *available at* 2003 WL 22937718.

Mendez v. Brown, 311 F. Supp.2d 134 (D. Mass. 2004).

possible to identify persons at risk. Does the rationale for individual restrictions fail for persons who can establish that their moderate obesity poses no extra costs to society?

Public Health Law Enforcement (Table 3)

There are two classes of enforcement actions, civil and criminal law. The standards for criminal law enforcement are set by the Constitution. Criminal law punishments can be fines or imprisonment. Criminal law can only be used to punish for past behavior and the crime must be clearly defined by a statute or a regulation implementing a criminal statute. When a person is prosecuted for a crime he or she is entitled to appointed counsel, trial by jury in most cases, and the case must be proven beyond a reasonable doubt. Civil law cannot be used to imprison individuals in order to punish them; its remedies are limited to fines and other restrictions on behavior. Civil law can be used to punish past behavior or to prevent future risks. Civil law cases need only be proved by a preponderance of the evidence, there is no constitutional right to appointed counsel in most cases, and the standards for behavior do not need to be as clearly defined as for criminal prosecutions. Civil law is also used to quarantine and otherwise restrict individuals to prevent future harm.

Most of the strategies discussed in this White Paper involve the regulation of business, such as FDA labeling requirements for processed foods, or the management of public agencies, rather than restrictions on individual behavior. The primary enforcement tools are those already in use by federal and state agencies. These include:

1) Injunctions (court orders) to stop non-compliant behavior, such as when a restaurant does not comply with food labeling regulations;

2) Civil fines, such as those used against medical care providers who do not comply with Medicaid guidelines for reimbursement for treatment of obesity;

3) Seizure orders, such as those used by the FDA to seize unsafe food or drugs; and

4) Criminal prosecutions, which are reserved for serious violations that lead to injuries or major fraud against the Medicare or Medicaid program.

When a public health agency orders a business or an individual to comply with a public health law, it must provide the appropriate due process. If the violation poses an immediate threat to the public health, such as the potential sale of contaminated food, the agency may act without a prior court hearing, perhaps by seizing the food to prevent its sale.[43] In most cases the agency will go through an administrative enforcement procedure, which will include informal consultations with the regulated party, an administrative hearing, and, if necessary, a court hearing for an enforcement order.

[43] N. Am. Cold Storage Co. v. City of Chicago, 211 U.S. 306 (1908).

Tort Claims in Public Health (Table 4)

Private legal actions have a long history in public health. Private legal actions arise from the common law tradition, such as nuisance claims, and other tort actions, or are created by specific statutes, such as the private enforcement provisions of the antitrust laws. Tort actions are the most important private legal actions in the obesity and physical activity area. Tort law provides a private remedy to pay money damages to persons who are injured by the conduct of others. This can complement state public health regulations. For example, a diner in a restaurant who is served tainted food may have tort action against the restaurant for any injuries caused by its negligence.[44] The health department can close the restaurant for endangering the public,[45] but the health department does not compensate the injured diner.

The Policy Role of Tort Law

Tort claims have two policy roles in public health. First, in some limited circumstances, they can force defendants to agree to change their behavior in ways that cannot be required by legislation. For example, a defendant in a tort claim brought over injuries caused by a defective product might agree to limit the advertising of the product as part of a settlement agreement. As long as the product and its use are lawful, if the government required the same limitations through legislation, the courts would likely find that these laws violated the commercial speech doctrine.

Second, tort claims can be brought by private individuals or by a state or federal attorney general to force policy changes that are not supported by the legislature. An example is the settlement in the state tobacco litigation. The tobacco companies agreed to pay the states a percentage of their revenue from cigarette sales and to limit the sale of cigarettes under certain conditions, such as through vending machines. These restrictions could have been imposed through legislation, but many legislatures were unwilling to pass such laws. (As discussed in the section on preemption, the legislature can pass laws to prevent tort claims in areas where it believes they are being improperly used.)

There are limits to the public policy benefits of making policy through tort law. For example, the tobacco settlement only binds the companies that are part of the settlement. While states have passed laws to apply the terms to new companies, this cannot be done for parts of the settlement that involve constitutionally protected behavior. These laws imposing the terms of the tobacco settlement on new companies also act as a restraint on competition, protecting the profits of the very companies who conspired to harm the public against new entrants who have not engaged in deceptive behavior.

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[44] Averitt v. Southland Motor Inn of Oklahoma, 720 F.2d 1178 (10th Cir. 1983).

[45] Camuglia v. City of Albuquerque, 375 F. Supp.2d 1299 (D.N.M. 2005).

Effects on Scientific Policy

Tort law as a public health intervention for obesity poses four problems. First, judgments in legal cases are final and cannot be appealed or later reversed because the underlying scientific evidence is found to be incorrect. For example, a plaintiff recovered damages for a birth injury allegedly caused by her mother's use of a spermicide. The plaintiff's expert testimony was based on a preliminary research report whose own authors warned that it was inconclusive. When further research showed that the study was wrong, the defendant attempted to have the verdict set aside. The court refused because the evidence in tort cases cannot be reopened.[46] Different juries looking at the same allegations, such whether a vaccine causes an injury, often reach different conclusions, leading to conflicting legal standards.

Second, legal standards and evidence in tort cases are evaluated by jurors and judges who are not experts in the underlying science. The lawyer's duty in tort cases is to present the most compelling case for the client, not to present a fair and balanced treatment of the evidence. While judges are charged with reviewing scientific evidence to determine if it meets basic legal standards for credibility, the judge is dependent on the information presented by the attorneys and their experts.[47] While there have been many cases challenging the refusal of a judge to admit evidence, procedural rules make it very difficult to appeal the admission or non-admission of evidence.[48] A case may be proven if the evidence is more probable than not, which is a much lower standard than is generally accepted for scientific proof. For example, in some older cases, while scientists agreed that modern vaccines for childhood illness were generally safe, litigation against the vaccine manufacturers for scientifically unfounded claims threatened to destroy the vaccination system in the United States.[49]

Third, tort claims are based on injuries that have already occurred to individuals. The public's interest is not formally before the court. Even if the product did cause injury to the plaintiff, it may have great benefit to others. The value of this abstract benefit is balanced against the real injuries claimed by the plaintiff. Based on this, juries will sometimes award large judgments against the product manufacturer to deter the use of what they see as a dangerous product. In doing so, they may force the manufacturer to quit selling the product, and it will become unavailable to persons who can benefit from it. Some drugs that assist in weight loss have already been removed from the market because of costs and fears driven by legal claims. While these were drugs with significant risks, these risks might be worthwhile for a severely obese person in a controlled setting.

Fourth, the standards for holding a product manufacturer, such as a drug company, liable for injuries, are much easier to satisfy than those for holding a service provider, such as a physician

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[46] Wells v. Ortho Pharm. Corp., 788 F.2d 741 (11th Cir. 1986) (Ga.).

[47] Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137 (1999); Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

[48] Gen. Elec. Co. v. Joiner, 522 U.S. 136 (1997).

[49] Office of Technology Assessment, Compensation for Vaccine-Related Injuries: A Technical Memorandum (1980).

or nutritionist, liable. For example, it is much more difficult to prove a case against a surgeon for complications resulting from obesity surgery than against a drug manufacturer for complications resulting from use of a weight loss drug. This can create a legal bias toward surgical procedures, even if the rates of surgical complications are much higher. In contemporary fast food litigation, the plaintiffs are seeking to use this special standard for tort cases involving products to justify holding manufacturers liable for causing obesity, while disregarding the customers' responsibility.[50]

[50] Pelman v. McDonald's Corp., 237 F. Supp.2d 512 (S.D.N.Y. 2003).

Example Legal Strategies

Developing legal strategies

There are many factors to consider when developing legal strategies to manage public health problems. This section discusses the general considerations in using government powers and legal tools to develop strategies to manage obesity and physical inactivity. It is followed with examples of possible strategies chosen to illustrate the different possible approaches to the problem. These examples are roughly based on existing scientific knowledge. They are intended as illustrations of the application of governmental powers across the three levels of government, not as recommended strategies. The examples are meant to be templates, with the specific strategies to be filled in by the subject matter expert scientists, based on best practices. Most importantly, it is assumed that strategies will be modified through time as better information becomes available. The objective of this section is to illustrate the broad range of possible strategies and to stress that with a complex, long term problem such as obesity, there will be no single effective strategy. Change will come with time and the application of many strategies, with each contributing only a small part to the final results.

The most important lesson from the previous section on government powers is that courts generally defer to the expertise and political decisions of the legislature and public agencies. The courts do not review the soundness of science underlying public policy interventions unless there is essentially no support for the government's position.[51] It is the responsibility of legislatures and public health agencies to assure that the public health interventions they enact are based on good science and are periodically reviewed and revised when better information is available. Strategies that are not scientifically well-founded will undermine the public and political support for interventions to manage obesity and physical inactivity.

Legislation or Agency Action?

Developing public health strategies for managing obesity and physical inactivity is complicated because the scientific basis for the strategies is in its infancy, and because there are many local factors that mediate against a single, national solution. Such complex problems demand flexible regulation and broad powers to affect many different regulatory areas. While the legislature is the source of agency power, direct legislation of specific public health strategies has two pitfalls. First, the process is time consuming, and, once legislation is passed, the legislature is often unwilling to return to laws to modify them as the science develops. Second, legislatures do not have the technical expertise to evaluate appropriate strategies, and public health officials are only one among many constituencies that they consult on legislative decisions. In some cases,[52] the

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[51] Chlorine Chem. Council v. E.P.A., 206 F.3d 1286 (D.C. Cir. 2000) (rare example where court rejects a governmental standard based on inadequate science, as opposed to failure to comply with statutory guidance, as in Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst., 448 U.S. 607 (1980).

[52] D. A. Salmon, M. Haber, E. J. Gangarosa, L. Phillips, N. J. Smith, & R. T. Chen, *Health Consequences of Religious and Philosophical Exemptions From Immunization Laws: Individual and Societal Risk of Measles*, 282 JAMA 47-53 (1999); K. M. Edwards, State Mandates and Childhood Immunization, 284 JAMA 24 (2000).

law that is passed will be so modified as to be contrary to best public health practices, or so limited that it is very difficult to implement.

