Political Economy of Medical Foods Reimbursement

Soji Adelaja and Amish Patel*

Abstract

Medical foods (MFs) fall in-between food and drugs. Because they are more expensive than normal foods, some states have mandated insurance companies (or their own state agencies) to provide coverage for the afflicted community, leaving a checkered pattern of coverage across the US, where insurance laws fall within state domain. To investigate the legislative adoption process, this paper develops a political economy model of medical food reimbursement (MFR) and coverage policy and identifies five categories of causal factors. Analytical logit regression models confirm the positive influences of metabolic clinics, the political clout of the afflicted community, literacy rate, education and income on the probability of adoption. The countervailing interests of the insurance industry and the non-afflicted community, as well as the income effect (affordability hypothesis) were confirmed. Results further indicate that the choice of reimbursement mechanism is affected largely by the same variables as legislative adoption.

Keywords: medical foods, insurance reimbursement, logit, political economy, legislative adoption.

* Selected paper to be presented at the 2005 Annual Meetings of the American Agricultural Economics Association (AAEA), Providence Rhode Island, July 24th to 27th, 2005. The authors' information are as follows: Soji Adelaja (adelaja@msu.edu) is the John A. Hannah Distinguished Professor in Land Policy and Director of the Land Policy Program at Michigan State University. He holds joint appointments in the departments of Agricultural Economics; Geography; and Community, Agriculture, Recreation and Resource Studies (CARRS). Amish Patel (apatel@estes-express.com) is Vice President, DP Systems Inc., Midlothian VA. Soji Adelaja, the contact author, can be reached at the following address: Land Policy Program, 317 Manly Miles Building, 1405 South Harrison Rd., East Lansing, MI 48823, USA. Tel: 517-432-8800; Fax: 517-432-8769.

Political Economy of Medical Foods Reimbursement

A medical food (MF) is "a specially formulated metabolic food prescribed by a physician" (see 21 CFR 101.9(j)(8)). Like prescription drugs, whose costs are typically covered by insurance companies (via state legislative mandates), MFs are a necessity for a healthy and normal life for individuals with metabolic disorders. However, MFs are close to regular food, whose costs are typically absorbed by consumers. Because MFs 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 MFR policy and level of reimbursement. Prescription drugs are subsidized or reimbursed by healthcare plans from insurance companies. However, prescription food or MF is not always covered, due in part to opposition by insurance companies.[1] Products within the MF category include special formulations for patients with celiac sprue, phenylketonuria, irritable bowel disease, maple syrup urine disease, diabetes, and others.[2]

Unless state law mandates the subsidization or reimbursement of MF expenditures by state agencies or insurance companies, the high procurement cost limits the ability of the afflicted to enjoy good health and quality of life. According to the Food Industry Review, the average individual in the United States consumes approximately $2,793 worth of normal food annually (The Food Institute, 2001). As shown in Table 1, MFs are 100% to 4000% more expensive.[3] Clearly, for families with individuals whose survival depends on MFs, staying healthy could be a financial challenge.

In response to concerns about the burden on individuals/families with metabolic disorders requiring MF for survival, U.S. Public Law 100-290 (P.L. 100-290) was passed in 1988 as an amendment to the Orphan Drug Act. P.L. 100-290, which better defined medical food as "food

only being prescribed by physicians for medical necessity," provided the foundation for state mandates requiring the provision of state or insurance company reimbursement (US Congress 1990). The adoption of medical foods reimbursement (MFR) policy varies by state. Some do not mandate coverage of MF while others provide full coverage with no dollar or age restrictions. For example, Kentucky limits reimbursement of MF to $4,000 annually with no age restriction, while 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. When MFR 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.[4]

The afflicted community has something to gain from lobbying for legislative adoption of MFR policy. Given the disparity in the costs of medical and non-MFs, the health, purchasing power and quality of life of the afflicted community are impacted by the adoption of such policy. The families, physicians and dieticians of the afflicted are expected to join them in advocating for legislative adoption of such policy. The MFs industry also has something to gain from legislative adoption. Such policy lowers the price of MFs and enhances consumer affordability and market penetration. Because the effective client cost of MF acquisition is dependent on legislation, the marketing, pricing and growth strategies of MF companies are endogenous to public reimbursement policy and companies must factor into their plans the variability across states in political economic factors.[5] Besides, the diversity of arrangements for reimbursement creates an atmosphere of uncertainty for the industry. Information on the determinants of legislative adoption and 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 opponents of reimbursement. Healthcare professionals, for example, can

be better informed in advising their clients on how to plan for their long-term health, considering the political economic situation in their state. [6]

The dynamic nature of MFR legislation pits the pro-reimbursement community against insurance companies and other opponents. Insurance companies can be expected to oppose such legislation if it increases insurance payout per capita. Depending on the nature of the market (demand, supply and pricing of premiums) for medical insurance policies, reimbursement mandates could increase (or decrease) insurance costs and, thereby, affect company profitability. The costs of medical care associated with dietary non-compliance must be contrasted with the increased costs associated with insurance reimbursement in order to determine whether an insurance company would favor MFR. The non-afflicted community may also oppose legislative mandate due to fears about increased costs. Information about the likelihood of passage of MFR legislation will also be useful to insurance companies and other opposing communities in conceptualizing their premium pricing strategies and opposition.

While some medical literature exists on the usage and need for MF, nothing is available on the legislative adoption process. No study has identifies the determinants of legislative adoption or empirically investigated their impacts. Given the importance of such analysis, this study does just that. It conceptualizes the determinants of legislative adoption of MFR policy, including political motives, relative sizes and political clout of the beneficiaries and opponents of legislative adoption, legislative adoption factors, healthcare insurance industry profits motives, the desire to provide coverage that is consistent with change in consumer tastes and preferences, proximity or spillover effects from other states, and other socioeconomic and demographic factors. State level information on relevant variables was collected, including data on the status of MFR policies and associated regulations. Two empirical logit models were estimated: one to evaluate the effects of key factors responsible for the passage of MFR laws in general, and the

other to evaluate the effects on MFR laws that involve only insurance industry reimbursement. The differentials in the coefficients of these two models are used to assess the differences in motivation for mandated state reimbursement and mandated insurance industry reimbursement.

Definition and History of Medical Foods

In this study, we define medical food as foods designed to provide complete or supplemental nutritional support to individuals who are unable to ingest adequate amounts of food in a conventional form, or to provide specialized nutritional support to patients who have special physiological and nutritional needs. Such foods can be delivered in many forms, e.g., sterile liquids that may be consumed directly or fed by a nasogastric or intestinal tube, rehydratable dry powders, and an edible solid or semisolid form (e.g., chewable bars). This definition of MF, which was first incorporated into the Nutrition Labeling and Education Act of 1990 (NLEA) (P.L. 101-535), is now the current authoritative definition (U.S. Congress, 1990).

The chronology and features of state adoption of MFR policy are depicted in Figure 1 and Table 2, while the timeline for federal policies on MFs is presented in Table 3. As of 1999, consumers in 35 states can expect to receive reimbursement or coverage by one of the modalities mentioned above for MF expenditures they incur. The legislators in 24 states passed MFR legislation mandating insurance companies to reimburse for MF expenditures. In other states, the law mandates a state agency (Department of Health and Human Services, etc.) to reimburse for MF expenditures. Some agencies actually procure MF for patients with metabolic diseases that require special dietary attention. Those mandating a state agency for coverage are 5. In 6 states, the reimbursement agencies are both state agency and insurance companies.

