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Political Economy of Medical Food Reimbursement in the U.S.

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Medical foods, which fall in the gray area between food and drugs, are a necessity for persons with inborn errors of metabolism. Being more expensive than regular foods, some U.S. states have mandated insurance companies to provide coverage for the afflicted community. To investigate the legislative adoption process, this paper develops a political economy model of medical food reimbursement and coverage policy. Analytical cross-state logit regression models confirm the positive influences of metabolic clinics and the political clout of the afflicted community on the probability of adoption. The countervailing interest of the insurance industry and the afflicted community were also confirmed. Results suggest that efforts by medical food companies to influence the political process could yield food market and distribution channel opportunities in states contemplating legislative adoption.

Introduction

A medical food is “a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation” (U.S. Congress, 1988). Like prescription drugs, the costs of which are typically covered by insurance companies (via state legislative mandates), medical foods are a necessity for a healthy and normal life for individuals with metabolic disorders. However, medical foods are also close to regular foods, whose costs are typically absorbed by consumers and are not covered under drug insurance. Because medical foods are at the boundary between food and drugs, they are controversial and represent a gray area of food and health policy.

Drug reimbursement policy falls within the realm of powers granted to the states. States, however, differ in demographic and other characteristics, and therefore the propensity to adopt

insurance-mandated medical food reimbursement policy and the level of reimbursement chosen. Prescription drugs are subsidized or reimbursed by healthcare plans from insurance companies based on the state’s reimbursement schedule. However, prescription or medical foods are not always covered, due in part to opposition by insurance companies¹.

The afflicted and members of their family stand to gain by lobbying for adoption of medical food reimbursement policy. Given the disparity in the costs of medical and non-medical foods, the health, purchasing power and quality of life of the afflicted community are impacted

¹ By voluntarily extending coverage to medical foods, an insurance company can attract a disproportional number of the afflicted. Hence, the company may still not extend coverage unless forced by legislation even when the cost of mitigating the adverse effects of ingesting the wrong food exceeds the cost of providing coverage for medical foods. Products within the medical foods category include special formulations for patients with celiac sprue (CS), phenylketonuria (PKU), irritable bowel disease (IBD), Urea Cycle Disorder (UCD), Glycogen Storage Disorder (GSD), Propionic Acidemia (PA), Methyl Malonic Acidemia (MMA), maple syrup urine disease (MSUD), and diabetes. For patients with these disorders, medical foods are almost unavoidable as the afflicted must avoid specific foods, components or nutrients to prevent illness or death or must ingest increased amounts of certain metabolites to stimulate a specific metabolic pathway for survival (Bistran, et al., 1976). Studies have shown that even small reductions in intake can yield substantial health benefits. (Browner, et al., 1991; Zarkin and Anderson, 1992).

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by such adoption. The physicians and dieticians of the afflicted, the medical food industry, and facilities that provide metabolic treatment, also called metabolic clinics², usually join the afflicted in advocating for legislative adoption of such policy. The medical foods industry could benefit from legislative adoption as such policy can lower the prices of their products and enhance consumer affordability and market penetration. The medical foods area is one where efforts by producers and distributors to organize the proponents of adoption lobby law makers can create a game-changer in the development of new market opportunities in a state.

Insurance companies are known to almost consistently oppose such legislation based on the argument that it decreases profitability by increasing insurance payout per capita and the cost of insurance to the non-afflicted community. Perhaps, their real concern is that once a state adds some medical foods to the reimbursement schedule, it becomes easier to add other items that may not be real medical necessities. Consistent with their stand on healthcare in general, the non-afflicted community has been silent in the reimbursement debate. Perhaps, the small size of the afflicted community suggests minimal impacts on their budget, especially when many of them are covered by employer paid insurance. Information on the determinants of legislative adoption, including the marginal impact of lobbying efforts on the probability of adoption, is therefore of significant value, not only to the afflicted community and other pro-reimbursement advocates, but also to the insurance companies and other opponents of reimbursement. Medical food producers and distributors are particularly interested, as legislative adoption can bring the entire community of afflicted people into the market, due to the cost eliminating nature of adopted legislation. Such

information can be used in predicting the likelihood of policy change, medical food legislation in states that have not yet adopted, the potential benefits of lobbying efforts, as well as in choosing optimal strategy for impacting such change.

Regarding the political dynamics of legislative and policy adoption, several studies suggest various legislative causal factors, including (1) the characteristics of the policy and its goals (Bardach, 1997; Derthick, 1972; Rosenbaum, 1976; Sabatier and Mazmanian, 1983); (2) the characteristics of implementing agencies (Edwards, 1980; Nakamura and Pinderhughes, 1980); and (3) the beliefs and attitudes of key policy actors (Bardach, 1997; Marshall et al., 1986; Mitchell, 1981; Sabatier and Mazmanian, 1983; Van Horn and Van Meter, 1976). Aaron (2002) identified the escalating costs of health care expenditures, access to healthcare, the quality of healthcare and competition between healthcare insurance companies as important determinant factors in adopting health care policies. In addition, Weekes (1997) identified consumer demand for alternative health care services and the growing interest of private insurers in providing coverage for various alternative treatments as another determinant in adopting health care policies.

While some literature exists on the usage and need for medical foods, despite the intense controversy surrounding the issue, to the best of our knowledge, nothing is available in the economic, political and marketing literature on the legislative adoption process. Given the importance of such analysis, this study conceptualizes the determinants of legislative adoption of medical food reimbursement policy, including (1) political and economic powers and motives, (2) socio-economic, demographic, and other legislative adoption factors, and (3) interstate proximity to other adopters (spillover effects). An empirical logit model is estimated to evaluate the effects of key factors hypothesized to determine the passage of medical food laws mandating insurance industry reimbursement. Implications for the lobbying efforts of medical foods companies are also highlighted.

² A metabolic clinic is a facility focused on helping patients with metabolic disorders. It has a broad range of specialists ranging from nutritionists, nurses and social workers to metabolic geneticists, genetic counselors and psychologists. According to the Mayo Clinic, such clinic provides comprehensive diagnostic and management services for people with known or suspected inborn errors of metabolism (<http://www.csmc.edu/2548.html>).

Background

Like prescription drugs, medical foods are necessary for healthy and normal life for individuals with metabolic disorders. According to FDA, for a product to be considered as Medical Food, it must be 1) food for oral or tube feeding 2) labeled for a specific medical disorder, disease or condition and 3) intended to be used under medical supervision. Diabetes mellitus (DM), malabsorption, phenylketonuria (PKU), homocystinuria and maple syrup urine diseases (MSUD) are examples of metabolic disorder diseases (Ogles and Akcicek, 2002). An example of medical foods is gluten-free cereal to avoid wheat allergies, health bars with added medication, and transgenic plants for oral vaccination against infectious diseases, and transgenic cows and lactoferrin for immune enhancement.