Impact of Existing Laws

The starting point in developing legal strategies to manage public health problems is to analyze existing laws to determine if the problem being addressed is partially caused by the unintended consequences of past laws. If so, modifying these laws to eliminate or reduce the unintended consequences is a critical part of any legal strategy. For example, separating commercial and residential development was an important public health strategy in the early 20th century, when industrial facilities in residential neighborhoods posed a grave threat to health. The resulting single use suburban neighborhoods reduce the opportunities for individuals to walk in their daily lives. Since a key to building neighborhoods that encourage walking is having places to which to walk, these zoning laws might be modified to allow some business development as part of neighborhoods. As detailed in the subsequent sections, there are many laws whose unintended consequences exacerbate the problems of obesity and physical inactivity.

Identifying laws and public policies that unintentionally impact obesity and physical activity is critical. If these are not addressed, they will undermine other strategies and may lead to paradoxical results because their confounding effects will not be factored into the analysis of the strategy under study.

Regulatory Timeframe

Some public health problems develop quickly, require quick action, and, once managed, pose few long-term issues. In most cases, these involve technological interventions, not behavioral changes. For example, an outbreak of salmonella due to improper sanitation in a food processing facility might quickly sicken many people, and would require quick action to remove the product from the stores. Once the problem was corrected at the facility, there would be no further threat to the public. Such short-term threats can be handled by pulling resources from other public health activities, and justify significant legal intrusions (seizure of food, searches, public notices of hazard) because they will be limited in time. Such short-term threats also capture public and media interest, increasing the support for the public health department's actions. As importantly for public support, the intervention works quickly.

In contrast, public health problems that require complex behavioral changes and/or major infrastructure modifications require long-term strategies. Unlike short-term problems which can often be managed by temporarily diverting resources from other work, long-term problems require devoted staff and stable funding through time. Such interventions face the difficulty of maintaining public support and participation, and, in the absence of active public support, the legislative funding necessary for continued operation. These are most difficult when the proposed behavioral changes have little immediate benefit but are to prevent long-term illness. Smoking is one example of this type of problem, although smoking both harms and discomfits bystanders, creating a constituency that supports continuing regulation of smoking. Sexually transmitted infections (STIs), including HIV/AIDS, are another example, but one where the

behavior has no immediate effect on bystanders. This has made it difficult to sustain control programs through time at high enough levels of staffing and funding to be optimally effective.

The changes in eating and physical activity patterns that underlie current problems with obesity and physical activity occurred over many years and were driven by complex societal changes. The personal behavioral changes necessary to reverse these trends must be life-long. As research on dieting has shown, obesity is a life-long problem. Legal strategies for managing obesity and physical inactivity must be structured for the long term. They must have their own funding and staff, and they cannot depend on resources borrowed from other programs. They must have significant public support, which limits the pace at which changes can be made that influence personal behavior.

Levels of Government

As discussed in the section on governmental powers, strategies can be implemented through legislation, administrative regulations, executive orders, and through using the spending power to provide incentives to encourage the desired behavior. All of these methods will need to be used in managing obesity. Each proposed intervention should be analyzed to determine the appropriate level of government and the appropriate agency to carry out the intervention. In many cases, more than one level of government will be involved. Areas where there is general public consensus, such as modification of food labeling to provide more information to consumers, can be done through direct federal legislation. As with tobacco regulation, more politically difficult changes may be best done at the state and local levels, accepting that some states will take the lead and others may not follow. Through time, experience from states that successfully deal with these problems will drive the public consensus in other states. As consensus builds, the federal government can increase the use of national standards to facilitate change. The federal government can encourage the states to adopt best practices through public education and through grants to fund state and local interventions.

Environmental versus Personal Regulation

Environmental modifications are politically easier to implement than personal restrictions. Strategies based on education and environmental modification should be used in preference to strategies that involve using financial or other penalties to force changes in personal behavior. Thus, providing better opportunities for people to walk in their communities is more likely to succeed than strategies that attempt to coerce people into walking. Improving access to fresh fruits and vegetables at lower costs relative to prepackaged foods and meat can shift consumer behavior without engendering hostility.

Data Collection and Surveillance (Table 5)

Determining the epidemiology and pathophysiology of obesity depends on collecting good data on many individuals through long periods of time. Most of the available data for obesity comes from behavioral science studies that depend on self-reported data. While this data is very useful, it would be valuable to have more broadly based data developed through a reporting system

based on medical records, school records, and other objective sources. This is especially important for obesity, which is not a simple binary state but one that requires estimation along a continuum.

While the courts grant both the state and federal governments broad powers to collect epidemiologic data, almost all public health reporting is done through state and local laws. Table 5 thus focuses on state and local reporting laws and regulations, rather than possible federal laws. There is no legal impediment to federal reporting requirements, which could be based on the Commerce Clause or implemented through conditions on state and local grants.

The government is expected to protect the individual's privacy from unnecessary disclosure, but the courts have made it clear that individual privacy is secondary to the need for public health and safety.[53] The Health Insurance Portability and Accountability Act (HIPAA), which sets federal privacy standards for medical information, provides a broad exception for public health reporting.[54] The government may require third parties such as physicians and medical laboratories to report information about their patients, and the government may authorize public health investigators to review the records held by third parties. These reports are used in all states to track infectious diseases and to provide an early warning for emerging diseases.[55] Governmental agencies with relevant public health data, such as the Veterans Administration hospitals, school districts, and prisons can be required to make pubic health reports.

Table 5 lists several potential sources of data about obesity and physical activity. All of these data sources currently provide some public health data, so that adding reporting on obesity and/or physical activity could be accomplished by modifications of existing reporting laws and regulations. Obesity and physical activity data would not pose any privacy or HIPAA issues that have not been raised with other public health reporting requirements. The most significant change would be the volume of information. Communicable disease reporting generates relatively few reports compared to the volume of data that would be generated by laws requiring the reporting of obesity-related information, especially if that information were to include tracking information on the treatment of obesity-related conditions such as diabetes. Such a data stream would tax the capabilities of many state and local health departments and might reduce their ability to manage traditional public health reporting data. Any new reporting laws that would generate a significant volume of new data should include funding for staff and equipment to manage the data, either in the public health departments or in agencies such as Medicaid and Medicare intermediaries which already process large volumes of medical information.

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[53] Whalen v. Roe, 429 U.S. 589 (1977).

[54] HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services, 52 Morbidity & Mortality Wkly. Rep. (MMWR) 1-12 (April 11, 2003).

[55] Emerging Infectious Diseases: Review of State and Federal Disease Surveillance Efforts, GAO-04-877 (September 30, 2004).

School-Based Interventions (Table 6)

K-12 schools are in a unique position as both a regulator and a target of regulation. All schools, public and private, control their students' nutritional and physical activity during the school day. For many students this day begins early with breakfast at school, and may end late in the day after sports or other extra-curricular activities. In the 1950s and 1960s, most schools limited access to snacks outside of the school cafeteria to structured snack breaks with school-provided milk for younger children. Students were provided a nutritionally balanced plate lunch in the cafeteria with few options other than bringing their own lunches from home. Younger students had recess time to play and older students were required to participate in structured physical education.

Unintended Consequences of Other Social Policies

Over the past 40 years, many schools have moved from serving as careful controllers of snacks and school-provided meals to purveyors of sodas, snack foods, and fast foods throughout the school day. School nutritionists have long understood the potentially adverse impact of these changes on student eating habits, but these changes were driven by economic policies unrelated to nutritional concerns. In all but the wealthiest school districts, school budgets have been cut through time, and schools have been forced to enroll many more students than their design capacity. School districts have been offered lucrative contracts from vending machine companies to allow soda and snack machines in the schools. This arrangement provides a source of funds to cover shortfalls in school budgets. While the federal laws on school lunch programs have attempted to regulate nutrition in the schools, these vending machines were allowed under the exemption for the sale of promotional foods.

School overcrowding meant that many schools did not have the cafeteria space to serve students in the traditional lunch periods and did not have the space to prepare the plate lunches. Fast foods, especially those provided by outside vendors, could be prepared and served in less space and more quickly than traditional lunches.

Policies that regulate snack and fast food sales in schools should take into account their impact on school finances and whether they will make it more difficult to provide lunches in overcrowded schools. This will reduce opposition to new policies but may anticipate substitution issues: replacing sodas with fruit juice will keep the revenue constant, but may increase the calories consumed.

Schools have also been under pressure to increase the academic content of their curriculums, but economic and social constraints do not allow the lengthening of the school day. This puts pressure on schools to limit recess and physical education times. Budgetary pressures also limit the staff available to supervise students at recess and run physical education programs in some

schools. Liability concerns have caused some schools to remove traditional playground equipment and limit access to playgrounds after school hours.[56]

Regulatory Authority

The federal government directly regulates schools through laws such as the Rehabilitation Act and the Americans with Disabilities Act, both of which deal with treatment of disabled students. The federal government also regulates schools by attaching conditions to funds for programs such as federally subsidized school lunches. States regulate schools directly through laws passed by the legislature and indirectly through state agencies with regulatory authority over schools. For example, the Texas Department of Agriculture has authority over school nutrition programs in that state. The Department was able to establish administrative orders controlling many aspects of food service in public schools without requiring additional legislation. Since administrative orders, as opposed to regulations, do not usually require public notice and comment, they are much quicker to implement and may be easily modified as more is learned about the best approach to the problem being regulated.

Private schools are also regulated by the state and federal governments, but generally face fewer regulations than public schools. Home schools are only minimally regulated in many states. As the states and the federal government develop obesity and physical activity regulations and guidelines for schools, they will need to determine if these will apply to all schools uniformly.

Universities

Universities have much less control over their students' lives, but many do run dormitories and either provide food service on campus or regulate it through contracts with private food service providers. Universities can also require physical education courses for graduation, with some universities having significant fitness requirements. While K-12 schools have been the focus of inquiry for childhood nutrition, universities play an important role in the transition to independent living. Most universities collect health data on entering students, which could include reportable information about nutrition status. Additional information could be collected as part of physical education courses. Universities are very dependent on federal education funding, which could be a vehicle for regulating on-campus nutrition, requiring data collection, and encouraging physical education requirements.