Conceptual Framework

An appropriate starting point for modeling the evolution of MFR legislation is to review the literature on the political economy of legislative and policy adoption. These studies suggests

at least three categories of legislative causal factors: (1) the characteristics of the policy and its goals (Bardach, 1977; Derthick, 1972; Rosenbaum, 1980; Sabatier and Mazmanian, 1979); (2) the characteristics of implementing agencies (Edwards, 1980; Nakamura and Pinderhughes, 1980); and (3) the beliefs and attitudes of key policy actors (Bardach, 1977; Marshall, Mitchell and Wirt, 1986; Mitchell, 1981; Sabatier and Mazmanian, 1979; Van Horn and Van Meter, 1977). Specific proxies have been used to represent these factors in prior modeling-based studies on policy choices.

In an attempt to explain the roles of specific factors, Dye (1966) identified four variables that determine legislative adoption: (1) inter-party competition, (2) division of party control, (3) the electoral system and voter participation, and (4) degree of inequality in voter representation. Inter-party competition is expected to result in new public policy as political parties vie for votes). With respect to the division of party control, the dominant party is expected to be more likely to get its policies passed). With respect to the electoral system and voter participation, lower income, lower-status, poorly educated, and non-white groups, which typically support democrats, are expected to have lower voter participation rates. Hence, a small voter turnout should hurt democrats. Finally, with respect to the degree of inequality in voter representation, which he called mal-apportionment, less well represented groups are less likely to have policies evolve that benefit them (Dye, 1966).

Rosenbaum (1976) showed that legislative adoption often lead neighboring governments to consider the same or similar legislation. The reasons are as follows: (1) political leaders look to regional neighbors for legislative innovation, because their neighbors probably have problems similar to their own; (2) there is a widespread attitude that laws should be adapted to those of governments within a close proximity; and (3) officials are members of organizational affiliations, putting them in close contact with their neighboring counterparts (see Sharkansky,

1970). Of course, it is also possible that passage of a strong piece of legislation by a neighboring principality may provide a wake-up call to opponents of the law, encouraging them to work to defeat similar legislation.

Studies on health care policy provide additional insights. Aaron (1991) identified the following determinants of health care policies: (1) the escalating costs of health care expenditures, (2) access to healthcare, (3) the "quality of healthcare, and (4) inter-company factors such as competition between healthcare insurance companies (this can prove to be beneficial to consumers). 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 further determinants.

The political economy model used in this study is based on Dye's basic infrastructure (Dye 1975), with further guidance from others. The competing interest groups include the insurance community, the afflicted community, and the non-afflicted community, but for modeling simplicity, we assume that the interests of the non-afflicted community can be accounted for in the objective function of the insurance community. These groups will exert pressure on the legislature to make choices based on their relative strength in the political arena. 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 (such as increased public health and increased patronage). However, it also tries to keep premiums down to optimize the utility of its clientele and its own long-term survival. On the other hand, afflicted households wish to maximize utility (or quality of life) from its insurance coverage of traditional healthcare costs plus MFs.[7]

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. Causal factors in the political economy model would include various factors discussed above.

To specify the political economy model for MFR policy, we start with the utility functions for various parties to the debate. The utility of the i^{th} household is given by: $u^i = u^i(g)$, where g is a vector of consumption goods, including health coverage and reimbursement of expenditures in medicine. Hence, households would be willing to pay a premium to obtain such benefits. Coverage for MF causes the premium for all households to increase but confers more than commensurate benefits to the afflicted community while the non-afflicted community gets less benefits than the increased premiums. Each household maximizes utility $u^i(g)$ subject to the constraints it faces.

Insurance Companies

The representative insurance company earns income, y^i, from providing health insurance coverage to the public, q: $y^i = pq - c(q) - \alpha\beta(x)$, where p is the 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 MFs or the afflicted community size, β is cost per unit to provide health coverage/MFR for the afflicted community, $\beta(x)$ is the total cost of providing coverage for the afflicted community where $\beta(x) = \beta(x(q))$ and β_x , $\beta_{xx} > 0$, and α is a measure of the proportion of the total cost that insurance companies are expected to bear. As mentioned above, 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 quantity of

externalities associated with MFs is assumed to be an increasing function of the population 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 the non-afflicted by lobbying the government to not legislate regulations that would force reimbursement and thereby result in premium increases. Alternatively, the afflicted community would seek to have Government take and force the insurance industry such measures that reduce the burden on them and spread the cost of MF on others. Assume that the insurance companies are required to pay a fraction α of this cost to cover for MFs. If $\alpha = 0$, they effectively have full dismissal of responsibility in payments for MFs costs such that they do not bear any cost of coverage. On the other hand $\alpha = 1$ effectively dismisses all responsibility for the afflicted community to pay for their own MFs and puts the full burden on insurance companies. When $0 < \alpha < 1$, the financial burden is distributed between the two groups. Since a high value of α places much of the burden of the coverage for MFs on the insurance companies and the non-afflicted community raises the total cost of providing healthcare coverage and lowers profits, they would, therefore, want and lobby for a lower value of α. On the other hand, insurance coverage for MF, increased premiums and less healthcare coverage reduce the utility of the afflicted households without any compensating change in income. Hence, they lobby for a higher value of α. In choosing the level of α, the government must carefully weigh the sentiments of the two communities and the possible electoral impacts of their decision.

To simplify the analysis, it is assumed that the insurance industry is a single product industry, providing only health insurance. Multi-product scenarios can easily be introduced without much effect on subsequent results. The utility of the insurance company may be expressed as:

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

where *h* is the health index or a measure of the general level of health in the community. By providing health coverage, insurance companies generate a lot of goodwill. Since insurance companies generate a lot of health and well being, the marginal utility of general level of health in the community is likely to be very low to them. Thus, for simplicity we may ignore h in the insurance companies' utility function. The utility function obeys the restriction $u^i_y > 0$, and u^i_x, u^i_{xx}, u^i_{yy}, $u^i_{xy} < 0$. The convexity of the cost function implies c_q, $c_{qq} > 0$. The insurance company chooses the scale of providing health insurance coverage to the public to maximize utility as defined by (1). The first order condition for an interior maximum is:

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

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 the marginal cost of providing standard health insurance coverage to the public and the marginal cost of covering MF purchased by the afflicted community plus 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 α (and other exogenous variables); $q^* = q^*(\alpha)$. That is:

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

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

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

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

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

A sufficient condition for $d^2q^*/d\alpha$ 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 $d^2q^*/d\alpha^2 = 0$, implying that $q^*(\alpha)$ is a linear function. For the rest of the analysis we assume that $d^2q^*/d\alpha^2 \geq 0$.

Afflicted Community

The utility function of the afflicted community is given by: $u^d(y^d, x, h)$. Afflicted households favors healthcare coverage for MF, 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 $h_q > 0$. Insurance companies benefits from healthy individuals as well as increased expenditure on the part of the government for health related issues, h should be regarded as an index of this.