The high procurement cost limits the ability of the afflicted to enjoy good health and quality of life. As shown in Table 1, using the example of PKU, medical foods solutions can be 131% to 3833% more expensive than its normal food counterpart.³ Clearly, for families with individuals whose survival depends on medical foods, staying healthy could be a financial challenge.

In response to concerns about the burdens on individuals/families with metabolic disorders requiring medical food for survival, the U.S. Congress adopted the Orphan Drug Amendments (U.S. Congress, 1988) and the Nutritional Labeling and Educational Act (U.S. Congress, 1990). These legislations better defined the drug status of medical foods and provided the foundation for state mandates requiring the provision of insurance company reimbursement. Today, the adoption of medical foods reimbursement policy varies by state.⁴ When reimbursement legislation exists in a state, typically, governing laws provide reimbursement schedules for medical formula and/or food which may set a limit on the annual dollar amount of reimbursement and/or on age.⁵

The chronology and features of state adoption of medical food reimbursement policy are depicted in Table A.1 in the Appendix. The criteria for medical foods reimbursement by state is presented in Table A.2. The timeline for federal policies on medical foods is further delineated in Table A.3. As of July 2003, consumers in 29 states could expect to receive reimbursement or coverage for medical food expenditures they incur through insurance companies, while consumers in 21 states could be expected not to.

Table 1. Cost Comparison of Low Protein Products and their Regular Counterparts

Description of Food	Regular Food	Low Protein Food	Percentage Increase	Shipping & Handling
Spaghetti (16 oz)	\$1.25	\$5.00	300%	
Flour (1 pound)	\$0.18	\$7.08	3833%	
Crackers (16 oz)	\$0.79	\$15.85	1906%	\$5 to \$25
Cream Filled Wafers	\$0.49	\$2.95	502%	per order
Jello (3 oz.)	\$0.55	\$1.27	131%	
Tomato Sauce (4 oz.)	\$0.25	\$4.07	1528%	

Source: National PKU News, Table of Data on Food Costs, <http://www.pkunews.org/rights/lobby5.htm> July, 2003.

³ By extrapolation, per capita annual cost of medical foods is about \$14,000, compared to \$3,800 for normal food. By adding one afflicted member, the food bill for an average family of 3 with a 1999 mean family income of \$62,636 (US Census Bureau, 1999) could rise from \$11,400 (18%) to \$21,600 (36%).

⁴ For example, Kentucky limits reimbursement of medical foods to \$4,000 annually with no age restriction. Maryland sets no dollar or age restrictions. Colorado only covers males below the age of 22 and females below the age of 36 and imposes no annual dollar restriction.

⁵ A "reimbursement schedule" is a legislative mandate on a state agency or insurance industry.

The checkered pattern of legislative adoption, coupled with the typical deliberate nature of such processes, suggests the need to explain the factors that lead to state of adoption of medical foods reimbursement policy. The fledgling medical foods industry, whose survival or emergence depend largely on state-level legislative adoption, is particularly interested in understanding this process as it could inform the efforts to allocate marketing funds toward organizing, advocacy and lobbying for legislative adoption.

Conceptual Framework

The political environment of states may play an important role in shaping public policies. States vary in terms of the adoption of health policies and particular health care programs (Miller, 2005). For example, in the case of medical foods, some states have adopted full or partial reimbursement and other states have not (Table A.1). What influences some states to likely support medical food reimbursement legislation? Understanding the fundamental factors that influence states' adoption of specific policies or legislation is crucial for both the afflicted community and insurance companies to influence the political process towards their respective advantages.

Dye (1966) identified several additional political, socio-economic and demographic factors that determine legislative adoption: interparty competition, division of party control, the electoral system and voter participation, and degree of inequality in voter representation⁶. Interparty competition refers to the initiation of new legislation as a means of competing for votes. Division of party control refers to the extent of control of the state government by either party, Democrats or Republicans. Each party tends to favor certain types of legislation. For instance, usually Republicans support legislations that

promote less regulation while Democrats support more regulation and government intervention (Cook et al., 1988; Grogan, 1994). Considering Medical Foods Reimbursement, Democrats may favor medical food reimbursement legislation while Republicans may oppose this legislation as they favor less regulation and government intervention. Since people differ in their needs, the policy intervention they support differs with their socio-economic characteristics such as income, age and race groups (Shingles, 1989; Brown, 1988; Coughlin, 1980). Dye (1966) suggests that adoption of legislations is influenced by policy preference of the constituencies, for example, urban versus rural constituencies or rich versus poor constituencies.

The political processes of neighboring states will tend to have an impact on the legislative process of nearby states. Rosenbaum (1976) highlights the influence of neighborhood political process and its spillover effect. Politicians tend to follow the political process of their neighboring states mainly because nearby states tends to face similar challenges, and to avoid movement of people from neighborhood states (Miller, 2005; Rosenbaum, 1976).

This paper, therefore, utilizes the political economy framework to identify the determinants of medical foods reimbursement policy adoption. The framework is based on Dye's basic infrastructure (Dye 1975). We focus mainly on the choice by the government to pass legislation mandating the insurance industry to reimburse for medical foods.

The competing interest groups include the insurance community and the afflicted community. The interest of the non-afflicted community is accounted for in the objective function of the insurance community. Hence, both the insurance industry (as an agent of the non-afflicted) and the afflicted community (supported by their sympathizers) exert pressure on the legislature to make choices based on their relative strength in the political arena and their economic interests.

The insurance industry's actions are based on the desire to maximize the utility it derives from collecting insurance premiums, turning a profit, and generating any beneficial externalities. It tries to keep premiums down to optimize the utility of its clientele and its own long-term sur-

⁶ The dominant party is expected to be more likely to get its policies passed. Lower income, lower status, poorly educated, and non-white groups, which typically support democrats, are expected to have lower voter participation rates. Finally, less well represented groups are less likely to have policies evolve that benefit them (Dye, 1966).

vival (such as increased public health and increased patronage). Therefore, it is expected that the larger the size of the insurance community (companies, clients and employees), the more influential the opponents of legislative adoption, and the less support for legislation. On the other hand, afflicted households wish to maximize utility (or quality of life) from insurance coverage of traditional healthcare costs plus medical foods.⁷ Hence, the afflicted population is hypothesized to have a negative impact on the profit objective of the insurance industry by increasing healthcare payouts per capita.

