

III. Erroneous Claims Denials For IDPN Therapy

Despite the clear coverage of IDPN therapy under HCFA's Manuals and the DMERC Supplier Manual, since the transition to DMERCs, virtually all claims for IDPN therapy for nongrandfathered patients have been denied.¹ The problems appear to fall into seven major areas, summarized below. Specific sample and fair hearing decisions illustrating these problems are attached as exhibits.

A. Inappropriate Denials Based On "Supplementation"

Many IDPN claims have been denied on the ground that the therapy only provides a certain percentage of the patient's daily caloric intake and is, therefore, supplemental in nature.² We submit that these denials reflect a fundamental misunderstanding of IDPN and the prosthetic device benefit.

Enteral supplements (such as Ensure, Isocal, and Nepro) consumed orally have never been covered under the Medicare program and have been stated to be supplemental.³ These products are given in between or in conjunction with meals for the purpose of bolstering the patient's total caloric intake, not to provide the patient with the nutrients necessary to maintain reasonable weight and strength commensurate with the patient's overall medical condition. DMERC officials have recently extrapolated this same rationale to apply to any form of "supplementation," whether it is enteral or parenteral. As

¹ The Region C DMERC paid claims for IDPN for a few months during the transition from local to regional carriers. Since approximately October 1994, all claims submitted to the Region C DMERC for nongrandfathered claims have been denied as well.

² Sample review letters and fair hearing decisions are attached at Tab A; see also decision attached at Tab J.

³ See, e.g., HCFA-Pub. 6, § 65-10.3 (nutritional supplementation to boost protein-calorie intake not covered under Medicare Part B); PEN Manual at p. 6 (nutritional supplementation given in addition to usual daily diets not covered under Medicare Part B).

previously stated, however, neither the Act, the HCFA Manuals nor the DMERC Supplier Manual preclude coverage of intravenous nutrition on this basis.

Under the prosthetic device benefit, parenteral nutrition therapy is covered when it replaces *all or part* of a missing or malfunctioning internal body organ. Further, these provisions -- as well as the DMERC Supplier Manual itself -- state that the degree of malfunction needed to qualify must be such that the patient is not able to absorb sufficient consumed nutrients to maintain reasonable weight and strength commensurate with the patient's overall medical condition. It is quite clear from the language of the statute, as well as the HCFA manuals, that IDPN is a covered benefit when the patient suffers from a significant gastrointestinal malfunction which prevents absorption of sufficient nutrients to maintain the patient's health status. Just as a leg prosthesis is covered for a below knee amputation, and a cardiac pacemaker is covered for a conduction disturbance of the heart, parenteral nutrition is covered for patients who have partial but significant malfunctioning of their gastrointestinal tract if the malfunction results in clinically significant malnutrition and cannot be feasibly overcome with consumed food. In other words, nutritional depletion is not an all or nothing determination.

DMERC claims processors have informed our members that any claim for parenteral nutrition to be administered less than daily is not covered. Again, there is no requirement under the Medicare coverage provisions that parenteral nutrition be administered daily. Indeed, the DMERCs' own written medical policies state that claims for parenteral nutrition ordered less than daily are to include documentation supporting the need for the therapy, as set forth above.

We understand that HCFA has recently clarified in comments to the DMERCs that coverage under the prosthetic device benefit can be total or partial. The patient need not rely upon either enteral or parenteral nutrition for his or her total nutrition in order to be eligible for PEN therapy. As long as the patient has a dysfunction of the gastrointestinal tract with accompanying malabsorption

such that the patient is unable to maintain weight and strength commensurate with the patient's general condition, coverage is indicated. Because this clarification is simply a restatement of current coverage policy, we submit that the claims denials on the basis of "supplementation" must be reversed, and all claims must be paid.

B. Incorrect Application Of Total Parenteral Nutrition Requirements To IDPN Claims

In many cases, the DMERCs have inappropriately applied the requirement with respect to TPN of 20-35 cal/kg/day to claims for IDPN.⁴ Under the DMERC medical policies, these rules are only applicable to coverage for total parenteral nutrition. As noted, TPN is usually contraindicated for a renal patient due to the requirement for a surgical incision to place a subclavian catheter, increasing infection complications and potential fluid and electrolyte overload. Therefore, claims denials on this basis are invalid.