In order to understand how the afflicted community views the insurance industry with such exogenous changes as an increase in their income or an increase in the health index, let us suppose that they are permitted to choose the level of q. If so, they would choose q such that $u^d{}_x x_q + u^d{}_h h_q = 0$. That is, the disutility associated with covering the afflicted community for MFs costs 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 output q as a function of

afflicted community income and government expenditure on health issues: $q^d = q^d(y^d, \omega)$. It can be shown that:

(7) $$\frac{dq^d}{dy^d} = \frac{u^d_{xy} x_q + u^d_{hy} h_q}{u^d_y x_{qq} + u^d_{xx}(x_q)^2 + h_q x_q u^d_{xh} + \lambda_q (x_q u^d_{xh} + h_q u^d_{hh})}$$; and

(8) $$\frac{dq^d}{d\omega} = \frac{u^d_{xh} x_q + u^d_{hh} h_q}{u^d_y x_{qq} + u^d_{xx}(x_q)^2 + h_q x_q u^d_{xh} + \lambda_q (x_q u^d_{xh} + h_q u^d_{hh})}$$

It is plausible that an increase in the afflicted community income raises the demand for health coverage but lowers the demand for government and insurance companies coverage of MF expenditures, $u^d_{hy} < 0$. 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 $u^d_{hh} < 0$. It is seen that under these conditions dq^d/dy^d and $dq^d/d\omega$ are both unambiguously negative. If the health index were to increase, the afflicted community would desire less coverage of MFs by insurance companies since the government would be covering them, and hence, would want to restrict the price level of premiums charged by health insurance companies for coverage.

Government

The government comprises elected representative of the people (the afflicted and non-afflicted communities and the insurance industry). The government behaves rationally in the sense that it only decides on such measures (or legislation) as it believes would raise the electoral prospects. The utility function of the government may thus be regarded the same as the expected total vote function:

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

where I = a proxy for voting population of insurance companies and the size of the non-afflicted community, A = voting population of the afflicted community, Π^j = probability that the average

j^{th} groups household will vote for the government, j = i, d, n; γ = an index of the political clout of the insurance companies and the non-afflicted community, υ = an index of the political clout of the afflicted community, and θ, Ω = other exogenous variable that may influence $\Pi^{j.}$

Since an increase in α raises the cost of coverage and reduces insurance companies income or ability to cover, insurance companies and the non-afflicted are likely to reduce political support for a government that imposes a higher α on them such that $\Pi^{i}_{\alpha} < 0$. 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; $\Pi^{d}_{x} < 0$. At any given level of α, and hence 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 alpha implying $\Pi^{i}_{xy} < 0$. For a similar reason, $\Pi^{d}_{x\omega}$, $\Pi^{i}_{\alpha\gamma}$, < 0. It is further assumed that $\Pi^{i}_{\alpha\alpha}$, Π^{d}_{xx}, are also negative.

Recognizing the sentiments of the public as expressed by the signs and magnitudes of the derivatives above, the government chooses α in order to maximize the electoral support. The first order condition for maximization is:

$$(10) \qquad I\frac{\delta\Pi^{i}}{\delta\alpha} + A\frac{\delta\Pi^{d}}{\delta x}x_{q}\frac{\delta q}{\delta\alpha} = 0$$

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

$$(11) \qquad \frac{d^{2}V}{d\alpha^{2}} = I\Pi^{i}_{\alpha\alpha} + A\Pi^{d}_{x}x_{q}\frac{d^{2}q}{d\alpha^{2}} + A\Pi^{d}_{x}x_{qq}(\frac{dq}{d\alpha})^{2} + A(x_{q})^{2}\Pi^{d}_{xx}(\frac{dq}{d\alpha})^{2}.$$

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: $\alpha^* = \alpha^*(I, A, \gamma, \theta, y^d, \omega, \upsilon; \Omega)$.

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

$$(12) \qquad \frac{dq}{d\alpha} = \frac{-I\Pi^i_\alpha}{A\Pi^d_x x_q}.$$

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

$$(13) \qquad \frac{d^2q}{d\alpha^2} = \frac{I}{A(\Pi^d_x x_q)^2}[x_q \Pi^d_x \Pi^i_{\alpha\alpha} - (\Pi^i_\alpha \Pi^i_x x_{qq} + \Pi^i_\alpha (x_q)^2 \Pi^i_{xx})\frac{dq}{d\alpha}].$$

The second derivative is clearly negative such that isovote lines are concave downward. Three such lines are shown in Figure 2. 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* (α) 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.

An immediately noticeable feature in Equation (12) is that the slope of the isovote line is proportional to the ratio of the population insurance companies and non-afflicted communities 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

companies output response functions shifts to the right. Hence, an increase in the relative population of afflicted community raises the optimum. The opposite happens when the insurance companies population rises relative to afflicted community.

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

$$(14) \qquad \Pi^i_\alpha dI + I\Pi^i_{\gamma\gamma} d\gamma + \Pi^d_x x_q \left(\frac{dq}{d\alpha}\right) dy^d + Ax_q \Pi^d_{x\omega} \left(\frac{dq}{d\alpha}\right) d\omega + Ax_q \left(\frac{dq}{d\alpha}\right) \Pi^d_{x\upsilon} d\upsilon + \phi d\alpha = 0,$$

where

$$(15) \qquad \phi = I\Pi^d_{\alpha\alpha} + A\Pi^d_x x_q \left(\frac{d^2 q}{d\alpha^2}\right) + Ax_{qq} \Pi^d_x \left(\frac{dq}{d\alpha}\right)^2 + Ax_q \left(\frac{dq}{d\alpha}\right)^2 \Pi^d_{xx} < 0.$$

Therefore, the following can be obtained:

$$(16) \qquad \frac{d\alpha^*}{dA} = -\frac{\Pi^d_x x_q \left(\frac{dq}{d\alpha}\right)}{\phi} > 0, \qquad (17) \qquad \frac{d\alpha^*}{dI} = -\frac{\Pi^i_\alpha}{\phi} < 0,$$

$$(18) \qquad \frac{d\alpha^*}{d\gamma} = -\frac{I\Pi^i_{\alpha\gamma}}{\phi} < 0, \qquad (19) \qquad \frac{d\alpha^*}{dy^d} = -\frac{A\Pi^d_{xy} x_q \left(\frac{dq}{d\alpha}\right)}{\phi} > 0,$$

$$(20) \qquad \frac{d\alpha^*}{d\omega} = -\frac{A\Pi^d_{x\omega} x_q \left(\frac{dq}{d\alpha}\right)}{\phi} > 0, \text{ and} \qquad (21) \qquad \frac{d\alpha^*}{d\upsilon} = -\frac{A\Pi^d_{x\upsilon} x_q \left(\frac{dq}{d\alpha}\right)}{\phi} > 0.$$

Equation (16) and (17) confirm the diagrammatic results that an increase in the insurance industry and non-afflicted population (with afflicted population constant), will reduce α^* while an increase in afflicted population will raise it. Equation (18) suggests that as the political clout of the insurance community and their non-afflicted allies increases, the government will find it more electorally beneficial to reduce α and reduce the amount of MFs coverage insurance companies must bear. Equation (21) suggests that as the political clout of the afflicted community increases, the government will find it less beneficial to reduce α and support MFR.