Food Regulation (Table 7)

The federal government shares the regulation of food with the states and local government. The Department of Agriculture regulates some aspects of food production and sanitation, especially

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[56] Allen E. Korpela, LL.B., Annotation, *Tort Liability of Public Schools and Institutions of Higher Learning for Injuries Due to Condition of Grounds, Walks, and Playgrounds*, 37 A.L.R.3d 738 (2004); Chris Kahn, *In the Pursuit of Safety, Teeter-Totters and Swings are Disappearing from Playgrounds*, South Florida Sun-Sentinel, July 18, 2005, *available at* http://www.sun-sentinel.com/news/local/broward/sfl-cplaygroundjul18,0,4929507.story?coll=sfla-news-broward.

meat production. The FDA regulates prepared packaged food content, labeling, and some food safety issues, such as the use of antibiotics in farm animals. The states regulate food handling and preparation for sale in restaurants and for catering, some aspects of the preparation of packaged food, and, to a limited extent, the labeling of food. In some states restaurant and food sanitation inspections are done by city and county health departments, as well as the state. The FDA, Agricultural Department, and state authority overlap in many areas of food regulation. Federal standards may also preempt state standards, and state standards that impede the sale of food in interstate commerce may violate the Dormant Commerce Clause.

The regulation of food sanitation, labeling, and content has been a key part of public health for more than 100 years. Vitamin and mineral supplementation of food and milk have dramatically reduced deficiency diseases such as rickets, pellagra, and goiter. While the role of food content regulation is still uncertain in obesity control, the federal government has the power to regulate the content of foods to control caloric density, serving size, or nutrient composition, based on future scientific findings. For example, if high fructose corn sweetener were found to contribute to the development of insulin resistance syndrome in humans,[57] the federal government could regulate its use, require specific labeling, or re-examine the sugar tariff system to lower the price of sugar to reduce the economic incentive to use high fructose corn sweetener.

The federal government regulates the labeling for packaged foods, and there are studies in progress to determine the most effective labeling strategies to address obesity. There are few state or federal regulations on the labeling of prepared foods at the point of sale. While most fast food franchisees provide information about the nutritional content of their foods, this is usually not readily available at the point of sale. Few restaurants provide nutritional content information on the menu or in any other form. Both the state and federal governments have the authority to require such labeling, and it would be a logical area of regulation as data is developed on the most useful information for consumers. Food advertising may also be regulated, subject to the evolving commercial speech restrictions on government regulation of truthful advertising.

Food prices pose a more difficult regulatory problem. United States agriculture policy since the 1950s has focused on reducing the cost of food. In constant dollars, food prices today for meat, dairy, grain, and processed foods are much lower than they were in 1950. The cost of fresh fruits and vegetables is also lower in relative terms, but not as low as the other food products. As with other consumer goods, consumption has increased with the falling prices, and food choices have shifted toward the cheaper foods.[58] This has led to less healthy food choices, while the overall decrease in food costs has encouraged larger portion sizes. The federal government could use tax policy and subsidies to lower the cost of fresh fruits and vegetables relative to processed foods and meat. Foreign trade regulations can influence the supply of fresh produce from Central and South America. The states play only a small part in agriculture policy, but they can use laws and regulations to encourage cooperative farms and other ventures that can produce

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[57] S. S. Elliott, N. L. Keim, J. S. Stern, K. Teff, & P. J. Havel, *Fructose, Weight Gain, and the Insulin Resistance Syndrome*, 76 Am. J. Clin. Nutr. 911–22 (2002).

[58] David M. Cutler, Edward L. Glaeser & Jesse M. Shapiro, *Why Have Americans Become More Obese?*, Discussion Paper 1994, Harv. Inst. of Econ. Research (January 2003), *available at* http://post.economics.harvard.edu/hier/2003papers/2003list.html.

fruits and vegetables for local consumption. States can also require that public agencies, prisons, and schools incorporate more fresh produce into institutional meals. This would benefit the persons eating the meals and encourage the food distribution system to make more produce available.

Food Support Programs

Research has shown that people who face food insecurity - going hungry when their money runs out before the end of the month - also have problems with obesity.[59] There is also evidence that families facing food insecurity economize in ways that lead to less healthy diets.[60] The federal Department of Agriculture runs nutrition support programs to help people get adequate calories. The best known are the school lunch programs, Food Stamps, and WIC - Special Supplemental Nutrition Program for Women, Infants, and Children, which provides food to supplement the diets of low-income women, infants, and children up to age 5 who are at nutritional risk. WIC has been a pioneer in trying to develop support guidelines that result in a nutritious diet, and until recently these have not included concerns with obesity. WIC is now considering revising its food basket to address obesity, among other revisions based on current nutrition research.[61]

As federal grant programs, these are entirely under the control of the federal government. WIC closely controls the foods that can be purchased, there are categorical restrictions on Food Stamps, such as no alcohol, and there are standards for school lunches. The federal government has the authority to further direct food choices under these programs, particularly to encourage more healthy food choices under the Food Stamps program. This can be done through restrictions on the use of Food Stamps, as is now done with certain items. It could also be done by providing additional Food Stamps payments if the recipients buy certain foods, such as fresh fruits and vegetables. Given that fresh fruits and vegetables are more expensive on a per-calorie basis, this would offset the pressure to buy cheaper food with the limited benefits. Since the federal government sets the standards of eligibility for WIC and Food Stamps, it could modify the eligibility to include at-risk poor people who are now excluded, such as older children, and broaden the focus of the programs to make them a vehicle for encouraging healthy food choices in these populations.

Some families depend on more than one support program - perhaps free breakfasts and lunches at school, WIC at home for younger children, and church food banks for older children. Since these programs are not coordinated, it can be very difficult for families to assemble nutritious meals with a good variety of fresh produce and other foods that can help provide a balanced lower calorie diet. The state and federal governments could develop voluntary standards and

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[59] Centers for Disease Control & Prevention (CDC), *Self-Reported Concern About Food Security Associated with Obesity: Washington, 1995—1999*, 52 MMWR 840-42 (September 5, 2003), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5235a3.htm.

[60] Food Research & Action Center (FRAC), *Report: The Paradox of Hunger and Obesity in America* (2003), *available at* http://www.frac.org/html/news/071403hungerandObesity.htm.

[61] Institute of Medicine, *Proposed Criteria for Selecting the WIC Food Packages: A Preliminary Report of the Committee to Review the WIC Food Packages Food and Nutrition Board*, (National Academy Press 2004).

best practices for private food support programs and use grant funds to encourage programs to adopt these. This could help these programs move from primarily providing calories to providing more balanced meals. It is also important to assure that there are no gaps in the nutritional support that create food insecurity with its risk of increasing obesity.

Encouraging Physical Activity through the Built Environment (Table 8)

Land Use Regulations

Historically most people had jobs that included physical work, including homemaking, which was physically demanding. With changes in the job market and with more labor-saving devices in the home, physical activity as a part of daily life declined in the United States. Part of this decline is also due to changes in the built environment.

Land use regulation in the United States developed as a public effort to improve health by separating residential development from dangerous industrial environments. William Blake's vision of dark, satanic mills was more than a metaphor for families forced to live near 19th century factories and tanneries. Air and water pollution, as well as physical threats from explosions and dangerous facilities open to children, made these neighborhoods major health concerns. New York passed one of the first comprehensive land use laws,[62] and the United States Supreme Court upheld the constitutionality of land use planning in 1926.[63] These laws dramatically improved the safety of urban life for lower income families and established the principle that residential housing should be separated from industrial and commercial development. The courts have allowed federal, state, and locality governments broad powers to regulate land use. The major limit is that if the government takes the use of the land, the government may have to pay the land owner the land's fair market value.

As illustrated in Table 8, the government can directly regulate land use, for example by requiring sidewalks or by permitting mixed use development that would encourage walking. Since the federal government controls the major mortgage lenders and regulates mortgage lending in general, land use modifications can also be done as conditions for financing. The government can also use grants to support the modification of existing neighborhoods and make such modifications a condition of permits to build more houses in those neighborhoods. In the land use area, the government's powers are limited by political considerations and community acceptance much more than by the courts.

While studies show that urban residents are more active than those in suburbs, in some urban areas where the geography is conducive to walking, fear of crime keeps people inside.[64] Even in

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[62] City of New York Board of Estimate and Apportionment, Building Zone Resolution (July 25, 1916), *available at* http://biotech.law.lsu.edu/cphl/history/laws/ny_index.htm.

[63] Village of Euclid, Ohio v. Ambler Realty Co., 272 U.S. 365 (1926).

[64] Mitch J. Duncan , John C. Spence, & W. Kerry Mummery, *Perceived Environment and Physical Activity: A Meta-Analysis of Selected Environmental Characteristics*, 2 Int'l J. Behavioral Nutrition & Physical Activity 11 (2005), *available at* (http://www.ijbnpa.org/content/2/1/11).

suburban neighborhoods parents are frightened of allowing their children to play unattended and wander far from home as children did in prior generations. Crime control is part of encouraging physical activity, especially in children. This is most important in the poorest neighborhoods, which also have the highest obesity rates.

Building Regulation

Most building codes are developed by national groups and adopted, with modifications, by state and local governments. The federal government also plays a role in shaping these codes through laws such as the Americans with Disabilities Act, which has specific building mandates for access by the disabled. Land use regulations establish the broad outlines for development, and building codes govern the construction of individual structures. There is considerable overlap, with some localities using land use codes to regulate building setback and parking requirements and others making that part of the building code. The primary purpose of building codes is safety: keeping the building from falling down; reducing the threat of fires; making sure occupants can get out safely if there is a fire; assuring that there is adequate ventilation, heating, and cooling; and, for residential buildings, ensuring that rooms are adequate for the intended occupancy. After the terrorist attack on September 11, 2001, security has also become a major concern. (This has been an issue for many federal buildings since the Oklahoma City bombings.)

One example of the impact of building codes on physical activity is the regulation of the use of stairs. Multi-floor office buildings are a good opportunity for many people to exercise by walking to their floor and between floors. Fire codes often require that stairways be behind closed doors and be on the sides of buildings, to prevent them from spreading fires and to protect from fires in the building core. This makes them less convenient for routine use. Security concerns, both ordinary business security and security measures aimed at terrorists, often require that stairs be secured and there not be any re-entry to the floors once someone is in the stairway. This makes it impossible to use stairs to move between floors of the building. The Americans with Disabilities Act requires elevators in most buildings that are more than one story tall to assure access by disabled individuals. The Act also requires that persons using such accommodations not be stigmatized, which is widely interpreted to mean that elevators cannot be restricted to use by the disabled. Thus fire and security concerns make stairs less accessible, while the ADA makes elevators more widely available, both reducing the incentive and opportunity for occupants to use the stairs.