C. Denial Of Claims Based On Absence Of Tests Or Procedures That Are Not Required Under The DMERC Medical Policy

Another basis for denying IDPN claims is that the claim submitted reportedly lacked information that tube feeding had been tried and failed.⁵ As noted, there is no requirement in the Medicare Coverage Issues Manual, the Medicare Carriers Manual or any of the DMERC Supplier Manuals that g-tube feeding be tried prior to coverage of IDPN therapy. There are sound clinical reasons for not requiring such tube feeding, as discussed previously in Section I. Further, in responding to comments on the draft medical policies, the DMERCs specifically said that coverage should not be required to be established based on extraordinary tests or procedures not part of normal medical care of

⁴ Sample review letters and fair hearing decisions are attached at Tab B. We note that two of the review letters also inaccurately refer to the claim for IDPN as "enteral supplies."

⁵ Sample fair hearing decision is attached at Tab C. This issue is also discussed in several of the decisions attached at Tab A and B.

the patient. In response to a comment that the written guidelines for enteral and parenteral nutrition required documenting "unfavorable events," the DMERCs respond:

It is not the intent to subject patients to a "challenge" of a covered formula just to obtain documentation of an advanced adverse reaction. If the patient's records indicate known, or a likely, untoward reaction to a therapy, this documentation alone meets the test of medical necessity.⁶

Contrary to their own written policies, the DMERCs are apparently attempting to require nephrologists and other clinicians to subject already severely compromised patients to yet another surgical procedure, creating an increased risk of infection and accompany cardiac and pulmonary malfunction. It is well settled that carriers are required to follow their own standards in adjudicating claims.⁷ In this case, there is absolutely no basis for requiring tube enteral feeding prior to coverage of IDPN.

D. Denials Based On Inaccurate Clinical Conclusions

Several of the fair hearing decisions have upheld claims denials based on inaccurate clinical statements. For example, in one hearing decision, the hearing officer (not a physician) concluded that "gastroparesis is an upper GI diagnosis and does not represent an absorption problem of the GI tract."⁸ No authority is cited for this proposition, and, in fact, it is blatantly wrong. Gastroparesis is the paralysis of the stomach. Dorland's Illustrated Medical Dictionary, 26th ed. (1981). This condition hampers ingestion and compromises absorption of nutrients. Essentially, the patient experiences diarrhea and vomiting and is not able to ingest, let alone absorb, nutrition.

⁶ See Region A comments and responses to draft medical policy on enteral and parenteral nutrition, comment 4 (Section II, Tab G) (emphasis added). Similar comments were issued by each of the DMERCs.

⁷ See, e.g., Morton v. Ruiz, 415 U.S. 199 (1974).

⁸ Copy attached at Tab D.

Other fair hearing officers have upheld denials on the grounds that the evidence documented no "permanent absorption defect of the small intestine."⁹ Again, there is absolutely no requirement in the HCFA Manuals, nor in the DMERC Supplier Manuals, that the patient evidence a defect of the small intestine. Rather, as noted, the requirement for coverage is a problem with absorption of nutrients due to a disease or malfunction of the gastrointestinal tract. In addition, some fair hearing officers have upheld claims denials on the ground that no fecal fat test or other test used to document malabsorption had been submitted.¹⁰ First, there is no requirement to conduct a fecal fat test on patients prior to coverage. While fecal fat has been used to help verify malabsorption, it is difficult to obtain patient cooperation. Second, lower albumin levels and protein levels are tests used to document malabsorption which accompany every claim for IDPN therapy. As noted, lower albumin levels are a regular and reliable measure of malnutrition in renal patients. Therefore, denials based on the absence of a fecal fat study are completely without merit.

E. Inappropriate Denials For Additional Information

Numerous claims submitted by IDPN suppliers have been improperly denied for an alleged lack of information. Our review shows, however, that such claims have generally included extensive documentation supporting the physician's order. When asked to specify what additional information is required, carrier staff are often unwilling or unable to specify what is needed.