The legislature (the ultimate decision maker) must then balance the interests of these interest groups in maximizing its own objectives, subject to pressures from the electorate and from competing economic and political interest groups (Tullock, 1967; Stigler, 1971; Peltzman, 1976). It, therefore, advances legislation that maximizes public acceptance.

Insurance Companies

The representative insurance company earns income, y^i , from providing health insurance coverage to the community of covered people (q): such that $y^i = pq - c(q) - \alpha\beta(x)$, where p is the average premium collected for health insurance coverage, c is the marginal cost of providing health insurance coverage, x is the number of individuals with the need for medical foods or the afflicted community size, β is expected cost per unit to provide medical food reimbursement for the afflicted community, $\beta(x)$ is the total expected cost of providing medical foods reimbursement for the afflicted community (where $\beta_x, \beta_{xx} > 0$) and α is a measure of the proportion of the total or maximum medical foods reimbursement cost that insurance companies are expected to bear. Increased premiums or reduced healthcare coverage are irksome to both the afflicted and non-afflicted communities. $\alpha\beta(x)$ is the externality by the afflicted community that

can be either absorbed by the insurance company (with an impact on premiums) or by the afflicted community. $q - x$ is the number of people in the non-afflicted community. The extent of externalities associated with medical foods is assumed to be an increasing function of the community of covered people since the larger the population, the larger the afflicted community (i.e. $x_q, x_{qq} > 0$)⁸.

The insurance industry attempts to prevent the afflicted community from transferring their externality to them by lobbying the government not to legislate regulations that would force reimbursement and thereby result in premium increases. Alternatively, the afflicted community would seek to have government force on the insurance industry such measures that reduce the burden on them and spread the cost of medical food to others. Whether or not the externality is transferred or not is given by α . When α is low enough, one might observe the absence of medical food reimbursement law. High values of α might imply the presence of medical food reimbursement law. In the extreme scenario of $\alpha = 0$, the afflicted community assumes responsibility for full medical food cost while $\alpha = 1$ may imply that insurance companies are responsible for the full reimbursement of medical food cost. Afflicted households are likely to lobby for $\alpha=1$ or full coverage and insurance companies for $\alpha=0$ or avoid complete reimbursement. The government must carefully weigh the sentiments of the two communities and the possible electoral impacts of their decision in choosing α .

The utility function of the insurance company may be expressed as:

$$(1) \quad u^i(g) = u^i(y^i, x, h) = u^i[pq - c(q) - \alpha\beta(x(q)), x, h],$$

where h is the health index or a measure of the general level of health in the community. Healthy people reduce health insurance payouts. While general health is important, and insurance companies generate a lot of it, its impact on

⁷ Non-afflicted household also try to maximize their utility, except that the need for medical food coverage is not a big issue for those who prefer not to bear the cost of the afflicted community.

⁸ We assume that the non-afflicted community and insurance companies are not in conflict regarding the desire to keep premiums down.

medical foods is likely to be miniscule. Therefore, we assume the marginal utility of the general level of health is very low to insurance companies. Thus, for simplicity, it is ignored in the insurance companies' utility function. The utility function obeys the restrictions $u^i_y > 0$, and $u^i_x, u^i_{xx}, u^i_{yy}, u^i_{xy} < 0$ where the superscript i denotes the insurance companies. The convexity of the cost function implies $c_q, c_{qq} > 0$. The insurance company chooses the scale of health insurance coverage to the public to maximize utility as defined by (1). The first order condition for an interior maximum is:

$$(2) \quad p = c_q + \alpha\beta_x x_q - x_q(u^i_x / u^i_y).$$

As shown in equation (2), the scale of insurance enrollment is chosen optimally so as to equate the price charged for healthcare coverage (through premiums) to the sum of (1) the marginal cost of providing standard health insurance coverage to the public (2) the marginal cost of covering medical food purchased by the afflicted community, and (3) the money value of the disutility of incremental externalities. Solving this equation, we can express the optimum enrollment by the insurance company as a function of $\alpha(q^* = q^*(\alpha))$. That is:

$$(3) \quad \frac{dq^*}{d\alpha} = \frac{u^i_y \beta_x x_q - \beta(\theta u^i_{yy} + x_q u^i_{xy})}{\theta(\theta u^i_{yy} + x_q u^i_{xy}) + x_q(\theta u^i_{xy} + x_q u^i_{xx}) - u^i_y(c_{qq} + \alpha\beta_x x_{qq} + \alpha(x_q)^2 \beta_{xx}) + x_{qq} u^i_x} < 0,$$

where $\theta = p - c_q - \alpha\beta_x x_q > 0$. From equation (3), the insurance company's optimum coverage is a monotonically decreasing function of α .

To establish the curvature of the $q^*(\alpha)$ function, further assumptions are necessary. If utility function is linear and c, x and β functions are quadratic, then equation (3) reduces to:

$$(4) \quad \frac{dq^*}{d\alpha} = \frac{u^i_y \beta_x x_q}{u^i_y(c_{qq} + \alpha\beta_x x_{qq} + \alpha(x_q)^2 \beta_{xx}) + x_{qq} u^i_x};$$

and

$$(5) \quad \frac{d^2 q^*}{d\alpha^2} = \frac{(u^i_y \beta_x x_{qq} + u^i_y (x_q)^2 \beta_{xx})(-u^i_y(c_{qq} + \alpha\beta_x x_{qq} + \alpha(x_q)^2 \beta_{xx})) \frac{dq^*}{d\alpha} + (u^i_y)^2 \beta_x x_q (3\alpha x_q x_{qq} \beta_{xx} \frac{dq^*}{d\alpha} + \beta_x x_q + (x_q)^2 \beta_{xx})}{(-u^i_y(c_{qq} + \alpha\beta_x x_{qq} + \alpha(x_q)^2 \beta_{xx}) + x_{qq} u^i_x)^2}$$

A sufficient condition for $d^2 q^*/d\alpha^2$ to be positive is that $\beta_x x_{qq} + (x_q)^2 \beta_{xx} > -3\alpha x_q x_{qq} \beta_{xx} dq^*/d\alpha$. This is automatically satisfied if either x or β is linear in its argument. If both of them are linear, then $d^2 q^*/d\alpha^2 = 0$, implying that $q^*(\alpha)$ is a linear function. For the rest of the analysis we assume that $d^2 q^*/d\alpha^2 \geq 0$.