Equation (19) shows that a rise in the incomes of the afflicted community will also raise the level of α. This directly contradicts the expected effect of afflicted community income on the interest in raising the health index. Logan (1976) showed that communities with higher incomes, better educated residents, and greater proportion of homeowners have the necessary intellectual and financial resources to mobilize residents for lobbying the government. Equation (20) shows that an increase in the health index will also raise α and reduce the interest in reimbursement. If the health index impacts on interest in MFR, the reasoning would have to be increased government expenditure in the healthcare industry. At areas were the health index is declining, it would be useful to assess the extent to which the threat of the loss of these amenities translates into support for MFR.

The theoretical model above is overly simplistic in that it only identifies some of the determinants. 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 effects of other factors. For example, Protash and Baldassare (1983) suggest that white-collar workers possess the necessary technical skills to understand complex legal issues and motivate others to act to get their political agenda passed. It would be interesting to observe if white-collar workers are also more supportive of MFR than blue-collar workers. Other possible determinants of MFR may include rapid population changes, and political dynamics.

While α has been viewed as a continuous variable, in reality political decision-making is discontinuous and often occurs in a treadmill fashion so that what one observes a dichotomous manifestation of α. When α is low enough, one might observe the absence of MFR law. High values of α might imply the presence of MFR law. While a high value of α might also imply the passage of a strong law (eg. no age restriction on MFR and no annual dollar limitation), a lower level of α might imply a weak law. The analysis above suggests that whether or not a polity

adopts mandatory coverage of reimbursement and the scope of the coverage actually adopted depends on political motives, legislative adoption factors and healthcare industry profit motive. Coverage of changing consumer tastes and preferences, spillover, and proximity effects can be considered other exogenous socio-economic factors captured by Ω and θ.

The logit models framework is ideal for tackling the discrete choice problem at hand and is preferred to linear regression models which can suffer from a heteroskedastic error term, efficiency loss, and the inapplicability of classical statistical tests (Pindyck and Rubinfeld, 1981, Adelaja and Freidman, 1999). Also, with linear probability models, predicted probabilities can lie outside the zero to one interval, thereby producing biased predictions (Pindyck and Rubinfeld, 1981). The choice between logit and probit models is less clear as both produce identical results (Liao, 1994). However, since the logistic probability function, on which the logit model is based, has a fatter-tailed distribution when compared with the cumulative normal function, on which the probit model is based (Pindyck and Rubinfeld, 1981), when distributions have heavier tails, logit models are more appropriate (Liao, 1994). Since the United States is so diverse, there are stark contrasts between states. Thus, data on state variables should have a broad range. For this reason, a logit model is selected for this analysis.

Empirical Logit Model

The logit model assumes that the probability of observing a specific outcome (i.e. an individual state to pass legislation mandating MFR by insurance companies), P_i, is dependent on a vector of independent variables (X_{ij}) associated with state *i* and variable *j*, and a vector of unknown parameters β (Pindyck and Rubinfeld, 1981). The likelihood of observing the outcome of the dependent variable was tested as a function of explanatory variables.

(22) $P_i = F(Z_i) = F(\alpha + \beta X_i) = 1 / [1 + \exp(-Z_i)]$,

where P_i = the probability that a specific outcome is observed (i.e. an individual state passes legislation mandating MFR by insurance companies) given knowledge of the independent variables X_is; $F(Z_i)$ = represents the value of the standard logistic density function associated with each possible value of the underlying index Z_i; Z_i = the underlying index number or $\alpha + \beta X_i$; and βX_i is a linear combination of independent variables so that:

(23) $Z_i = \log [P_i /(1- P_i)] = \beta_{i0} + \beta_{i1}X_{i1} + \beta_{i2}X_{i2} + \ldots + \beta_{in}X_{in} + \varepsilon_I$.

Note that i = 1,2,. . . ,n are observations; Z_i = the unobserved index level or the log odds of choice for the i^{th} observation; X_{in} = the n^{th} explanatory variable for the i^{th} observation; β = the parameters to be estimated; and ε = the error or disturbance term. The dependent variable Z_i in the above equation is the logarithm of the probability that a particular choice will be made. The parameter estimates do not directly represent the effect of the independent variables (Pindyck and Rubinfeld, 1981). To obtain the estimators for continuous explanatory variables in the logit model, the changes in probability, P_i that $Y_i = 1$ brought about by a change in the independent variable, X_{ij} is given by:

(24) $(\partial P_i / \partial X_{ij}) = [\beta_j \exp (-\beta X_{ij})] / [1+ \exp (-\beta X_{ij})]^2$.

For qualitative discrete variables $\partial P_i/\partial X_{ij}$ does not exist. Probability changes are determined by:

(25) $(\Delta P_i /\Delta X_{ij}) = P_i(Y_i : X_{ij} = 1) - P_i(Y_i : X_{ij} = 0)$.

The change in probability for each explanatory variable was measured at the mean of all other independent variables. The actual specifications for each of the five models, as well as a description of the explanatory variables, the maximum likelihood estimates, and the prediction success of each model are provided in the tables throughout this study.

Data and Estimation

Two logit models were specified for estimation purposes. In the first model, the dependent variable is the existence of a state MFR law, be it an insurance industry mandate or a

state agency mandate. In the second, the dependent variable is the probability of an insurance industry mandate. Hence, the first logit model estimates the likelihood that a state will have MFR legislation (the influence of hypothesized factors on the adoption of a reimbursement law) while the second model estimates the probability that the mandate assigns the responsibility to the insurance industry. One estimates $\text{Log}[\{P(MFR_{yes})\}/\{1-P(MFR_{yes})\}] = \sum^{k}\beta_k x_k$, where Log is the logarithm and $P(MFR_{yes})$ is the probability of a state having a MFR law. With this logit transformation, the regression coefficients describe the change in the logarithm of the odds of a state having MFR law to those that do not, given a unit change in the value of the independent variable (Laio, 1994). The corollary is applicable in the case of model too as described above.

The data come largely from a survey of the Unites States MFR law status (Adelaja et al., 1999). It was then updated regularly until 2002. Relevant parties in all 50 states were contacted directly or researched to find out if MFR laws existed. The overwhelming majority of states were contacted by telephone. In most circumstances, employees at state metabolic clinic helped to determine whether the state has passed legislation for MFR. This was then confirmed through other means. In other cases, the state law reference librarian and/or the state's legislative office provided the necessary information. World Wide Web and other information supplemented and ground-truthed information found by phone. Data obtained were used to create a cross-sectional database for the fifty states.

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. Metabolic clinics provide an area where the afflicted community can gather in number for many reasons from food procurement and support to promoting public awareness. Metabolic clinics may also be considerable the staging grounds for lobbying state legislatures.

The political strength and clout of parties opposing MFR were proxied by the size of the non-afflicted community (NONAFFLICT) and the prevalence of the insurance industry within the state (PERINSUR). The former is proxied by the total population of the state less the afflicted community, while the latter is measured by the percentage of state residents covered by private insurance companies. It is expected that the larger the non-afflicted community, the more support for legislation, but also, the more influential the opponents of legislative adoption.