As the CDC has demonstrated with some of its buildings, stairs can be made more attractive and accessible, and traffic can be shifted from elevators to stairs. This depends on the physical layout of the stairs and the flexibility of the local building codes, as well as the building's security director. (It is also much more difficult to do when there are many different tenants in the building.) Governments could make codes on existing buildings more flexible and could require that new construction be planned to encourage stair use. This might require stairs for fire escape that are separate from the stairs that are provided for routine daily use. Security concerns might be met by separate stairs between sets of floors, just as some buildings have zoned elevators for security concerns. Buildings might be laid out in ways that would encourage walking within and between buildings. The EEOC could issue regulations that clarify the ADA to allow employers to encourage able-bodied workers to use the stairs, while making elevators

available to the disabled. These are all changes that are unlikely to be implemented without government regulation.

Medical Treatment and Insurance Issues for Obesity (Table 9)

Most of this White Paper addresses the prevention of obesity through environmental modifications intended to encourage better nutrition choices and more physical activity. These are classic public health approaches. While they will also help people who are obese lose weight, it will be a long process that requires significant behavioral change. For many people, the necessary behavioral changes and the length of the process will be unacceptable, either because of their inability to implement the behavioral changes or because they are so obese that their weight poses an immediate threat to their health. For these persons, obesity is an individual health problem that requires treatment through the medical care system. This may be through psychological counseling or other interventions to help them lose weight. In some cases, drug or surgical treatment may be required, which will include long-term care and monitoring. In many cases, the obesity treatment will be part of other medical care for obesity-related conditions such as diabetes.

The medical management of obesity cannot be done effectively through the public health system in the United States alone. It must be done through strategies that target the medical care and medical insurance systems, and the regulation of drugs, medical devices, and medical practice. Obesity treatment poses difficult regulatory problems. The histories of the FDA and many state medical licensing boards are replete with regulatory actions against quack cures for obesity. From tapeworm eggs to disastrous bowel surgery to amphetamines, obesity treatment historically occupied the fringes of medical treatment. Even modern treatments using drugs that have passed through the FDA regulatory process can run into problems. The experience with fenfluramine and phentermine (fen-phen) demonstrates that the public concern with obesity and demand for quick treatment can lead to the over-prescribing and misuse of new treatments. This can harm the public, and can also force the FDA to withdraw the approval for drugs that might be valuable in controlled clinical settings for subsets of patients.

The FDA regulates the approval of drugs and medical devices for sale. The FDA determines if drugs are safe and effective for at least one medical use. The FDA also reviews medical devices, although they get a lower level of scrutiny than drugs. The role of the FDA is difficult because the public wants safe drugs but it also wants promising new drugs available quickly. This is especially problematic for drugs used to treat obesity because they will be given to large numbers of persons for long periods of time. Since the FDA does not have the authority to regulate the use of drugs by physicians once the drug has been approved, many of the persons receiving the drug will differ from those used in the clinical trials evaluating the safety and efficacy of the drug. As with fen-phen, such use is likely to uncover side-effects that were not evident in the limited clinical trials used for drug approval. Dietary supplements sold for weight loss are not regulated by the FDA or any other agency when they enter the market. The FDA may only regulate them when it can convince a court that the supplements have proven health

risks, as happened with ephedra, a food supplement commonly used for weight loss.[65] Since Congress limited the FDA's authority over food supplements in the early 1990s, there has been a huge increase in dietary supplements for obesity treatment.

There is limited direct federal regulation of medical practices outside the standards for payment under federal health benefits programs. A new technique for obesity surgery, for example, can be used without any regulatory approval. (There are federal regulations on medical research, but there is no requirement that new medical treatments be based on successful research.) The states regulate medical practice, which includes the use of drugs once they are approved by the FDA. The states can also regulate food supplements sold as obesity treatments, which is an important issue in the absence of federal regulation. Traditionally the state regulation of medical practice has been targeted to fraudulent treatments, such as chelation therapy for cardiovascular disease, which has no medical value and whose use is a fraud on the patient.[66] The states could expand their regulation to include the inappropriate use of otherwise effective treatments for obesity. Such oversight might have prevented the fen-phen tragedy, and also allowed the drugs to continue to be used in carefully selected patients. Since states are the only regulatory authority for medical procedures such as bariatric surgery, they have an interest in regulating the use of surgical procedures to assure that they are safe and effective and are not inappropriately used.

Medical Benefits and Health Insurance Regulation

The medical complications of obesity diminish the quality of life for many people. The long-term cost of medical care for these complications threatens both the private health insurance system and state and federal health care budgets. Obesity is more common in the poor, and in women, which means that a disproportionate share of the costs of obesity treatment will fall on the states through Medicaid and through state charity care programs. Public and private hospitals will also bear a disproportionate share of the medical costs of the sequella of obesity, particularly the complications of diabetes, through their legal duties to treat the medically indigent under the federal Emergency Medical Treatment and Active Labor Act.[67] Diabetes and cardiovascular disease secondary to obesity also impact the public and private disability systems as individuals are no longer able to work because of medical disability.

The states, the federal government, and private employers have a financial stake in reducing obesity. The difficult regulatory issue is that improving obesity treatment will increase costs for several years before the costs of treating complications of obesity go down. Most private employers are more concerned about current costs, and this focus is reinforced as more health costs are shifted to the workers themselves. While this might cause people to be more careful with health care spending, it also encourages them to skip the preventive care that is critical to managing obesity and its complications. State insurance benefits mandates can be

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[65] FDA, *FDA Announces Plans to Prohibit Sales of Dietary Supplements Containing Ephedra* (December 2003), *available at* http://www.fda.gov/oc/initiatives/ephedra/december2003/.

[66] People v. Privitera, 591 P.2d 919 (Cal. 1979); State Bd. of Med. Examiners v. Burzynski, 917 S.W.2d 365 (Tex. App. 1996).

[67] Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. § 1395dd (2005).

counterproductive in this area because they provide an incentive for employers to either shift to ERISA plans[68] that are beyond the reach of state regulation or drop employer funded health insurance altogether. Any expansions in coverage for obesity treatment must be based on evidence that the treatments work and have appropriate risk-benefit ratios. Medical treatments for obesity that are not effective, or that have serious secondary consequences, will raise the total cost of obesity care with no countervailing savings.

States and the federal government already fund categorical (single disease) clinics for important public health conditions such as tuberculosis and sexually transmitted infections, as well as for pre-natal care. Since obesity and the resulting diabetes are public health problems, it might make sense to fund clinics that treat individuals without regard to whether the patient has money or insurance. The objective of these disease-specific programs is to assure that patients with chronic diseases get consistent care irrespective of job or insurance status. Private health plans could be required to reimburse these clinics when their insureds sought treatment in them, with the incentive that they would provide cost effective and consistent care. This would arguably be within the ERISA carve-out that allows the state regulation of the business of insurance, as opposed to the specific terms of the plan.[69]

In the longer term, the federal standards being developed for evidence-based medicine, which will become practice standards in all the federally funded programs, will encourage preventive care and obesity management, just as they already encourage preventive care for diabetics. The federal government can encourage private insurers to use the same guidelines, which would solve the problem of inconsistent state regulation because of ERISA.

Direct Regulation of Personal Behavior

In some circumstances the state may restrict individuals to protect them from their behavior,[70] or because they can no longer care for themselves.[71] The state must show that these persons are not mentally competent. In a series of cases involving refusal of medical care, the courts have held that the state cannot force a mentally competent person to take care themselves.[72] It is unlikely that the courts would uphold laws that try to force people to lose weight or commit them to hospitals for obesity treatment. The law may have a greater role in childhood obesity. Morbid obesity in a child can be evidence of neglect. There has already been one case where a state removed a child from the home because of morbid obesity.[73] BMI at some high level could be

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[68] Aetna Health Inc. v. Davila, 542 U.S. 200 (2004); Metro. Life Ins. Co. v. Massachusetts, 471 U. S. 724 (1985).

[69] Thomas R. McLean & Edward P. Richards, *Health Care's 'Thirty Years War': The Origins and Dissolution of Managed Care*, 60 N.Y.U. Ann. Surv. Am. L. 283 (2004).

[70] Addington v. Texas, 441 U. S. 418 (1979).

[71] *In re* LaBelle, 728 P.2d 138 (Wash. 1986).

[72] Cruzan v. Director, Missouri Dep't of Health, 497 U.S. 261 (1990); Application of President Dir. of Georgetown College, Inc., 331 F.2d 1000 (D.C. Cir. 1964), *cert. denied*, 377 U.S. 978 (1964); Matter of Conroy, 486 A.2d 1209 (N.J. 1985) John F. Kennedy Memorial Hosp. v. Heston, 279 A.2d 670, 672-673 (N.J. 1971).

[73] Gerry Bellett, Mother Loses Custody Fight for "Morbidly Obese" Son, Ottawa Citizen, Jan. 7, 2005, at D15.

made reportable under the child abuse and neglect laws, which would allow child protective services to intervene to change the parents' behavior to protect the child.

Summary

Obesity and physical inactivity are now major preventive causes of illness in the United States, second only to smoking. The complex behavioral, genetic, and cultural etiology of obesity, combined with the number of persons affected, make obesity uniquely difficult to manage. Law, both as expressed by legislation, and through government agency action, has an important role in managing obesity and encouraging physical activity. This White Paper introduced the issues that affect the use of law to control public health problems. The courts allow the government broad latitude to protect the public health and safety. These powers must be used wisely, and interventions must be based on the best scientific information. Public trust is the most important limit on the public health powers. Public cooperation is essential for the long-term support necessary to manage obesity and increase physical activity.

Appendix

Table 1 - Constitutional powers for federal, state, and local governments.

TYPE OF POWER	FEDERAL	STATE	LOCAL GOVERNMENT
Constitution	Supreme law of the United States. Establishes the structure of the federal government and establishes and limits the powers of the federal and state governments. The federal Constitution is the supreme law of the land and preempts state and federal laws that the United States Supreme Court finds contrary to Constitutional powers and protections. Example: Brown v. Board of Education[74] declared state education segregation laws unconstitutional.	Establishes the structure and powers of the state and local governments, within federal limitations. Can provide greater, but not fewer individual liberty protections than the U.S. Constitution. Example: Washington State has more limits on the use of health department inspections of property than does the U.S. Constitution.	Powers come from the state constitution and the legislature.[75] They can be limited by terms of the city charter.
Preemption of subordinate jurisdictions	Congress has the power to pass laws that limit state action and void state and local laws. Example: The Cigarette Labeling Act limits state laws on the labeling of tobacco.[76]	State legislatures can preempt regulation and lawsuits[77] by local government, consistent with state constitutional provisions. Some states have prevented local governments from passing tobacco regulations stricter than those of the state.	N/A
Foreign Policy, Foreign Trade, and National Security	The federal government has the exclusive right to control relations with foreign governments, to regulate trade and immigration, and to provide for national defense. This includes the	State regulations that affect foreign trade or attempt to create foreign policy are unconstitutional.	Subject to the same restrictions as the state.