Afflicted Community

The utility function of the afflicted community is given by: $u^d(y^d, x, h)$. Afflicted households favor healthcare coverage for medical food, and unlike insurance companies, value such increases in healthcare coverage at the margin. Such health index comprises of the private industry healthcare coverage λ and government provision of coverage ω . Therefore $h = \lambda + \omega$. Since the health index is monotonically related to providing health insurance coverage to the public, it is possible to write λ as an inverse function of

insurance company enrollment. That is, $\lambda = \lambda(q)$, and $\lambda_q > 0$ such that $h_q > 0$.

The afflicted community chooses the level of q by choosing x such that $u^d_x x_q + u^d_h h_q = 0$. That is, the disutility associated with covering the afflicted community is set equal to the utility derived from the positive externality of the health index. This equation may be solved to express afflicted community desired enrollment q as a function of afflicted community income and government expenditure on health issues. That is:

$$q^d = q^d(y^d, \omega). \text{ It can be shown that:}$$

$$(6) \frac{dq^d}{dy^d} = \frac{u_{xy}^d x_q + u_{hy}^d h_q}{u_y^d x_{qq} + u_{xx}^d (x_q)^2 + h_q x_q u_{xh}^d + \lambda_q (x_q u_{xh}^d + h_q u_{hh}^d)}; \text{ and}$$

$$(7) \frac{dq^d}{d\omega} = \frac{u_{xh}^d x_q + u_{hh}^d h_q}{u_y^d x_{qq} + u_{xx}^d (x_q)^2 + h_q x_q u_{xh}^d + \lambda_q (x_q u_{xh}^d + h_q u_{hh}^d)}$$

That is, an increase in the afflicted community income should raise the demand for health coverage but lower the demand for insurance companies' coverage of medical food expenditures, $u_{hy}^d < 0$. The marginal utility associated with coverage also declines if coverage implies much higher premiums, $u_{xh} < 0$. The law of diminishing marginal utility ensures that $u_{hh}^d < 0$. It is seen that under these conditions dq^d/dy^d and $dq^d/d\omega$ are both unambiguously negative.

Government

The government comprises elected representatives of the afflicted community and insurance industry. It behaves rationally in the sense that it only decides on such measures (or legislation) as it believes would raise its electoral prospects. Recall that the non-afflicted community is very silent in the reimbursement debate on medical foods. However, insurance industry employees are not and such companies, though their financial support for candidates, can mobilize votes of the non-afflicted. The government's utility function may thus be regarded the same as the expected total vote function.

The utility function of the government is expressed as:

$$(8) u^G = V = I\Pi^i(\alpha, \gamma; \theta) + A\Pi^d(x, y^d, \omega, v; \Omega);$$

where I = a proxy for voting influence of insurance companies on the non-afflicted community (including its employees), A = voting population of the afflicted community, Π^j = probability that the average j^{th} group will vote for the government, $j = i, d$; γ = an index of the political clout of the insurance companies and the non-afflicted community, v = an index of the political clout of the afflicted community, and θ, Ω = other exogenous variable that may influence Π^j .

Since an increase in α raises the cost of coverage and reduces insurance companies income or ability to cover, insurance companies are likely to reduce political support for a government that imposes a higher α on them, such that $\Pi_{\alpha}^i < 0$. On the other hand, an increase in α reduces the burden on the afflicted and raises the probability that the afflicted community would vote for the government; $\Pi_x^d < 0$. At any given level of α, x and q , an increase in the income of the afflicted households makes them desirous of an increase in α such that they are less likely to politically support the government unless it takes measures to raise α , implying $\Pi_{xy}^i < 0$. For a similar reason, $\Pi_{x\omega}^d, \Pi_{\alpha\gamma}^i < 0$. It is further assumed that $\Pi_{\alpha\alpha}^i$ and Π_{xx}^d , are also negative.

The government chooses α in order to maximize electoral support. The first order condition for maximization is:

$$(9) I \frac{\partial \Pi^i}{\partial \alpha} + A \frac{\partial \Pi^d}{\partial \alpha} x_q \frac{\delta q}{\delta \alpha} = 0$$

This equation defines a maximum, provided $d^2V/d\alpha^2 < 0$. Hence,

$$(10) \frac{d^2V}{d\alpha^2} = I\Pi_{\alpha\alpha}^i + A\Pi_x^d x_q \frac{d^2q}{d\alpha^2} + A\Pi_x^d x_{qq} \left(\frac{dq}{d\alpha}\right)^2 + A(x_q)^2 \Pi_{xx}^d \left(\frac{dq}{d\alpha}\right)^2$$

Given the earlier assumptions, this expression is negative such that the equation above unambiguously defines a maximum. The equation simply states that in order to maximize V, the government sets the value of α such that the expected marginal decrease in insurance companies' and non-afflicted community votes due to an increase in x is just offset by the expected marginal increase in afflicted community's votes. Solving the equation, we can find optimum α^* as a function of the exogenous variables: $\alpha^* = \alpha^*(I, A, \gamma, \theta, y^d, \omega, v; \Omega)$.

To show the determination of α^* graphically, one can define an isovote line in $q-\alpha$ space by setting $dV = 0$ and holding all the exogenous variables constant such that

$$(11) \quad \frac{dq}{d\alpha} = \frac{-\Pi_{\alpha}^i}{A\Pi_x^d x_q}$$

The slope of the isovote line is negative. To establish the curvature of the isovote line differentiate the slope with respect to α :

$$(12) \quad \frac{d^2q}{d\alpha^2} = \frac{I}{A(\Pi_x^d x_q)^2} [x_q \Pi_x^d \Pi_{\alpha\alpha}^i - (\Pi_{\alpha}^i \Pi_x^i x_{qq} + \Pi_{\alpha}^i (x_q)^2 \Pi_{xx}^i) \frac{dq}{d\alpha}]$$

Equation 12 is negative which indicate that isovote lines are concave downward. Three concave lines are shown in Figure 1 (see Appendix B). Lower isovote lines represent higher total expected votes. The government would therefore want to be on as low an isovote line as possible. In choosing a lower isovote line, the government is constrained by the insurance community's output response function $q^* = q^*(\alpha)$ which is similar to a budget line. The optimum choice of α is determined at the tangency point between an isovote line and the insurance companies response function. At the tangency point, the slopes of the two functions are equal, as required by the first order condition (10). The fact that the isovote lines are concave downward and $q^*(\alpha)$ is either convex or linear guarantees that there is a unique tangency point which defines a maximum.