To capture the effects of political motives of the legislature, several factors were identified. The percentage of the state legislators that are Democratic (DEMOC) offers the opportunity to test the notion that democrats are more favorable in their support of families and individuals with medical conditions. Inter-party competition (COMP) was constructed as one minus the percentage of the majority party. The percentage of the voting population above 18 (VOTE) was used to capture the influence of the electoral vote on the legislature and allows one to test the hypothesis that those over 18 are more likely to support MFR policy.

The legislative adoption factors include the percentage of the state's expenditure on healthcare and hospitals (HEALTHPERCAP). High health care costs should trigger an adverse vote. The state's per capita income (INCOME) should have a positive effect since it indicates that the public can afford to bear MF expenditures out of pocket. Whites Americans have a higher incidence rate of certain metabolic diseases like phenylketonia and this could influence the political landscape. Similarly, state legislators may find it easier to cater to White Americans who dominate the electorate. Hence, the percentage of White (WHITE) and African (BLACK) Americans were included as causal factors.

The nature of competition in the insurance industry is identified as a proxy for industry profit motives. It was measured as the number of insurance companies in the state (INSURCOMP). The more insurance companies, the more opportunities for consumer choice of

a has to choice a healthcare provider meeting his or her approval, thus increasing the competition between insurance companies and thereby affecting profits. Another health insurance profit motive variable was the size of the state's insurance industry. Since consistent data on the annual sales of insurance companies was not available at the state level, the annual amount of salary paid by the insurance industry (INSURPAY) was used to proxy the size of the insurance industry. The size of the afflicted community (AFFLICT) was hypothesized to have a direct impact on the profit objective of the healthcare industry. A large afflicted population may threaten the bottom line healthcare payout per capita. Since no concise data is kept by the National Institute of Health on the incidence of metabolic diseases per state, an estimate on the number of individuals with metabolic diseases was taken by using the state's population multiplied by given ratios per metabolic disease. It is postulated that this variable is a causal factors in measuring the critical mass of the afflicted community not just the percentage of the afflicted community. This measure of political clout is consistent with the notion that is is size, and not percentage, that is a prerequisite for coalition.

With respect to consumer tastes and preferences for healthcare insurance services, several demographic variables were specified. These include the percentage of the population with a high school education (HIGH), the percentage of the population above the age of 65 (AGE65), the percentage of white collared workers (WHTCOL), the number of non-fatal illness incidence rate per 100 full-time workers (ILLNESS), and the birthrate of the state (BIRTH). The incidence of education and white collared workers suggests greater public awareness and mobilization potential of citizens for government lobbing. Elderly people are generally more susceptible to diseases. The illness rate provides information on the access to healthcare. Finally, the recent adoption of MFR policy in a neighboring state (NEIGH) is used to proxy the spillover effect on own passage of MFR legislation.

The following empirical econometric models were specified for estimation:

(26) ***Model 1***: $\text{Log}\left[\frac{P(MFR_{yes})}{(1-P(MFR_{yes})}\right] = \beta_1(\text{META}) + \beta_2(\text{COMP}) + \beta_3(\text{DEMOC}) + \beta_4(\text{VOTE}) +$

$\beta_5(\text{PERINSUR}) + \beta_6(\text{NONAFFLICT}) + \beta_7(\text{HEALTHPERCAP}) + \beta_8(\text{INCOME}) + \beta_9(\text{BLACK}) +$

$\beta_{10}(\text{WHITE}) + \beta_{11}(\text{AFFLICT}) + \beta_{12}(\text{INSURCOMP}) + \beta_{13}(\text{INSURSAL}) + \beta_{14}(\text{AGE65}) +$

$\beta_{15}(\text{BIRTH}) + \beta_{16}(\text{HIGH}) + \beta_{17}(\text{ILLNESS}) + \beta_{18}(\text{WHTCOL}) + \beta_{19}(\text{NEIGH}) + e$, and

(27) ***Model 2***: $\text{Log}\left[\frac{P(MFRI_{yes})}{(1-P(MFRI_{yes})}\right] = \beta_1(\text{META}) + \beta_2(\text{COMP}) + \beta_3(\text{DEMOC}) + \beta_4(\text{VOTE}) +$

$\beta_5(\text{PERINSUR}) + \beta_6(\text{NONAFFLICT}) + \beta_7(\text{HEALTHPERCAP}) + \beta_8(\text{INCOME}) + \beta_9(\text{BLACK}) +$

$\beta_{10}(\text{WHITE}) + \beta_{11}(\text{AFFLICT}) + \beta_{12}(\text{INSURCOMP}) + \beta_{13}(\text{INSURSAL}) + \beta_{14}(\text{AGE65}) +$

$\beta_{15}(\text{BIRTH}) + \beta_{16}(\text{HIGH}) + \beta_{17}(\text{ILLNESS}) + \beta_{18}(\text{WHTCOL}) + \beta_{19}(\text{NEIGH}) + e$,

where $P(MFR_{yes})$ is the probability of a state having any MFR law and $P(MFRI_{yes})$ is the probability of a state having a MFR law mandating insurance company coverage. These models were estimated using the logit function approach and data available for the states. Given the limited sample size (50) and the number of variables for which coefficients had to be estimated, there was concern about sample size. However, 50 states is indeed the total population, so the issue of having a representative sample is moot. To reduce multicollinearity and heteroskedasticity, an attempt was made to streamline the variables in the final models rather then to include those that were not statistically significant.

In preliminary investigations, it was found that many variables needed to be dropped from the models due to high degree of correlation between variables, and non-convergence of the models. The variables that were dropped due to statistical insignificance include COMP, BLACK, INSURCOMP, INSURPAY, AGE65, BIRTHRATE, and NEIGH. Given the

demographic nature of these variables, the results suggest that purely demographic factors play a lesser role in MFR legislative adoption.

The discourse thus far has focused on adoption of any reimbursement legislation. The choice of coverage mechanisms are explored next. Naturally, one would expect the choice of coverage mechanism to be driven largely by factors that relate to the size and political clout of the insurance industry, the ability of the state to provide coverage rather than having the insurance industry provide coverage. Naturally, (PERINSUR), (HEALTHPERCAP), and (INCOME) would be important factors. Specifically, the likelihood that state legislation will mandate insurance companies to foot the bill will decrease as (PERINSUR) increases, as (HEALTHPERCAP) increases, and (INCOME) decreases. Based on the expectation that democrats are more liberal with respect to state versus insurance provision of services, one would expect the (DEMOC) variable to adversely related to insurance industry mandates. Similarly, one would expect (VOTE) to be positively correlated to insurance mandated policy adoption. Factors such as (META), (AFFLICTED), (HIGH), and (ILLNESS) are difficult to predict largely because they relate to the demand side of insurance reimbursement and do not provide any indication of legislative choice (supply-side). In other words, the community of citizens who demand legislative adoption are left to the legislative process to decide how it is going to delivery such healthcare coverage.

Empirical Results

The two-logit models were estimated according to the specifications in equations (26) and (27). Table 4 lists the explanatory variables used in these regression models. Explanatory variables were added or dropped based on how they impacted the models significance and explained variance. Via the Chi-square statistic, the null hypothesis that the coefficients of all the independent variables as a set are equal to zero, was rejected at a significance level of 0.05

for each model. Both models included the same variables, so that comparisons could be made between independent variables across the models.