[74] Brown v. Board of Education, 347 U.S. 483 (1954).

[75] Williams v. Mayor & City Council of Baltimore, 289 U.S. 36 (1933).

[76] Cipollone v. Liggett Group, Inc. 505 U.S. 504 (1992), *available at* (http://biotech.law.lsu.edu/cases/tobacco/cipollone_v_liggett_group_inc.htm).

[77] Morial v. Smith & Wesson Corp., 785 So.2d 1 (La. 2001).

	power for the president to make treaties with the advice and consent of the Senate. The president has broad national security and foreign affairs powers that do not require congressional approval. Example: The North Atlantic Treaty Organization (NATO) which provides for common defense with Europe.		
Commerce Clause	Gives the federal government the power to regulate businesses that operate across state borders, or other activities that affect these businesses. This is a very broad power because the United States Supreme Court defines interstate commerce very broadly. Example: The FDA regulates drugs sold in interstate commerce, but not drugs made and sold only in a single state.	Limits the right of states to regulate business in a way that would treat out of state businesses differently from instate businesses. The "dormant" commerce clause doctrine limits state regulations that would adversely affect interstate commerce, even when the regulation is applied equally to in-state and out of state businesses. Example: State milk regulations that discriminated against out of state dairies were unconstitutional.	Subject to the same restrictions as the state.
Tenth Amendment All powers not given to the federal government are reserved to the states.	Over the past 50 years the United States Supreme Court has allowed the federal government, under the Commerce Clause, to legislate in areas traditionally reserved to the states. Example: The federal Medical Device Amendments of 1976 limit state powers to regulate the safety of medical devices.[78]	The major power reserved to the states was the police power, the power to protect the public health and safety. Unless limited by specific Congressional legislation, the state's police power is very broad. Example: Mandatory vaccination laws, public health reporting and investigation laws.	State legislatures may authorize local government to use the police powers. Example: City and county restaurant inspection programs.
Eleventh Amendment Prohibits citizen lawsuits for damages against states.	Congress cannot give a citizen a right to sue a state unless it is authorized by the Fourteenth Amendment, which, as a later amendment, can overrule an earlier amendment. Example: The Civil Rights Acts can authorize suits against the state because they are based on the Fourteenth and Fifteenth Amendments.	This carries over the sovereign immunity the states had as independent sovereigns before they ratified the Constitution. Protects the state itself from legal claims by individuals, unless authorized by the state, but does not apply to state officials, who can be sued personally. Allows the state to provide broad protections for public	The Eleventh Amendment only applies to the state, not localities.

[78] Brooks v. Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001); Massachusetts v. Hayes, 691 F.2d 57 (1st Cir. 1982).

		health actions. Example: The United States Supreme Court ruled that individuals cannot sue state universities under the federal age discrimination laws.	
Spending Power	Congress sets regulatory direction by increasing and decreasing agency funding. Congress uses financial incentives to encourage states to carry out policies that it cannot directly require. Example: Federal funding of state vaccination programs to encourage vaccinations for childhood diseases.	The state legislature sets policy through funding decisions for state agencies. States use incentives to encourage local government and individuals to carry out state policy. State public health policy is heavily influenced by Congressional incentives. Example: State funding of local public health programs.	Local government funds projects that it supports, and it also provides financial incentives to encourage private projects. Example: Many cities fund services for the homeless.
Taxing Power	The federal income tax code pervasively regulates the economy through taxes on economic gain. Congress subsidizes activities by reducing the taxes on them, by allowing more generous deductions for costs, and by paying direct subsidies such as earned income tax credit. Congress discourages activities by increasing taxes and limiting their deductibility. Example: Taxes on "gas guzzler" cars to reduce sales and tax credits to encourage the purchase of hybrid power cars.	All states tax property. Most states also tax income and sales. States use tax subsides and penalties as does the federal government, but also use tax policy to compete with other states to attract industry and high income individuals. States can use taxes to affect consumption of alcohol and tobacco. High state tax differentials on goods can be evaded by cross border sales, including Internet sales. Example: State cigarette taxes to discourage smoking and state homestead tax exemptions to encourage homeownership.	Localities use the same mix of taxes as states, subject to state imposed limits. Localities use tax policy to compete for business with other localities, limiting tax options for good. Localities often have additional taxing authorities such as school and hospital districts. Example: Local property tax incentives for new businesses.

Table 2 - Sources of legal rules and guidance.

DOCUMENT	FEDERAL	STATE	LOCAL GOVERNMENT
Constitutions	The United States Supreme Court and lower courts use the Constitution as the starting point for judicial review of legislation and executive branch orders.	The state constitution provides the benchmark for state courts to review state and local legislation. State constitutions, especially in states with a frequently used public amendment process, may also contain specific regulatory provisions in the same form as legislation.	The role of a constitution is provided by state constitutional provisions and legislation, such as home rule charters.
Treaties	Treaties with foreign governments are reserved for the President to make, and become law when approved by the Senate. Treaties can preempt state law and override previously passed federal law. The President may abrogate treaties without congressional approval. Example: North American Free Trade Agreement	N/A - States have no treaty making powers and no power to affect foreign policy. State laws that conflict with treaties are unconstitutional.	N/A
Statutes	Passed by Congress and enforced by the President. Establish the structure, powers, and funding for federal agencies. Can delegate broad powers to agencies or give very specific direction. Can preempt state laws under certain circumstances. Example: The Occupational Safety and Health Act, which established OSHA and NIOSH and set up a federal system to protect worker health.	Passed by the state legislature. Establish the powers and funding for state agencies and for some local governments. Can delegate broad powers to the agencies or give specific directions. Can limit the powers of local governments. Example: Laws establishing and empowering the state health department.	Some local governments can pass ordinances, which have the effect of statutes. Example: Local ordinances prohibiting smoking in public places.
Executive Orders	The President can change agency policy with executive orders, within the discretion allowed by statutes and administrative regulations. Executive orders, including specialized types such as Presidential Decision Directives, are very important in national security law.	State agencies can change policy within their allowable discretion. This can be ordered by the executive head of the agency, which can be the governor or another elected official, such as the state attorney general. Example: A governor's order declaring a natural	Local agencies can change policy at the direction of the mayor, manager, or council. Example: City council orders to the police department to increase

	Example: The Executive Order requiring federal regulations to be reviewed by the Office of Management and Budget.	disaster and ordering the evacuation of coastal areas in a hurricane.	patrols in a high crime area.
Administrative Rules/Regulations	Congress can give agencies the power to make regulations that have the same legal effect as statutes. These allow agencies to use their special expertise on technical regulatory matters. Must be published for public comment. Can be quicker to pass and modify than statutes. Gives regulated parties more specific direction than do most statutes. Can be overruled by Congress. Example: OSHA regulations on the prevention of transmission of bloodborne pathogens in hospitals.	The legislature can give agencies the power to make regulations that have the same effect as statutes. Must be published for public comment. Can be quicker to pass and modify than statutes. Gives regulated parties more specific direction than provided by most statutes. Can be overruled by the state legislature. Example: State health department regulations that establish which diseases are reportable to the health department.	Some local agencies, such as health departments, can pass administrative rules. These are used extensively in large agencies such as the NYC Health Department. Example: Restaurant inspection regulations.
Court Decisions	The federal court system is a common law system where the decisions of judges become binding statements of law. The federal courts are a hierarchical system, with the Circuit Courts binding the lower District Courts, and the United States Supreme Court binding all the federal courts, and the state courts when ruling on a constitutional issue. The decisions of the United States Supreme Court give practical effect to the powers and protections in the U.S. Constitution. Court decisions are published and indexed to facilitate access to their legal rules and interpretations. Example: Jacobson v. Massachusetts,[79] which held that the constitutional right to protect the public health and safety was paramount over	All states except Louisiana use a hierarchical, common law system mirroring the federal system. (Louisiana's system is very similar to other states, but there is less reliance on precedent and appeals courts have broader powers.) State district court (lowest court) decisions are generally not published and are not formal precedent. Example: City of New York v. New St. Mark's Baths[80], which upheld the state's right to close gay bathhouses to prevent the spread of HIV.	Cities and counties, depending on the state law, have municipal courts, justice of the peace courts, and other local courts. These court opinions are generally not published and are not precedent. This makes researching public health law very difficult because so much of public health happens at the local level. Example: Local public health matters such as dog impoundment cases are brought to municipal courts in many cities.

[79] Jacobson v. Massachusetts, 197 U.S. 11 (1905).

[80] City of New York v New St. Mark's Baths, 497 N.Y.S.2d 979, 130 Misc. 2d 911 (N.Y. Sup. Ct. 1986).

	an individual's right to be left alone, and upheld a mandatory smallpox vaccination law.		
Administrative Agency Adjudications (Rulings in specific cases)	Administrative agencies have proceedings to decide controversies between the agency and regulated parties, including an agency appeals process. While these decisions are not binding in future proceedings, they are a guide to agency interpretations of the law and the agency must account for changes in their policy in future adjudications. Example: Rulings of the Federal Trade Commission.	State agencies have the same type of proceedings and they are used in the same way. Example: Rulings of the state Worker's Compensation Commission.	City agencies also carry out adjudications. Although they are not usually published in formal proceedings, they are reduced to writing and are important records of agency position. Example: Rulings of the Zoning Commission.
Administrative Agency Guidelines	These are agency documents that explain the law and how the agency believes that it should be interpreted. They are not binding on the agency or the regulated parties, but are very important tools in explaining agency policy. Example: Department of Justice guidelines on employer compliance with the Americans with Disabilities Act.	State agency guidelines are treated the same as federal agency guidelines. Some states limit the use of guidelines and other informal agency guidance. Example: State Medicaid guidelines.	City and county agencies also provide guidance to regulated parties. Example: City health department guidelines on reporting diseases reportable under state law.

Table 3 - Public health enforcement tools.