Equation (12) shows that the slope of the isovote line is proportional to the ratio of the scope of the influence of insurance companies to afflicted community population. If the ratio falls due to, say, a faster increase in afflicted population, the absolute value of this slope falls such that the isovote lines become flatter at any α . This has the implication that the tangency point E between the isovote and insurance enrollment response functions shifts to the right. Hence, an increase in the relative population of afflicted community raises the optimum. The opposite happens when the scope of insurance companies rises relative to the population of the afflicted community.

To formally demonstrate the effects of changes in the exogenous variable on α^* , totally differentiate equation (10) and rearrange as follows:

$$(13) \quad \Pi_{\alpha}^i dI + \Pi_{\gamma\gamma}^i d\gamma + \Pi_x^d x_q \left(\frac{dq}{d\alpha}\right) dy^d + Ax_q \Pi_{x\omega}^d \left(\frac{dq}{d\alpha}\right) d\omega + Ax_q \left(\frac{dq}{d\alpha}\right) \Pi_{xv}^d dv + \phi d\alpha = 0,$$

where

$$(14) \quad \phi = \Pi_{\alpha\alpha}^d + A\Pi_x^d x_q \left(\frac{d^2q}{d\alpha^2}\right) + Ax_{qq} \Pi_x^d \left(\frac{dq}{d\alpha}\right)^2 + Ax_q \left(\frac{dq}{d\alpha}\right)^2 \Pi_{xx}^d < 0.$$

Therefore, the following can be obtained:

$$(15) \quad \frac{d\alpha^*}{dA} = -\frac{\Pi_x^d x_q \left(\frac{dq}{d\alpha}\right)}{\phi} > 0,$$

$$(17) \quad \frac{d\alpha^*}{d\gamma} = -\frac{\Pi_{\alpha\gamma}^i}{\phi} < 0,$$

$$(16) \quad \frac{d\alpha^*}{dI} = -\frac{\Pi_{\alpha}^i}{\phi} < 0,$$

$$(18) \quad \frac{d\alpha^*}{dy^d} = -\frac{A\Pi_{xy}^d x_q \left(\frac{dq}{d\alpha}\right)}{\phi} > 0,$$

$$(19) \frac{d\alpha^*}{d\omega} = -\frac{A\Pi_{x\omega}^d x_q \left(\frac{dq}{d\alpha}\right)}{\phi} > 0, \text{ and}$$

$$(20) \frac{d\alpha^*}{dv} = -\frac{A\Pi_{xv}^d x_q \left(\frac{dq}{d\alpha}\right)}{\phi} > 0.$$

Equations (15) through (20) confirm the diagrammatic results. That is, an increase in the scope and size of the insurance industry (with afflicted population constant) will reduce α^* ; an increase in afflicted population will raise α^* ; as the political clout of the insurance community and their non-afflicted allies increases, the government finds it more electorally beneficial to reduce α^* ; as the political clout of the afflicted community increases, the government finds it less beneficial to reduce α^* ; a rise in the incomes of the afflicted community will raise the level of α ; and an increase in the health index will also raise α . This directly contradicts the expected effect of afflicted community income on the interest in raising the health index.

The theoretical model above is helpful in identifying the determinants of insurance industry mandated medical foods reimbursement policy adoption. However, it is important to note that the model does not preclude other determining factors. θ and Ω are incorporated into the model as exogenous factors to capture other factors.⁹ It suggests that whether or not a polity adopts mandatory reimbursement and the scope of the coverage actually adopted depend on political motives, legislative adoption factors, the clout of the afflicted community, healthcare industry profit motive, spillover and proximity effects and other exogenous socio-economic factors to empirically implement the theoretical model and other exogenous socio-economic factors to empirically implement the theoretical model above, since the choice variable in reality is binary, representing adoption or non-adoption, a binary choice endogenous variable is preferred.

⁹ Other possible determinants of medical food reimbursement may include rapid population changes and political dynamics.

Empirical Framework

The logic model framework is specifically utilized in this research. The conceptual model helped in identifying determinants and their potential effects. With the logit function, the regression coefficients describe the change in the logarithm of the odds of a state having MFA (Medical Food Adoption) law mandating insurance industry to reimburse those that do not, given a unit change in the value of the independent variable (Laio, 1994). Given the nature of the decision by government, the logit model is used in estimating the impact of determinants on the probability of legislative adoption of medical food reimbursement policy mandating insurance companies to reimburse.

The logit model assumes that the probability of observing a specific outcome (i.e. an individual state to pass legislation mandating medical food reimbursement by insurance companies), P , is dependent on a vector of independent variables (X_{sr}) associated with state s and variable r , and a vector of unknown parameters, Y_k . The likelihood of observing the outcome of the dependent variable as a function of explanatory variables can be given using the following logit function:

$$(21) \begin{aligned} P[MFA_r = 1 | x_{1r}, \dots, x_{kr}] &= \frac{1}{1 + \exp(-Y_1 x_{1r} - \dots - Y_k x_{kr})} \\ &= \frac{1}{1 + \exp(-\sum_{s=1}^k Y_s x_{sr})} \end{aligned}$$

where $MFA_r = 1$ if a state passes legislation mandating medical food reimbursement by insurance companies, else $MFA_r = 0$ if there is no legislative mandate. X_{sr} is the set of explanatory variables, and Y represents model parameters to be estimated.

To obtain the estimates for explanatory variables in the logit model, the changes in probability, MFA_i , brought about by a change in any of the independent variables, X_{ij} , is given by:

$$(22) \quad (\partial MFA_r / \partial X_{sr}) = [Y_j \exp(-YX_{sr})] / [1 + \exp(-YX_{sr})^2].$$

Marginal probabilities associated with change in any of the explanatory variables are given by:

$$(23) \quad (\Delta MFA_i / \Delta X_{sr}) = MFA_r(X_{sr} = 1) - P_i(X_{sr} = 0).$$

The maximum likelihood function for expression in (22) can be given as:

$$(24) \quad \ln(L(Y_1, \dots, Y_k)) = - \sum_{i=1}^n (1 - MFA_r) \sum_{s=1}^k Y_s X_{sr} - \sum_{i=1}^n \ln(1 + \exp(-\sum_{r=1}^k Y_r X_{sr}))$$

Therefore, the specification for medical food adoption is estimated by a maximum likelihood procedure that generates estimator values by maximizing the log-likelihood function in (24), i.e.,

$$\ln(L(\hat{Y}_1, \dots, \hat{Y}_k)) = \max \ln(L(Y_1, \dots, Y_k)).$$

Data

The data came largely from a survey of the United States medical food reimbursement law status which was collected between 1999 and 2003. Relevant parties in all 50 states were contacted directly to find out if medical food insurance reimbursement laws existed. This was followed by pulling relevant legislation in these states. Data obtained were used to create a cross-sectional database for the fifty states.¹⁰ Other sources of data included U.S. Census,

Bureau of Labor Statistics and others as depicted in Table 2. Data on independent variables used in the analysis were for the latest year available before state legislative adoption, except in the case of states with no legislation where the data used was for the last year before 2003.