Aggregate Model of Medical Food Reimbursement

The dependent variable is the probability of a state having a MFR law given the explanatory variables. Some 35 states had MFR legislation and 15 states did not. The aggregate model correctly predicted the state of the dependent variables in 88 percent of the states when the actual values were plugged into the predicted model.[9] The chi-square statistic rejected the null hypothesis that the explanatory variables as a set were insignificant in explaining variation in the dependent variable, at 0.05 level of significance. The McFadden's R^2 results for the model was 0.47, which indicates that 47 percent of the variation in the dependent variable was explained by the model. According to Bell (1994), this percentage was very good for cross-sectional data (Table 5).

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 MFR legislation which is significant at the 5% level. For every metabolic clinic in the state, the chance of MFR legislation being enacted increases by 14 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 results suggest that for every 1000 non-afflicted individuals (NONAFFLICT), the likelihood of enacting MFR legislation drops by 3.9 percent. The coefficient of non-afflicted was significant at the 10% level. For every one percent of the state covered by private insurance companies, the likelihood of MFR legislation drops by 3.8 percent. These strong results suggest that the non-afflicted and the private insurance industry have a stake in the negative outcome of MFR legislation and thus oppose the passage of reimbursement laws. However, the strong role

of insurance companies is highlighted by the relative size and level of significance of the (PERINSUR) variable vis-à-vis the non-afflicted variable.

With respect to the (VOTE) political variable, results suggest that as the state has more active voters, the likelihood of MFR legislation to be enacted decreases (10% level of significance). For every percent of active voters in a state, the likelihood of passage decreases by 1.7 percent. This result supports Dye's voter participation theory. The majority of any state with regards to reimbursement legislation is the non-afflicted community and the insurance industry. As more individuals from a state vote, the probability of the non-afflicted community being the majority voting party increases which supports the negative effect of the voting variable. However, the part of Dye's theory on party affiliation (DEMOC) was statistically insignificant. The notion that democrats are more liberal and offer broad welfare enhancing programs in therefore not supported by this study.

The (HEALTHPERCAP) variable captures existing state commitment to public health and state financial support for such care. The findings suggest that for every 10 dollars spent on per capita healthcare in a state (HEALTHPERCAP), the likelihood of MFR decreases by 4 percent. The impact of (HEALTHPERCAP) on MFR legislation is significant at the 5% level, suggesting that the more money a state spends on healthcare per capita, the less likely MFR 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.

For every 1000-dollar increase in per-capita income (INCOME), the likelihood of MFR increases by 6.2 percent. Hence, whether or not the state has financial resources to cover the additional costs of MF seems to be taken into consideration by legislators. This also suggests a positive income elasticity of demand for MFR legislation. Recall that the policy supply side can

be garnered from the results of model two. The percentage of White Americans (WHITE) coefficient was statistically insignificant, suggesting that state ethnic differences do not play a role in MFR legislation. Related concepts of bias, self-protection, etc are thus rejected.

The findings suggest that as the size of the afflicted community (AFFLICT) increases the likelihood of passage increases. 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 MFR legislation will pass through state government successful. This finding further confirms the political clout argument.

Consistent with Protash and Baldassare the likelihood of MFR increases as the percentage of the state population with a school high education or higher (HIGH) increases. Hence, the 'high status' communities, those with higher education levels, have the necessary intellectual and financial resources to mobilize their citizens to press for measures that attempt to reimburse MF. However, the illness rate (ILLNESS) in a state proved not to be statistically significant.

Disaggregate Model of Medical Foods Reimbursement

The disaggregate Model estimates the factors leading a choice to mandate insurance industry coverage of MFR, rather than a state program. The analysis differentiates between the types of reimbursement mechanism included in MFR law. There are 30 states with insurance industry legislative mandate for MFR and 20 states without. The disaggregate model correctly predicted the state of the dependent variable in 76 percent of the states. The chi-square statistic rejected the null hypothesis that the explanatory variables as a set were insignificant in explaining variation in the dependent variable, at 0.05 level of significance. The McFadden's R^2

is 0.31, which is also very good for cross-sectional data (Bell, 1994). The results for model two appear in Table 5.

As expected, the coefficients of the disaggregate model are less significant than the aggregate model. This is consistent with the notion that the consumer demand issues affect the adoption of legislation but have lesser effect on the specific provisions made to accommodate the needs of the afflicted. The coefficient (META) variable is significant at the 10% level, suggesting that the more metabolic clinics in the state, the more likely the state will pass insurance industry mandates of MFR legislation rather than pass state funded mandates. The effects of META on both models are similar.

For every percent of the state covered by private insurance companies (PERINSUR), the percentage likelihood of insurance industry mandate of MFR legislation to pass drops by 5.4 percent with a significance level at 5%. The effect is greater on insurance industry mandates than on general MF reimbursement. For every 1000 non-afflicted individuals (NONAFFLICT), the likelihood of insurance industry mandate of MFR legislation to become enacted by state legislations drops by 7.7 percent with a significance level at 10%. Again, this variable had almost double the effect on insurance industry mandate of MF versus general MFR. NONAFFLICT and PERINSUR which proxy the political clout of the insurance industry are both significant and have a negative sign.

Per capita healthcare expenditure has the same amount of effect on general MFR legislation as it does for insurance industry mandate of coverage for MF expenditures. For every 10 dollars spend on per capita healthcare (HEALTHPERCAP) in a state, the likelihood of insurance industry mandate of MFR decreases by 6.2 percent. The coefficient for (HEALTHPERCAP) is significant at the 5% level. Similarly to model one, INCOME was not significant in model two. As the afflicted community (AFFLICT) increased per individual the

likelihood of insurance industry mandate of MFR increases by 28 percent with a significance level of 10%. The afflicted community has almost double the effect on insurance industry mandate of MFR than in general MFR legislation. The likelihood of insurance industry mandate of MFR increases by 7.6 percent as the percentage of the state population with a high education or higher (HIGH) increases by a 1 percent. The coefficient for (HIGH) is significant at the 5% level and is almost double the effect on general MF mandate.

Conclusion

This paper is unique in its application of the political economy framework to the emerging area of medical foods. 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 MFR laws than those that have not.

The area of medical foods is interesting. While the issues surrounding MFR are largely isolated due to the limited size of the afflicted community, these products provides 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 even the most medical of foods. This suggests that the less medical of foods would also be opposed by them. On the other hand, it is 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. Evidence that the size of the demanding community matters while the insurance community is experiencing consolidation suggests the need for the insurance industry to brace itself or this eventuality by being forward looking.

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%	$5 to $25 per order
Flour (1 pound)	$0.18	$7.08	3833%	
Crackers (16 oz)	$0.79	$15.85	1906%	
Cream Filled Wafers	$0.49	$2.95	502%	
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, October 1999.