LEGAL TOOL	DESCRIPTION	EXAMPLE	VALUE	POLICY ISSUES
Permits, licenses, registrations, pre-market approval	Party must submit information about the activity or product and get permission before entering the market. Some permits and all licenses regulate ongoing activities and provide for entry onto the premises for inspections to determine whether the licensee is complying with the license provisions and other relevant laws.	Building permit. Restaurant food handling license. FDA new drug approval process.	Shifts burden of proof of safety and compliance to the regulated party. Allows entry and inspection without a court order or showing of probable cause. Allows closing the business based on administrative inspections, without a court order.	Significant administrative delay and costs to regulated parties. Can evidence collected as part of an administrative search be used for criminal prosecutions for activities unrelated to the purpose of the license?
Administrative orders	Specific order by the health department to comply with a public health regulation or statute, to correct a dangerous condition, or to stop a dangerous behavior. Orders are typically issued by inspectors of licensed or permitted businesses, but can be issued to individuals. Orders are normally documented in writing and given to the target, but group orders can be used in emergencies.	An order to an individual to undergo communicable disease testing. An order to close a restaurant unless food sanitation problems are corrected. An order to evacuate an area threatened by a hurricane.	Quick and efficient because the court is not involved. Many orders are obeyed without further legal process.	Not self-enforcing. Agency must go to court for enforcement, which requires a hearing and an order from the court. Violating the court order then allows the court to use the contempt process to force compliance.
Injunctions and seizure orders	Court order to comply with a legal duty, to stop an activity while the rights are resolved, or to allow the agency to seize dangerous property. Temporary injunctions are used in emergencies when there is not time for a	Stopping the sale of improperly prepared or labeled food. Forcing compliance with zoning regulations. Closing businesses such as bathhouses that pose a	Used to enforce administrative orders, or by private parties to force compliance with the law. Temporary injunctions	Not for ongoing regulation, just resolving specific problems.

	full hearing. Permanent injunctions require a hearing where all parties can present their case.	threat to the public health.	allow quick action.	
Direct Abatement	Fixing a problem caused by a private party and charging the party with a lien on the property.	Tearing down a dangerous building. Building a walkway to comply with code. A Superfund clean-up order.	Used when the owner is not available, there is no clear owner, or the owner or responsible party refused to comply with abatement orders.	May not get paid until the property is sold or seized for back taxes. Expensive abatement, such as Superfund orders, generates expensive litigation.
Civil penalties	A fine paid for violating an administrative law or regulation. Proof is preponderance of the evidence.	A fine for deceptive advertising of diet food.	Encourages compliance without the burden of criminal prosecution.	Often too small to matter if the practice is profitable.
Criminal Prosecution	Serious, intentional violation of regulations is a crime.	Prosecution of medical device company executives for selling an unapproved product.	The best deterrent for wrongdoing by individuals.	High standard of proof, must show significant intentional wrongdoing.

Table 4 - Tort claims

CLAIM	DESCRIPTION	EXAMPLE	VALUE	POLICY ISSUES
General Considerations	The primary purpose of tort claims is to compensate injured persons or other legal entities for damages caused by the improper actions of others. The secondary purpose of tort claims is to deter improper conduct in the future by holding the actor liable for the costs of the behavior. The third purpose of tort law is to punish bad actors for harm done in the past, which includes the awarding of punitive damages. Tort claims were historically brought by private attorneys representing private parties, who were paid a percentage of what they recovered. Increasingly state attorney generals are bringing tort claims on behalf of the citizens of their states.	A tort award to the victim of an automobile accident caused by talking on a cell phone while driving. A tort award against a manufacturer who used substandard parts in a product. The tobacco lawsuit brought by state attorney generals to compensate the state for costs of medical care for indigent smokers.	Provides compensation for injured persons and reduces the state's burden of caring for persons injured by accidents who were not covered by insurance. Can be a useful deterrent in situations where there is inadequate government regulation. Provides compensation for medical care costs that would be provided by national health coverage in other countries.	There is no recovery without a solvent defendant, which results in a limited award or no award in the majority of serious injures. At least 40% and usually much more of the recovery goes to attorneys and other transaction costs. They are a poor tool for public policy because the public's interest is not before the courts and because different courts, facing similar facts, reach inconsistent results.
Negligence	A type of remedial claim based on accidental injuries caused by not complying with appropriate standards.	A malpractice case based on negligent obesity surgery.	Payment can go to injured individuals, even when brought by the state.	If not based on good science, these can undermine prevention strategies by creating unfounded fears of public health interventions.
Negligence Per Se	Actions based on failure to follow a legal standard.	A claim based on a failure to post a required warning sign about the hazards of eating raw shellfish.	A tort claim, unlike a fine, goes to the injured person.	Courts are reticent to use statutes and regulations as tort standards.
Products Liability: Defective Manufacture	Products liability is a type of strict liability. If a product is defective and causes an injury, the manufacturer is liable, even if it has followed all	A claim based on botulism in canned soup.	Shifts the burden of injuries to the manufacturer, who can better bear the burden of	If the manufacturer is out of business, there is no recovery. There are controversies about how long

	appropriate standards and the defect was unpreventable.[81]		loss.	the manufacturer should be liable for durable products.
Products Liability: Design/Warning Defect	Design defects are associated with products that are dangerous even when properly manufactured. If the danger is known, then the manufacturer has a duty to warn consumers. For prescription drugs, the duty is to warn the prescribing physician.	Claims against the manufacturer of diet drugs for causing pulmonary complications. Claims against food processors alleging that they should have warned that using corn sweetener in soft drinks leads to obesity.	Can drive a badly designed product off the market. Provides an incentive for manufacturers to design safer products.	Courts sometimes allow claims based on bad science, such as the breast implant cases and many vaccine injury cases. These can result in unrealistic warning requirements that reduce the effectiveness of public health interventions.
Fraud; Misrepresentation	These are claims based on intentional deception.	Claims against herbal supplements that claim to cause weight loss.	Tort claims can be much more costly than fines. Private lawsuits can assist regulatory agencies.	Hard to establish standards: Is advertising fast food deceptive? Is a disagreement over scientific evidence intentional fraud? Is misstating scientific evidence, as with tobacco companies' denials of addition, fraud?

[81] Restatement (Second) of Torts, Special Liability of Seller of Product for Physical Harm to User or Consumer § 402a (1965). *See also* Brown v. Am. Home Prod. Corp. (*In re* Diet Drugs), No. 99-20593 (E.D. Pa. Aug. 28, 2000), *available at* 2000 WL 1222042; Feldman v. Lederle Labs., 479 A.2d 374 (N.J. 1984).

Table 5 - Data collection and surveillance.

DATA	SOURCE	VALUE	PUBLIC AGENCY	LEGAL TOOLS	POLICY ISSUES
Height, weight, physical condition, school-based physical activity, and food consumed at school.	K-12 Schools. Colleges and other post-secondary educational institutions have more limited data than K-12.	Best source of longitudinal data on children. Can also be a site for interventions.	State health department, State education agency, local school boards.	Statutes and regulations to require collection and reporting.	Parental privacy concerns, teacher resistance to new duties, limited school resources, concerns with stigmatizing children.
Height, weight, general physical condition, disease status, disease progression.	Medicare and Medicaid data.	Best current source of information on the elderly, disabled, and the poor.	HHS, CMS, state Medicaid office. Can be attached to conditions of participation for Medicare and Medicaid, tying compliance to reimbursement.	Statutes and regulations to require specific health information to be submitted along with billing information.	Privacy concerns when individual identifiers are used. Key data is not yet electronic so costs of compliance would be high.
Height, weight, general physical condition, disease status, disease progression.	Private insurance data.	Includes large segments of the population not covered by Medicare and Medicaid. Key for tracking obesity treatments and complications. Already electronic.	State health departments, state insurance commissions if tied to insurance quality regulation.	Statutes and regulations to require reporting of data held by insurers or access by researchers.	May require federal legislation to allow state access to data of ERISA plans. Politically difficult to require standardized data for reimbursement that is about the billable service.
Height, weight, general physical condition, disease status, disease progression for	Individual medical care records held by health care providers and	The biggest data set with the broadest reach. Approaches the complete	State health departments. HIPAA regulations should be amended to clarify that the	Statutes and regulations to require reporting of specific data, as is done for	Compliance with public health reporting laws is low for providers other than laboratories,

individuals who meet trigger criteria.	laboratories.	population sample.	public health reporting exception to HIPAA applies to obesity and chronic diseases.	communicable and occupational illness.	which can automatically report based on trigger data. Enforcement is politically difficult.
Birth and death records.	Vital Statistics Data.	Assure that obesity and chronic disease data is included on birth and death records.	State health department.	These are controlled by state regulation and coordinated by the federal government.	Inconsistent reporting reduces the value of vital statistics records. Difficult to enforce.
Diagnosis of obesity or diabetes.	Registry data.	Commonly used for cancer to provide baseline information for epidemiology studies.	State health department. Registry data is generally more available for research than are public health reports.	Registries can be voluntary, but can also be set up by state or federal government, although they are usually done by states.	Since the data can be more easily obtained, some individuals do not want their data included.
Research on self-reported data about obesity and physical activity.	Survey data.	Surveys are the main source of obesity data.	State health or public welfare department. CDC or other federal health research agency.	Laws or regulations can require compliance with government surveys (the census is an example).	Most public health professionals prefer that surveys be voluntary.

Table 6 - School-based interventions.

INTERVENTION	LEVEL OF GOVERNMENT			POLICY ISSUES
	FEDERAL	STATE	LOCAL	
Improve nutritional content of school lunches.	Modify nutritional requirements for participation in federal school lunch program. Expand commodity foods supplied to schools to include fresh fruits and vegetables.	Authorize state health departments to directly regulate individual schools to improve nutritional content of lunches. Use state educational department regulations to require school districts to set nutritional standards based on state established norms.	School boards directly control food service in schools and change policies to improve nutrition.	Federal school lunch regulations only affect participating schools. Private schools require direct regulation because they are not part of the government. Home school nutrition is not regulated in most states. Fresh fruits and vegetables raise the cost of lunches.
Control types of drinks provided and access to vending machines.	Change the promotional food exception in the school lunch program to provide more guidance to schools.	Use direct and indirect state regulations as with lunch regulations.	School boards can set policies that govern both the drinks provided and the hours of access to the vending machines.	Regulations should address offsetting the loss of vending machine income in poor schools. Do these policies have a disparate impact on poor children?
Control access and content of snacks in schools.	Same as soft drinks.	Same as soft drinks.	Same as soft drinks.	Snacks are necessary for students and some students have special needs. Regulations will need to focus on healthy and acceptable substitutions, not bans.
Nutrition Education.	The CDC could develop a comprehensive K-12 curriculum as a resource to the states and schools. Federal funding for school	Legislation to require comprehensive nutrition education based on state developed programs or a CDC curriculum.	School boards set the curriculum and could adopt a state or CDC curriculum on nutrition.	These standards would need to be applied to private and home schools. Culturally appropriate curriculums should be

	based nutrition education. Nutrition and health education as subject areas for the No Child Left Behind program.	Legislation to require nutrition to be included on state comprehensive exams.		provided in different parts of the country and in different ethnic communities. This will be complex to implement.
Physical education in schools. Many schools are cutting back on physical education programs for older students, turning break times into study periods. Many schools are eliminating or reducing recess for younger students to add academic time to the school day.	Federal funding to support physical education programs for older students in schools. CDC guidelines for physical activity in schools.	State education departments can require set periods of physical education time in schools. This should include physical education for older students and recess periods for younger students. States should review academic contact hours requirements to assure that they do not limit physical activity.	School districts can set levels based on CDC recommendations, which emphasize activity by all students and not just athletic competition. Physical activity should be seen as a necessary part of the curriculum for all students.[82]	Physical education takes time from the academic curriculum and requires additional teachers and facilities.