Consider first the political and economic variables. To measure the size, strength and political clout of the afflicted community, the number of existing metabolic clinics in the state (META) and the size of the afflicted community (AFFLICT) were chosen as proxies. These measures of political clout are consistent with the notion that size, and not percentage, are the prerequisite for coalition. The number of Metabolic and Disease Clinics is hypothesized to positively relate to legislative adoptions. Metabolic clinics provide an area where the afflicted community can gather in numbers for food procurement, promoting public awareness and staging lobbying efforts. AFFLICT (AFFLICTSQ) was added to test the hypothesis that at lower levels of afflicted population, an increase in the population of the afflicted raises concerns about legislative adoption and lowers the likelihood of adoption, up to the point where the numbers become large enough for the afflicted coalition to form and fight for reimbursement legislation. To measure the political strength and clout of parties opposing medical food reimbursement, the percentage of state residents covered by private insurance companies (PERINSUR) is used. To capture the political structure of the legislature and voters, the percentage of the state legislators that are Democratic (DEMOC) and the percentage of the voting population above 18 (VOTE) were used to test whether democrats are more favorable in their support of families and individuals with medical conditions and whether those over 18 are more likely to support medical food reimbursement policy.

Now consider the socioeconomic and demographic factors. State's per capita income (INCOME) is introduced to measure the affordability of the medical food expenditure by the public through legislative provision for insurance reimbursement. Whites Americans have a higher incidence rate of certain metabolic diseases like phenylketonuria¹¹ and this could influence the political landscape.

¹⁰ This survey was directed by the primary author and conducted primarily through a special undergraduate research course taught by the primary author and other instructors in 1999. The authors continued the survey effort until 2003. Legislative adoptions through July 2003 were included in the modeling exercise.

¹¹ Phenylketonuria is most common in whites in United States. (<http://emedicine.medscape.com/article/947781-overview>)

Table 2. Description of Independent Variables and Data Sources

Variable Name	Description of Variable	Source
<i>Political and Economic Variables</i>		
META	Number of Metabolic and Disease Clinics	Health Directory
AFFLICT	Afflicted population in the State	U.S. Census Bureau
PERINSUR	Percentage of Residents Covered by Private Insurance Companies	U.S. Census Bureau
DEMOC	Dummy Variable for State Legislature Controlled by Democratic Party	Statistical Abstract of United States
VOTE	Percentage of Population above 18 that voted	U.S. Census Bureau
<i>Socioeconomic and Demographic Variables</i>		
INCOME	Per Capita Personal Income	U.S. Census Bureau
WHITE	Percentage of Total White	U.S. Census Bureau
HEALTHPERCAP	Per Capita Expenditure on Healthcare	U.S. Census Bureau
HIGH	Percentage that Completed High School	U.S. Census Bureau
ILLNESS	Non-fatal Illness incidence rate per 100 full-time workers	Bureau of Labor Statistics
<i>Proximity and Time Variables</i>		
NEIGH	Presence of medical food reimbursement legislation in neighboring state	Direct Survey

Similarly, state legislators may find it easier to cater to White Americans who dominate the electorate. Hence, the state percentage of White population (WHITE) was included as an explanatory variable. The percentage of the state's expenditure on healthcare and hospitals (HEALTHPERCAP) was used as another proxy for income impact and economic burden on the non-afflicted. High health care costs should trigger an adverse vote.

Other socioeconomic and demographic factors include the percentage of the population with a high school education (HIGH) and the number of non-fatal illness incidence rate per 100 full-time workers (ILLNESS). HIGH suggests greater public awareness and mobilization potential of citizens for government lobbying. ILLNESS provides information on the access to healthcare. Finally, the recent adoption of medical food reimbursement policy in a neighboring

state (NEIGH) is used to proxy the spillover effect on own passage of medical food reimbursement legislation.

Empirical Results

Table 3 provides the parameter estimates of equation (21). The model correctly predicted the state of the dependent variables in 86 percent of the states when the actual values were plugged into the predicted model. The chi-square statistic led to the rejection of the null hypothesis that the explanatory variables as a set were insignificant in explaining variation in the dependent variable, at the 0.02 percent level of significance. The McFadden's R^2 result for the model was 0.45, which indicates that 45 percent of the variations in the dependent variable was explained by the model.

Table 3. Parameter Estimate for Medical Food Reimbursement Model

Independent Variable	Estimate	Standard Error	Change in Probability
Intercept**	-26.496	13.554	
<i>Political and Economic Variables</i>			
META*	0.895	0.522	0.113
AFFLICTED**	-0.005	0.002	-0.0006
AFFLICTSQ*	7.92x10 ⁻⁶	0.45 x10 ⁻⁶	0.99x10 ⁻⁷
PERINSUR**	-0.172	0.152	-0.022
DEMOC	2.463	3.138	-
VOTE	-0.107	0.094	-
<i>Socioeconomic and Demographic Variables</i>			
INCOME*	0.001	0.0004	0.0001
WHITE	-4.185	6.777	-
HEALTHPERCAP**	-0.040	0.021	-0.005
HIGH**	0.362	0.191	0.045
ILLNESS	0.267	0.540	-
<i>Proximity and Time Variables</i>			
NEIGH*	2.306	1.381	0.209

Significance of Chi-square Statistic: 0.002

McFadden's R²: 0.45

*: Significant at the .10 level

**: Significant at the .05 level

Marginal effects on probability adoption are not reported for variables where the estimated coefficients are not statistically significant.

Prediction Success

	Predicted		
Actual	0	1	Total
0	17	4	21
1	3	26	29
Total	20	30	50

Number of Corrected Predictions= 43

Percent of Corrected Predictions =86

The findings are largely consistent with a priori expectations. The results suggest that the more metabolic clinics in a state (META), the more likely the state would pass medical food reimbursement legislation. For every metabolic clinic in the state, the chance of medical food reimbursement legislation being enacted increases by 11.3 percent. This finding suggests that metabolic clinics are support infrastructure for the afflicted community and reflect the existing political clout of the afflicted community. The large size of the marginal effects of metabolic clinics suggests that this is a primary determinant of medical foods insurance reimbursement laws.