Table 2: Chronology of Medical Foods Reimbursement Legislation By State

State	Date Effective	State	Date Effective
Wisconsin***	March-83	North Dakota*	August-97
Washington***	September-88	Connecticut*	October-97
Texas*	September-89	New Jersey*	December-97
Alaska*	May-91	New York*	January-98
South Dakota*	March-92	Utah*	February-98
Massachusetts*	November-93	Nebraska**	April-98
Maine*	February-95	Vermont*	October-98
Florida*	May-95	California*	January-99
Maryland*	May-95	Hawaii*	January-99
New Hampshire**	June-96	Arkansas*	April-99
Tennessee*	July-96	Montana*	April-99
Pennsylvania*	December-96	Virginia*	March-00
Kansas***	April-97	Arizona*	April-00
Oregon*	May-97	Kentuck**	July-00
Missouri**	July-97	Colorado*	June-01
Nevada**	July-97	Louisiana**	June-01
North Carolina***	July-97	Minnesota*	Date Unknown
		West Virginia***	Date Unknown

Note: * insurance companies mandated to reimburse for medical expenditures.
** insurance company and state agencies are mandated to provide coverage.
*** state agency mandated to reimburse for medical expenditures.

Source: Interviews with state representatives, 2001

Table 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.

Table 4: Descriptions of Independent Variables and Data Sources

Variable Name	Description of Variable	Data Source
Political Motive Variable		
META	Number of Metabolic and Disease Clinics	1999 Health Directory
PERINSUR	Percentage Covered by Private Insurance Companies	1999 U.S. Census Bureau
NONAFFLICT	Population of the State	1999 U.S. Census Bureau
COMP	One minus the Majority Party	1996 Statistical Abstract of Unites States
DEMOC	Dummy Variable for Democratic State	1996 Statistical Abstract of Unites States
VOTE	Percentage of Population above 18 that voted	1998 U.S. Census Bureau
Legislative Adoption Variables		
HEALTHPERCAP	Per Capita Expenditure on Healthcare	1999 U.S. Census Bureau
INCOME	Per Capita Personal Income	1999 U.S. Census Bureau
BLACK	Percentage of Total Blacks	1999 U.S. Census Bureau
WHITE	Percentage of Total White	1999 U.S. Census Bureau
Health Insurance Industry Profit Variables		
AFFLICT	Population of the State	1999 U.S. Census Bureau
INSURCOMP	Number of Insurance Companies	1997 Economy Census
INSURPAY	Amount of Annual Salary Paid by Insurance Companies ($1000)	1997 Economy Census
Consumer Preference and Demographic Variables		
AGE65	Percent of population above age 65	1999 U.S. Census Bureau
BIRTHRATE	Total births per 1,000 total population	1999 National Vital Statistics Report
HIGH	Percentage that Completed High School	1999 U.S. Census Bureau
ILLNESS	Non-fatal Illness incidence rate per 100 full-time workers	1999 Burearu of Labor Statistics
Proximity Variable		
NEIGH	Presence of medical food reimbursement legislation in neighboring state	1999 Menu Direct Study

Table 5: Parameter Estimates for the Medical Food Reimbursement Models

Independent Variable	Estimate	Standard Error	Change in Probability
Intercept	-10.5261 (-12.5134) +	11.7998 (9.8896)	
Political Motive Variables			
META** (*)	1.8148 (0.7071)	0.7568 (0.4096)	0.142818 (0.150913)
PERINSUR** (**)	-0.4926 (-0.2545)	0.2061 (0.1222)	-0.038770 (-0.054308)
NONAFFLICT* (*)	-0.0005 (-0.0004)	0.0003 (0.0002)	-0.000039 (-0.000077)
DEMOC	3.3513 (2.7170)	3.4982 (2.6168)	
VOTE*	-0.2202 (-0.0394)	0.1231 (0.0794)	-0.017332 (----------)
Legislative Adoption Variables			
HEALTHPERCAP** (**)	-0.05098 (-0.0290)	0.0218 (0.0141)	-0.004012 (-0.006187)
INCOME* ()	0.0008 (0.0003)	0.0004 (0.0002)	0.000062 (----------)
WHITE ()	-6.5184 (-2.9249)	5.3879 (4.2468)	
Health Insurance Industry Profit Variable			
AFFLICTED* (*)	1.835 (1.3284)	0.9984 (0.7863)	0.144412 (0.283510)
Consumer Preference & Demographic Variables			
HIGH** (**)	0.4558 (0.3592)	0.2113 (0.1609)	0.035872 (0.076652)
ILLNESS	1.1846 (-0.1264)	0.7980 (0.4763)	

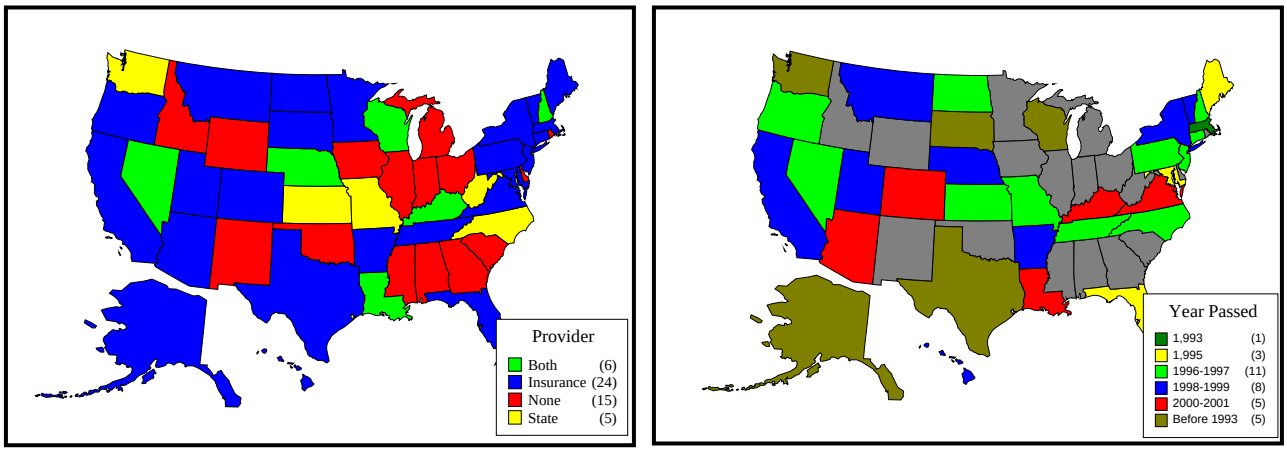
Significance of Chi-square Statistic: 0.05 (0.05)
McFadden's R2: 0.47 (0.31)
*: Significant at the .10 level
**: Significant at the .05 level

Prediction Success

	Predicted		
Actual	0	1	Total
0	12 (12)	3 (8)	15 (20)
1	3 (4)	32 (26)	35 (30)
Total	15 (16)	35 (34)	50 (50)

Number of Correct Predictions: 44 (38)
Percent of Correct Predictions: 88 (76)

+ Numbers in parentheses represent estimates for the disaggregate model of medical foods reimbursement (the insurance industry reimbursement scenario).