[82] CDC, *Increasing Physical Activity*, 50 MMWR No. RR-18 (October 26, 2001), *available at http://www.cdc.gov/mmwr/PDF/rr/rr5018.pdf*.

Table 7 - Food Regulation

INTERVENTION	LEVEL OF GOVERNMENT			POLICY ISSUES
	FEDERAL	STATE	LOCAL	
Calorie and portion size labeling on packaged food.	The FDA regulates packaged food labeling. The FDA can require labels which more prominently display calorie content, and require realistic portion sizes.	There is some latitude for additional labeling requirements by states, but these should not conflict with federal regulations or interfere with interstate commerce.	N/A	More information on labels makes them less likely to be read. Consumers may not understand the significance of calorie labeling.
Calorie labeling on restaurant food.	The federal government does not regulate menus, other than for fraud. The Interstate Commerce Clause would allow Congress to give the FDA the authority to require informational labeling on restaurant menus.	States regulate restaurant permitting and sanitation. Some states already require labeling on menus for hazards such as raw seafood. With legislative authority, state health departments could require calorie labeling on menus.	In many states, city and county health departments do the front line regulation of restaurants. Subject to limits in state law, cities and counties could require calorie labeling.	Restaurants oppose menu labeling because of costs of determining exact calorie counts and standardizing portions. States and localities cannot use labeling requirements to discriminate against national chains.
Vending and Point of Sale Labeling.	Not currently regulated. As interstate commerce, the federal government could require vending machine operators to post the calories of snacks and drinks on the face of the machine, and require point of sale postings for outlets such as movie theaters where the customer cannot read the package before purchase.	The state police power gives the state broad powers to regulate the conditions of local sales, unless, as with tobacco, the federal government has preempted state regulation. States could require posting of calories for vending machines and other points of sale for drinks and snacks.	In most states, local government may also require calorie information to be posted at the point of sale.	Adding more than just calorie counts will make the labeling too complex, and thus it will be ignored. An alternative would be to allow the vendor to affix visible calorie stickers to foods, which could be done at the time of packaging.
Restaurant portion size and	Not currently regulated.	Not currently regulated, but	Would probably require	Increasing the cost of meals

pricing (super-size discounts).	Since the federal government has broad authority to regulate prices, portion size/pricing could be regulated. Calorie labeling would create a demand for smaller portions.	within state authority, as long as in-state and out-of-state business are treated equally. States could require menus to include a certain percentage of calorie controlled portions.	legislative authority from the state.	has a disproportionate effect on the poor. Persons who eat a single meal a day or have physically demanding jobs would be hurt by increasing the cost of large portions.
Fast food and snack food taxes to raise funds for nutrition education and other programs.	The federal government has the authority to tax specific goods to support regulation costs and other programs, and does this with alcohol and tobacco.	States have many targeted taxes to raise earmarked funds.	Localities routinely tax prepared and restaurant food, although taxes on packaged food would depend on their grant of authority from the state.	It is difficult to assure that a tax targeted to raise revenue for a specific program will not be diverted into the general fund.
Snack food taxes to deter consumption.[83]	The Commerce Clause.	The state revenue and police powers. While it is likely that the courts would uphold this, there would be an issue of whether the tax was effective.	Same issues as the state, but there is less precedent for local taxes to discourage consumption, as opposed to raising revenue.	Economic analysis shows that the tax would have to be quite high to reduce consumption. Consumers may also shift consumption to non-taxed snacks, limiting the effectiveness of the tax.
Fast food taxes to deter consumption.[84]	Same as for snack food taxes.	Same as for snack food taxes. Tobacco taxes do deter consumption, but there is limited data for targeted food	Same as for snack food taxes.	The taxes would have to be high to affect consumption[85] because fast food plays an important role in meeting job

[83] Fred Kuchler, Abebayehu Tegene, & J. Michael Harris, *Taxing Snack Foods: What to Expect for Diet and Tax Revenues*, Agric. Info. Bull. No. 747-08 (August 2004).

[84] Jeff Strnad, *Conceptualizing the "Fat Tax": The Role of Food Taxes in Developed Economies*, Working Paper 286, John M. Olin Program in Law & Economics (July 2004), *available at* http://ssrn.com/abstract_id=561321; Heather Bednarek, Thomas D. Jeitschko, & Rowena Pecchenino, *Gluttony and Sloth vs. Bliss* (July 2003), *available at* http://ssrn.com/abstract=426700.

[85] Fred Kuchler & Nicole Ballenger, *Societal Costs of Obesity: How Can We Assess When Federal Interventions Will Pay?*, 25 Foodreview No. 3, 33-37.

		taxes.		pressures and serves as entertainment.[86] They would also affect non-obese persons, which would undermine public support. They might disproportionately affect the poorest in society, who benefit financially, if not nutritionally, from cheap fast food.
Increasing consumption of fruits and vegetables. Research shows that fruit consumption is inversely related to obesity.[87]	Federal agricultural policy has been very successful in driving down the cost of meat and grains. Federal farm programs could provide incentives to produce cheaper fruits and vegetables. Federal immigration law could make provisions for the seasonal workers needed for fruit and vegetable picking.	States are already encouraging farmer's markets and cooperatives that produce and sell fruits and vegetables locally. Fruit and vegetable production can be encouraged through property tax relief and other state tax incentives that make these crops more profitable.	Local government can encourage produce markets in local neighborhoods to make it easier for the poor to obtain fresh food.	Nutrition policy should recognize that fruits and vegetables are not equivalent for persons with diabetes.

[86] Shin-Yi Chou, Michael Grossman, & Henry Saffer, *An Economic Analysis Of Adult Obesity: Results From The Behavioral Risk Factor Surveillance System*, Working Paper 9247, Nat'l Bureau of Econ. Research (2002), *available at* http://www.nber.org/papers/w9247.

[87] Biing-Hwan Lin & Rosanna Mentzer Morrison, *Higher Fruit Consumption Linked With Lower Body Mass Index*, 25 Foodreview No. 3, 28-32.

Table 8 - Encouraging physical activity.

INTERVENTION	LEVEL OF GOVERNMENT			POLICY ISSUES
	FEDERAL	STATE	LOCAL	
Building code and neighborhood modifications. The best way to increase physical activity is to incorporate it into daily life. Many neighborhoods and offices are not constructed to encourage physical activity.	Most mortgages flow through quasi-federal agencies, and the federal government directly sets standards for some federally qualified programs. These standards could address sidewalks and other pedestrian-friendly measures. Since building is an interstate business, Congress has broad authority to regulate building standards in ways it has not done in the past.	States are directly involved in setting building codes and inspection standards. States have great latitude in setting land use requirements that benefit the public health and safety.	Local government has the most direct control over building standards and neighborhood layout. Local government adopts building codes and, through zoning boards in most cities, sets the layout of neighborhoods. As with state land use requirements, the courts have given cities broad zoning authority.	Some changes will increase the cost of housing, others may upset traditional beliefs, such as that housing and commercial space must be separated. The federal government has historically played a limited role in residential building and zoning standards. While its authority is broad, many states will resist losing their own authority to the federal government.
Open stairwells in buildings to encourage walking between floors.	Post 9/11 security concerns have dominated the federal approach to building access. While real concerns, the federal government should encourage building security departments and state and local government to assure that security concerns are balanced with the need to encourage physical activity.	Most building codes and fire safety regulations are state and local laws, so the states can modify building codes to require opening up stairs.	Modify building codes to require opening up stairs.	Fire safety concerns must be considered, but can be managed with technology such as doors that automatically close in emergencies. The Americans with Disabilities Act limits policies that force the use of stairs because it will discriminate against or stigmatize the disabled.
Employer incentives for employees to increase physical activity, such as	This could be encouraged through tax credits and workplace regulations.	This could be encouraged through tax credits and workplace regulations.	Localities might provide tax credits, but their role in workplace regulation is more	Some employers do this already as an employee benefit and to reduce their

break times, providing work out equipment and shower areas, and structured activities such as fitness classes.			limited than the state or federal government.	medical insurance costs. Low wage employers and those that do not provide benefits have less incentive to support these programs.
Encourage mixed use neighborhoods because people walk more if there is some place to walk to.	Eliminate unreasonable federal impediments to financing mixed-use neighborhoods.	Eliminate unreasonable state impediments to mixed-use neighborhoods.	Zoning codes originally banned mixed-use neighborhoods to separate domestic housing from dangerous commercial activities. These codes should be rethought to allow mixed neighborhoods while still keeping hazardous businesses out of neighborhoods.	Homeowners may resist mixed-use neighborhoods unless the city assures that businesses will be carefully regulated to protect the neighborhood. Gated communities will object that businesses will make security difficult.
Increase the availability of sidewalks in neighborhoods and cities.	Use federal mortgage and other programs to encourage sidewalk construction and maintenance.	Sidewalks could be made part of the building code, as some states have done with fire sprinklers.	Sidewalks could be made part of the zoning requirements.	The biggest problem will be financing the retrofitting of sidewalks into neighborhoods that do not have them. In addition to the construction costs, it may require modifying building set back requirements.
Community-based programs to encourage physical activity. These programs have been shown to significantly increase physical activity in a community.[88]	Use recommendations from the Task Force on Community Preventive Services to design grant and educational support for community-based programs to encourage physical	These programs depend on resources such as advertising and support for community educators, which can be provided by the state as well as the federal government.	Same as the state, plus the local government may be able to work with local community organizations such as churches that can participate in these efforts.	The Task Force found that these programs depended on community leader involvement; they were not effective if based only on advertising.