The findings regarding the impact of the size of the afflicted community on probability of adoption is captured by AFFLICT and AFFLICTSQ, the later testing for structural change

in the relationship between the size of the afflicted community and the likelihood of legislative action to reimburse. The results suggest that as the size of the afflicted community (AFFLICT) increases, the likelihood of legislative adoption marginally decreases by 0.06 percent, possibly signifying resistance by a more powerful insurance lobby against a small and perhaps less organized afflicted community.

However, at larger and larger afflicted community sizes, the probability of adoption from a marginal increase in the afflicted community size will actually increase by 0.99x10⁻⁵ percent. This effect reinforces the positive effects of metabolic clinics. Since the afflicted community has a vested interest in reimbursement and is the driving force to push reimbursement legislation into state legislators' hands, it is not surprising that the results suggest the afflicted community bears significant weight on the probability of whether medical food reimbursement legislation will pass through state government successfully.

The results suggest that for every one percent of the state covered by private insurance companies (PERINSUR), the likelihood of medical foods insurance reimbursement legislation adoption drops by 2.2 percent. The result suggests the

influence of insurance companies on their clientele, and that they have a stake in the negative outcome of medical foods insurance reimbursement legislation and thus oppose the passage of reimbursement laws.

Both the VOTE and DEMOC political variables were not statistically significant. These results challenge Dye's voter participation and party affiliation theories. These results can be explained by the fact that the medical foods issue is not a major political and voting issue as it affects few non-afflicted individuals. The notion that democrats are more liberal and offer broad welfare enhancing programs (medical foods reimbursement in this case) is therefore not supported by this study.

The (HEALTHPERCAP) variable captures existing state commitment to public health and state financial support for such care. The finding suggests that for every additional 10 dollar spent per capita on healthcare in a state, the likelihood of medical food reimbursement decreases by 5 percent. In other words, it suggests that the more money a state spends on healthcare per capita, the less likely medical food reimbursement legislation will pass. This result suggests that a state already spending a considerable amount on healthcare expenditures and subsidies is less likely to pass additional legislation increasing the total amount of money spent in healthcare.

Income (INCOME) is also a significant determinant of legislative adoption. Holding all else constant, a state registering a 100 dollars more per capital income has a 1 percent additional probability to adopt medical foods reimbursement legislation. The result confirms the income effect on legislative adoption, more so if a given state has a wider per capita income gap compared to the sample average. The coefficient of the white population (WHITE) was not significant, suggesting race is immaterial to legislators when it comes to medical foods.

The likelihood of medical food reimbursement increases as the percentage of the state population with a high school education or higher (HIGH) increases. Hence, those states with higher education levels seem to have the necessary intellectual and financial resources to mobilize their citizens to press for measures that attempt to reimburse medical food. For every 1

percent increase in the percentage of people in a state with high school education, the probability of medical food reimbursement legislation adoption increases by 4.5 percent.

Spillover effects of legislative adoption from neighboring states that already adopted the reimbursement legislation (NEIGH) is an important determinant. If a state is surrounded by other states that already adopted reimbursement legislation, the likelihood of adoption in that state is expected to increase by 20.9 percent. This result provides strong evidence that legislative spillovers have significant relevance to adoption of a program, perhaps due to the visibility and noticeability of legislative adoption in neighboring states by state legislators, and perhaps due to yardstick competition against which legislators want to excel.

Conclusion

This paper is unique in its application of the political economy framework to the emerging area of medical foods and the challenge medical food producers and marketers face in expanding their markets in an environment where policy is a game-changer. Because of the blurred line between food and drugs, medical foods are controversial, especially because the adoption of legislation mandating reimbursement forces the insurance industry to incur new costs (payouts) and possibly raise premium levels. While the size of the afflicted community is small in the United States, the resistance of insurance companies has been strong and palpable. One of the explanations for the strong resistance of the insurance industry is the fear that if states open the door for food reimbursement through medical foods, all sorts of things could eventually be reimbursed. Currently, there are many non-drug substances that confer significant health benefits to the afflicted. Examples include vitamins, certain botanicals, various medicinal plants, and various food substances. Insurance companies have a vested interest in protecting the reimbursement schedule for their state from what they consider to be frivolous practices in order to maintain profitability and industry integrity.

Confirmation of the political clout and other hypotheses suggest the endogeneity of public

choice even in an area as controversial as medical foods where the afflicted community is limited in number. What is intriguing about medical foods is that despite the small size of the pro-reimbursement movement, more states have passed medical food reimbursement laws than those that have not. Obviously, the role of the metabolic clinics complements the activities of the afflicted community.

While the issues surrounding medical food reimbursement are largely below the radar screen due to the limited size of the afflicted community, these products provide us with a glimpse of what may come as higher and more educated baby-boomers age, pursue healthier diets, and seek food that offer more than nutrition. Despite their preventative properties and potential health-care cost benefits, insurance companies have scoffed at reimbursing for expenditure on medical foods. This suggests that foods that confer health benefits but are not medical foods would also be opposed by them. On the other hand, it seems likely that baby-boomers will seek coverage for these foods. Given the fact that medical insurance laws are implemented at the state level and they are subject to the demographics and politics of each state, the ultimate determination of what happens to foods at the boundaries of traditional foods and drugs will be made as a consequence of the size and political clout of parties to the coverage debate.

Contentious debates will likely ensue in the future between the demanders of more liberal policies and those that wish to limit medical foods coverage. The fact that the insurance community is experiencing consolidation may suggest more favorable chances for adoption in the future.

Finally, results from this study should interest medical foods producers, wholesalers, distributors and marketers. The supply chain of this high technology component of the food industry is checkered at best, largely because legislative adoption is a silver bullet that can help crystalize the distribution system by reducing the cost of the product from what is typically very high to about zero. This creates instantaneous effective demand. The results suggest that medical foods companies can focus their efforts on states with

high income, with a high education of the afflicted, with fewer health insurance companies, with more metabolic clinics, with high per capita income, with high levels of education and that border other states that have adopted legislation. They may avoid states with high healthcare costs and those that have stronger private insurance tradition. The fact state racial and party compositions are irrelevant suggest that medical foods companies need not employ differential strategies due to these factors. We conclude by restating that findings here could be relevant to other food industries where policy plays a major role in the establishment of markets.