Source: Interviews with state representatives, 2001

Figure 1: Chronology and Nature of Legislative Adoption of Medical Food Reimbursement in the US

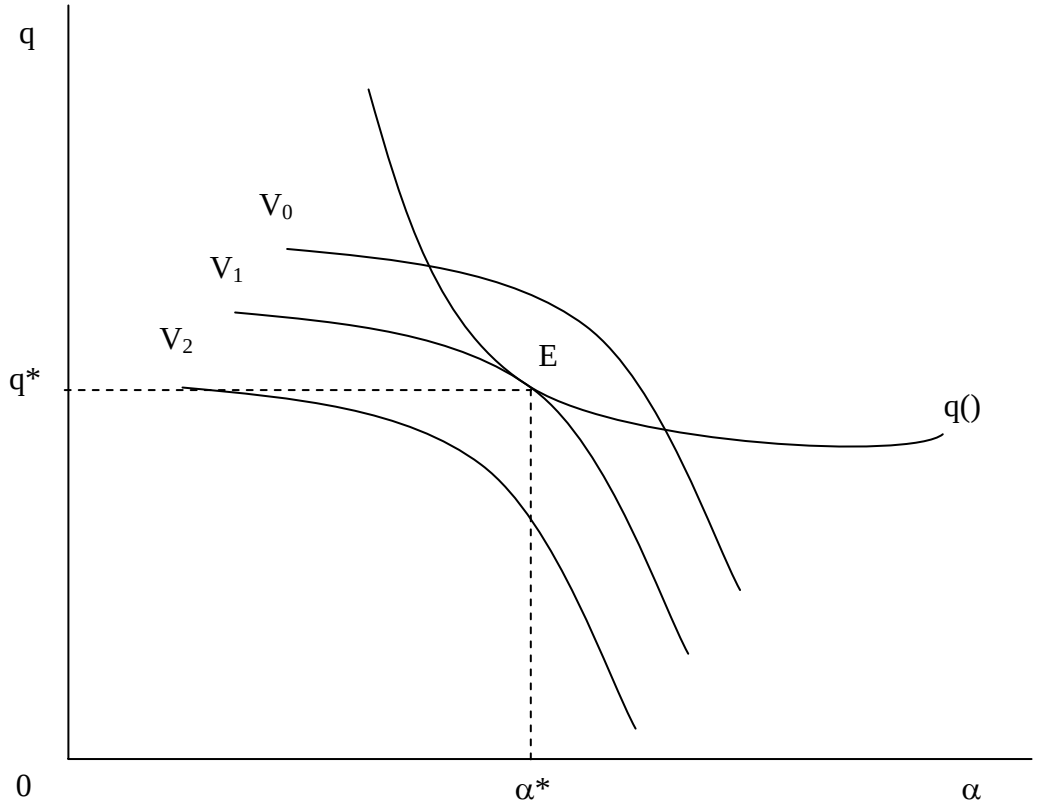


Figure 2: Optimal Level of Medical Food Reimbursement Protection

References

Aaron, H. J., (2002). Looking Backward: 2001-1991 The History of the Health Care Financing and Reform Act of 1988. The Brookings Review 40-45, Summer 2002.

Adelaja, A. O., & Friedman, K. (1999). Political economy of right-to-farm. *Journal of Agricultural and Applied Economics, 31,* 565–579.

Bardach, E. (1997). *The implementation game.* Cambridge, MA: MIT Press.

Bell, C., Roberts, R., English, B., & Park, W. (1994). A logit analysis of participation in Tennessee's Forest Stewardship Program. *Journal of Agricultural and Applied Economics, 26,* 463–472.

Derthick, M. (1972). *New towns in town.* Washington, DC: Urban Institute.

Dietary Supplement Health and Education Act of 1994. P.L. 103-417. State/4325-4335. (1994).

Dye, T. R. (1975). *Understanding public policy* (2nd ed.). Englewood Cliffs, NJ: Prentice-Hall.

Dye, T. R. (1996). *Politics, economics, and the public: Policy outcomes in the American states.* Chicago: Rand McNally.

Edwards, G. C. III. (1980). *Implementing public policy*. Washington, DC: Congressional Quarterly Press.

Liao, T. F. (1994). *Interpreting probability models: Logit, probit, and other generalized linear models.* Thousand Oaks, CA: Sage Publications.

Logan, J. R. (1976). Notes on the growth machine: Toward a comparative political economy of place. *American Journal of Sociology 82,* 349–352.

Marshall, C., Mitchell, D., & Wirt, F. (1986). The context of state-level policy formation. *Educational Evaluation and Policy Analysis, 8,* 347–378.

Nakamura, R., & Pinderhughes, D. (1980). Changing Anacostia: Definition and implementation. *Policy Studies Journal* [Special Issue No. 3].

Peltzman, S. (1976). Toward a more general theory on regulations. *Journal of Law and Economics 19,* 211–240.

Pindyck, R. S. & Rubinfeld, D. L. (1981). *Econometric models and economic forecasts.* New York: McGraw-Hill.

Protash, W., & Baldassare, M. (1983). Growth policies and community status: A test and modification of Logan's theory. *Urban Affairs Quarterly 18,* 397–412.

Rosenbaum, N. (1976). *Land use and the legislatures: The politics of state innovation.* Washington, DC: Urban Institute.

Sabatier, P., & Mazmanian, D. (1983). *Implementation and public policy.* Glencoe, IL: Scott Foresman

Sharkansky, I. (1970). *Regionalism in American politics*. Indianapolis, IN: Bobbs-Merrill.

Stigler, G. (1971). The theory of economic regulation. *Bell Journal of Economics, 2,* 3–21.

The Food Institute (2001). Food Industry Review, 1999. Fairlawn, NJ.

Tullock, G. (1967). The welfare costs of tariffs, monopolies and theft. *Western Economic Journal 5,* 224–232.

U.S. Congress. 1988. 100th Congress. Orphan Drug Ammendments of 1988.. P.L. 100-290. Ammendment of Section 526(a)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bb (ax1). Library of Congress, Washington, DC.

U.S. Congress. 1990. 101st Congress. Nutrition Labeling and Education Act of 1990. P.L. 101-535. Ammendment of Section 403 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 343. Library of Congress, Washington, DC.

Van Horn, C. E., & Van Meter, D. S. (1976). The implementation of intergovernmental policy. In C. Jones & R. Thomas (Eds.), *Public policy making in a federal system* (pp. 39–62). Beverly Hills, CA: Sage Publications.

Weekes, J. (Ed.) (1997). *Alternative medicine: Integration and coverage* (June, Vol. 1, p. 12; September, Vol. 2, p. 3). Reston, VA: St. Anthony.

Endnotes

[1] By voluntarily extending coverage to MFs, an insurance company can attract an disproportional numbers of afflicted. Hence, an insurance company may still 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 MFs.

[2] For example, in the US, inborn errors of metabolism such as Phenylketonuria, urea cycle disorder and glycogen storage disorder are present in about 1 in 10,000-12,000 new births or 200-400 new cases per year (total population of 20,000). MSUD, propionic acidemia, and methyl malonic acidemia are present in 1 in 120,000 births or 20-40 new cases per year (total population of 2,000). Celica Sprue is present in about 1 in every 4700.

[3] By extrapolation, per capita annual cost of MFs 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 $21600 (36%).

[4] A "reimbursement schedule" is a legislative mandate on a state agency or insurance industry.

[5] Lobbying for legislative change has become an essential aspect of marketing strategies for many companies and a supplement to advertising.

[6] Reimbursement enhances affordability, making market penetration easy in a reimbursement state. Therefore, like advertising, lobbying for legislative change is essentially now an aspect of marketing.

[7] The same applies to the non-afflicted household except the need for MF coverage is not an 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 and reduce services to the afflicted community.

[9] Based on a 50:50 classification scheme, states are classified by passage and non-passage of legislation. Model one and model two correctly predicted 88 percent and 76 percent, respectively.