[88] CDC, *Increasing Physical Activity*, 50 MMWR No. RR-18 (October 26, 2001), *available at http://www.cdc.gov/mmwr/PDF/rr/rr5018.pdf*.

	activity.			
Neighborhood safety[89] In many neighborhoods, fear of crime keeps older adults and children indoors. Fear of crime also leads to opposition to mixed-use neighborhoods.	The federal government has targeted neighborhood safety through its COPS program. This and other programs that help fund local crime prevention efforts should also be seen as public health efforts through their impact on healthy lifestyles.	States have an important role in neighborhood safety. While policing is mostly a local government activity, the localities with the highest crime are frequently the poorest, limiting what they can do without state assistance.	Policing is a local activity. Community safety is recognized as a public health issue as related to violent injuries. There is less awareness of the impact on obesity and chronic diseases, which tend to be more prevalent in the poor neighborhoods with the highest crime.	Crime prevention is expensive and complicated, depending on economic development as well as policing. The neighborhoods with the worst crime problems also have many other social problems, such as weak schools, which complicate interventions.
Playgrounds	The federal government can fund the purchase of land for playgrounds. The federal government could provide reasonable tort law protections against schools and cities for playground related injuries.[90]	States can both fund playgrounds and reduce the impediments to playground construction and maintenance. For example, many cities and schools have removed playground equipment and locked up playgrounds because of tort claims by injured children. The value of playgrounds to the public health might justify reasonable limits on tort liability for play ground injuries.[91]	Localities must both maintain playgrounds and assure that they are safe from criminal activity. The cost and legal liability have led some communities to close playgrounds or remove playground equipment. Cities cannot create their own legal immunity but depend on the state or federal government for legal relief.	Building new playgrounds requires expensive land purchases. Maintaining playgrounds and keeping them safe taxes the resources of the poorest areas that need them the most.

[89] Mitch J. Duncan, John C. Spence, & W. Kerry Mummery, *Perceived Environment and Physical Activity: A Meta-Analysis of Selected Environmental Characteristics*, 2 Int'l J. Behavioral Nutrition & Physical Activity 11 (2005). (http://www.ijbnpa.org/content/2/1/11)

[90] Stephen A. Brunette, *Cause of Action for Injury to Student in School Playground Accident*, 2 Causes of Action 2d 487 (2005).

[91] Elledge v. Richland/Lexington School Dist. Five, 573 S.E.2d 789 (S.C. 2002).

Table 9 - Medical treatment and insurance issues for obesity.

Problem	LEVEL OF GOVERNMENT			Policy issues
	FEDERAL	STATE	LOCAL	
Medical treatment for obesity and sequella. Consistent primary medical care is important for supporting weight loss and is critical for managing sequella such as diabetes.	The federal government pays for more than 50% of medical care though various programs, and many insurers follow the federal lead. The federal government should develop guidelines for obesity treatment as a companion to its guidelines for diabetes management. These guidelines both set standards of care and provide incentive for physicians to follow the guidelines. The federal government helps fund categorical programs for the treatment of other public health diseases such as tuberculosis. These programs treat people without regard to income or insurance status. This model should be considered for obesity and diabetes.	States have a special need to assure access to primary care for obesity and its sequella because obesity is more prevalent in the poor, who depend on state Medicaid programs. Access to treatment for obesity and diabetes will improve individual health, reduce long term Medicaid costs, and help people stay at work, improving the state economy. States can shift Medicaid funds to expand access to primary care and create special programs to provide obesity treatment. States can also use their regulation of hospitals to reduce current incentives to build specialty hospitals in lieu of primary care facilities.	Except for the largest cities, localities depend on state and federal funding for medical care and cannot independently set policy. Cities can experiment with the categorical clinic model for obesity in health department clinics, if the state and federal government support this.	Primary care physicians are paid much less than surgical specialists; hospitals and clinics make much more money on tertiary care. This is a particular policy problem since a significant part of the tertiary care is due to the failure of the primary care system. While surgical treatment for obesity should be the last resort for a patient with morbid obesity, financial incentives are making it a first line treatment.
Private insurance coverage for obesity and its sequella.	The federal government does not regulate private medical insurance, and the federal Employee Retirement Income Security Act (ERISA) prevents state regulation of a significant percentage of private insurance.	States have broad powers to regulate health insurance not covered by ERISA, but only limited authority over ERISA plans. While states are urged to mandate coverage for specific medical treatments, these	Cities have little role in insurance regulation, except as affects their own municipal employees.	While proper treatment for obesity and diabetes will save medical care costs in the long term, it will raise short-term costs. Private employers, and even states, have been reluctant to invest in more medical

	ERISA is important to allow national employers to have uniform plans for employees in different states. As an interstate business, private health insurance can be regulated by the federal government, which would allow consistent national standards.	mandates provide further incentives for companies to move to ERISA plans or to drop health insurance for their employees. States should work with insurers to develop effective coverage for obesity and diabetes, while recognizing the limitations of mandating coverage.		services because their investors or taxpayers have a short investment timeline. The federal government must provide leadership in this area.
Insurance surcharges and incentives. Some employers and states are considering surcharging obese individuals in group health plans who do not participate in weight loss programs.	The Americans with Disabilities Act does not apply to insurance rating, but forcing employees into weight loss programs could raise issues, at least for employees whose obesity renders them disabled. Since obesity is closely tied to race, at least in women, there may be issues of disparate treatment under civil rights laws. This would be a particular problem if other employees at high risk, such as smokers and motorcycle riders, are not surcharged. The HIPAA provisions on group health insurance may also limit the use of surcharges.	Some states have disability and civil rights laws having broader protections than the federal laws, which might be triggered by special medical insurance surcharges on obese employees. States also have an interest in assuring access to medical insurance, and employer rating schemes that raise costs on high risk employees might be against public policy. Since obesity and especially diabetes has a genetic component, special sanctions for the obese may raise genetic discrimination issues.	Some cities, such as San Francisco and New York, have their own antidiscrimination codes which may apply to programs singling out obese individuals for special charges or incentives.	Public health practice usually tries to limit stigmatization and discrimination against persons with public health conditions. Given the adverse consequences of limiting medical insurance for obesity and its sequella, both for the individual and for society, incentive/surcharge programs for the obese are problematic.
Unproven surgical techniques or the inappropriate use of effective procedures. These potentially affect a large number of persons and have long term medical and financial costs.	The federal government does not regulate medical practice or require proof of safety or efficacy for new medical and surgical procedures. The federal government does control what procedures it pays for, and should set rigorous	State governments regulate medical practice and can establish guidelines for new procedures and the appropriate use of existing procedures. The state should require reporting of all obesity related surgical procedures and their	Larger city and county health departments may also regulate medical practice, if allowed under state law, including requiring the reporting of obesity-related surgical procedures.	There is a tremendous demand for obesity surgery and the medical groups that provide it have large budgets for advertising and lobbying. While states have the power to regulate medical practice, most

	guidelines for obesity related procedures. The FTC can regulate advertising of obesity medical services if the claims are false or misleading.	outcomes to the state health department for epidemiologic analysis. The state can also regulate false and misleading advertising.		do little quality control. Federal regulations on medical research make it more difficult and expensive to test new procedures, but allow procedures to be used without any testing.
Inappropriate use of weight loss drugs. As the Phen-Fen experience shows, overuse of an effective drug in persons without serious obesity can lead to dangerous side-effects and removal of the drug from the market.	The FDA regulates the approval of a drug, but not its use by physicians. The only federal regulation of drug prescribing by physicians, other than for controlled substances, is through federal reimbursement rules.	The state should require reporting of weight loss drug prescriptions and the sales of OTC drugs and supplements, and any medical complications from their use. This would allow epidemiologic surveillance and the ability to identify inappropriate use. The state should consider regulations on the use of weight loss drugs and supplements.	Larger city health departments should also consider requiring reporting of weight loss drug use and carrying out surveillance for inappropriate use.	There is a huge potential market for weight loss drugs. In the past, all weight loss drugs had severe side effects and were eventually removed from the market for weight loss. New fears about the health effects of obesity will be used to justify using more risky drugs, which may be appropriate in some, but not most cases.
Safety and efficacy data on medical devices and drugs.	Sometimes called Phase IV drug trials, the federal government can require reporting of the side-effects of drugs when they are in the marketplace.	State health departments could track the use of drugs and medical devices used for obesity treatment and their side-effects.	Larger city health departments might set up reporting programs or participate in a state-based reporting system.	Post-market surveillance of drugs and medical devices requires the cooperation of physicians and hospitals, which is more logistically difficult than collecting information from manufacturers. Industry resistance to disclosing unfavorable data. Legal protections for trade secret data.
Safety and efficacy data on medical and surgical treatments.	There are no federal regulations or reporting requirements for medical and surgical treatments, other than standards for reimbursement. The federal government could require	The federal government leaves the regulation of medical care to the states. States could use this power to require reporting and tracking of medical and surgical treatments for obesity.	Larger city health departments might set up reporting programs or participate in a state-based reporting system.	Except for medical research, there is little governmental oversight on the introduction of new treatments and the use of existing treatments.

	reporting and tracking for treatments under the Commerce Clause.			
Inaccurate or misleading claims by sellers of unregulated weight loss aids sold under the food supplement exemption to the FDA's overview.	The Federal Trade Commission polices deceptive advertising and could target these ads.	States have broad power to regulate the sale of products that are not regulated by the federal government. States could bar the sale of these supplements unless they have proven health benefits.	Localities can also ban the sale of unproven supplements, but, except for the largest city health departments, will have limited resources to identify such products without state support.	Unless the claim is part of a direct product advertisement, it is protect by the First Amendment. Many politicians and public leaders believe supplement manufacturers should not have to show their products meet scientific standards for efficacy.
Inaccurate and/or dangerous medical information on the WWW or in books and articles.	These are protected by the First Amendment, even if they are deadly. The only allowable response is to provide comprehensive correct health information in the same venues. The CDC already provides much useful information and tries to expand this into popular media. This material should address specific health myths.	Many state health departments have public education programs on nutrition and physical activity which can be expanded. States should draw on the CDC's expertise and should include information about health myths and misinformation in school-based health education.	Local efforts should mirror the state efforts, with special emphasis on school-based education and local non-government organizations, including churches.	Misinformation about diet and health has been a significant problem for the past 100 years or more, and the Internet has made it more pervasive. Countering this misinformation is more difficult because of the distrust of the government on health issues.