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Appendix A**Table A.1 Chronology of Medical Foods Insurance Reimbursement Legislation by State through July 2003**

State	Date Effective	State	Date Effective
Texas	September-89	New York	January-98
Alaska	May-91	Utah	February-98
South Dakota	March-92	Nebraska	April-98
Massachusetts	November-93	Vermont	October-98
Maine	February-95	California	January-99
Florida	May-95	Hawaii	January-99
Maryland	May-95	Arkansas	April-99
New Hampshire	June-96	Montana	April-99
Tennessee	July-96	Virginia	March-00
Pennsylvania	December-96	Arizona	April-00
Oregon	May-97	Kentucky	April-02
Nevada	July-97	Colorado	June-01
North Dakota	August-97	Louisiana	June-01
Connecticut	October-97	Minnesota	Date Unknown
New Jersey	December-97		

Source: 1991 through 2001 personal interviews with state representatives by study team plus information from the national PKU News Website, October 2003, <http://www.pkunews.org/>.

Table A.2 Criteria for Medical Foods Insurance Reimbursement Across the United States as of July 2003.

State	Additional metabolic disorders	Annual dollar limit	Age Limit	State	Additional metabolic disorders	Annual dollar limit	Age Limit
Alabama	-	-	-	Montana*	All	No	No
Alaska*	None	No	No	Nebraska*	Select	2,000	No
Arizona*	Select	2,500	No	Nevada*	Select	2,500	21
Arkansas*	None	2,400	No	New Hampshire*	Select	1,800	No
California*	All	No	No	New Jersey*	All	No	No
Colorado*	All	No	21/25 ¹	New Mexico	-	-	-
Connecticut*	Select	No	No	New York*	All	2,500	No
Delaware	-	-	-	North Carolina*	-	-	-
Florida*	Select	2,500	24	North Dakota*	MSUD	3,000	No
Georgia	-	-	-	Ohio	-	-	-
Hawaii*	All	No	No	Oklahoma	-	-	-
Idaho	-	-	-	Oregon*	All	No	No
Illinois	-	-	-	Pennsylvania*	MSUD	No	21
Indiana	-	-	-	Rhode Island	-	-	-
Iowa	-	-	-	South Carolina	-	-	-
Kansas	-	-	-	South Dakota*	Unknown ²	No	No
Kentucky*	All	4,000	No	Tennessee*	Select ³	No	No
Louisiana*	All	2,400	No	Texas*	Select	3,500	No
Maine*	Select	3,000	18	Utah*	Select	No	No
Maryland*	Select	No	No	Vermont*	Unknown	2,500	No
Massachusetts*	Select	2,500	No	Virginia*	Unknown	2,000	18
Michigan	-	-	-	Washington*	-	-	-
Minnesota*	-	-	-	West Virginia*	-	-	-
Mississippi*	-	-	-	Wisconsin*	-	-	-
Missouri*	-	-	-	Wyoming	-	-	-

Note: * indicates states with insurance reimbursement for phenylketonuria while - indicates otherwise. Colorado limits vary with age - 21 for males and 35 for females; for states labeled "Unknown", there exists no interpretive state legislation on additional metabolic disorder coverage. For states labeled Select, only select metabolic disorders are covered.

Source: Personal interviews with State Representatives and information from the National PKU News website, October 2003, <http://www.pkunews.org/>.

Table A.3 Timeline of Federal Policies and Regulations Related to Medical Food

Year	Activity/Legislator
1906	Passage of the Pure Food and Drug Act.
1938	Passage of the federal Food, Drug and Cosmetic Act, regarding medical food as prescription drugs to assure that their use would be supervised by physicians and to prevent misuse by individuals.
1972	FDA revised its classification of medical food from "drugs" to "special dietary food" (21 CFR 105.3).
1973	The FDA defined medical food in 21 CFR 101.9(h)(4) as "food represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions."
1976	The Proxmire Amendment to the FD&C Act (Section 411) differentiated regulation of vitamin and mineral supplements from medical food.
1980	Congress passed the Infant Formula Act (FD&C Act, Section 412), which led to specific regulations (21 CFR 107.10 wt seq.) for the manufacturing of infant formula.
1988	FDA initiated a Compliance Program to enable the agency to evaluate how the medical food industry ensures proper formulation, appropriate microbiological standards, and reasonable therapeutic claims for these products. Passage of the Orphan Drug Act. Congress amended the Drug Act to include the first legal definition of medical food (21 U.S. Code 360ee (b)(3))
1990	The definition for medical food in the U.S. was incorporated into the Nutrition Labeling and Education Act of 1990, (NLEA) (P.L. 101-535) (21 U.S. Code 343) The NLEA, however, exempted medical food from the requirements of nutrition labeling to ensure that other specific regulations would be developed to control medical food.
1991	The Codex Alimentarius Commission approved standards for food for special medical dietary uses.
1994	The passage of the Dietary Supplement Health and Education Act, which expanded the vitamin-mineral category to include herbs, botanicals, proteins, extracts, and metabolites and renamed them as dietary supplements. It also allowed for structure function claims.
1995	The FDA announced the agency's general policy on the development and use of standards with respect to international harmonization of regulatory requirements and guidelines
2001	The FDA issued Food Compliance Program – "Medical Food – Import and Domestic" which provides regulations on the quality control standards and procedures for medical food.

Appendix B

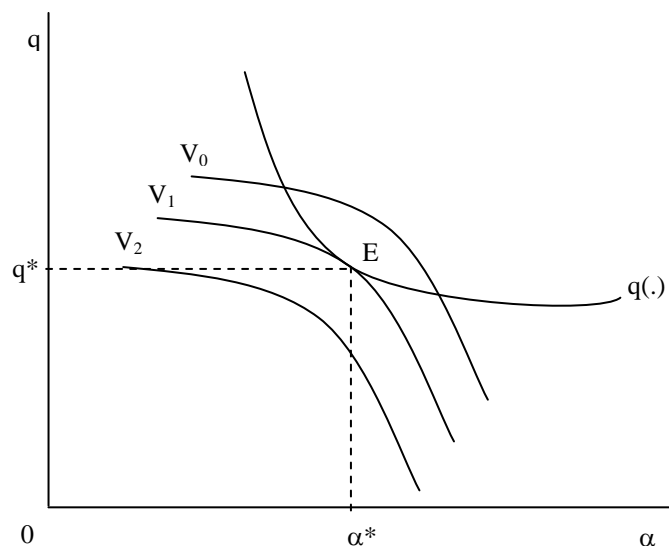


Figure 1. Optimal Level of Medical Food Reimbursement Protection