F. Inexperienced And Inadequate Provider Relations/Medical Review Staff

The DMERC medical review staff charged with adjudicating claims for IDPN therapy appears to have inadequate experience to conduct consistent, comprehensive reviews, for this therapy. We understand that some specialists in renal nutrition have met with DMERC staff about IDPN therapy.

⁹ Copies of sample decisions are attached at Tab E.

¹⁰ Sample fair hearing decision attached at Tab F.

but these efforts have not proved successful in addressing common misconceptions about IDPN, as discussed above.

In addition, the DMERCs' medical review staff have refused to explain medical review criteria and have denied claims for nongrandfathered patients while approving claims for grandfathered patients with virtually identical diagnoses and medical conditions.¹¹ Further, the staff appear predisposed to deny all claims for IDPN, regardless of the patient's condition. For example, DMERC claims review personnel have told our members that "we do not pay for this service," and that "claims for IDPN will be denied." These statements are clearly inconsistent with HCFA and DMERC policy that covers IDPN therapy for beneficiaries meeting applicable medical necessity criteria.

As you know, one of the purposes of regional claims processing for DMEPOS was to consolidate carrier personnel knowledgeable about these items in specialized carriers. This was the reason for establishing the PEN specialty carriers which, in fact, achieved such expertise and relatively smooth claims processing for suppliers and carriers alike. The DMERC's inability or refusal to provide this level of expertise is deeply troubling and, in fact, undermines the whole purpose of providing regionalized specialty carriers.

G. Extensive Delays In Carrier Claims Processing And Lack Of Independent Review At Fair Hearings

Beyond these substantive errors in medical review, the DMERC claims processing of claims for IDPN therapy has been exceedingly slow, with DMERCs failing to issue reconsideration decisions for several months following the initial denial. Moreover, we have significant concerns that the DMERCs are not providing fair hearings in accordance with the provisions set forth in the Medicare Carriers Manual regarding the appeals process.

¹¹ Samples of fair hearing decisions issued prior to the transition to DMERCs in which coverage has been upheld are attached at Tab G.

Pursuant to Section 1842(b)(3)(C) of the Act, carriers are required to establish and maintain hearing procedures for individuals dissatisfied with payment determinations. 42 U.S.C. § 1395(u)(b)(3)(C). The Medicare Carriers Manual provides that the purpose of the hearing is to allow the dissatisfied beneficiary or supplier (in the case of assigned claims) an opportunity to present the reasons for dissatisfaction with the determination and to receive a new determination based on the record developed at the hearing. The hearing officer is required to be an individual who "has not been involved in any way" with the determination in question. HCFA Pub. 14-3, § 12016.B. Moreover, ex parte contact by the hearing officer is specifically forbidden. Id. A hearing officer is disqualified if the individual was involved in any way in the initial or review determination. Id. at § 12016.C.

Due to the significant delays in processing the claims for IDPN therapy and for issuing review determinations, few claims denials have reached the fair hearing level. For example, of the 1,308 claims for nongrandfathered patients submitted by one member of the Coalition, only 32 (2%) have been reviewed at fair hearings and only two have been scheduled for an administrative law judge ("ALJ") hearing. Nonetheless, of those claims for which a fair hearing has been held, the hearing officers have routinely relied on the DMERC medical director for input on the claims decision. For example, one fair hearing decision states, "upon recommendations from the DMERC Medical Director, Adrian Oleck, M.D., I find that the evidence in this case lacks significant documentation to establish medical necessity for the parenteral nutrition therapy."¹² In another, the hearing officer states that "the opinion of the Medical Director [of Region A] has been given due consideration along with the medical documentation presented."¹³ Because the medical director is generally responsible for the initial claim denial and the review determination of the claim for IDPN therapy, the fair hearing does not result in an

¹² Copy attached at Tab F.

¹³ Copy attached at Tab H.

independent review of the determination. Further, such ex parte contacts with the medical director are explicitly forbidden.

In addition, several of the hearing officers' decisions are simply form letters in which the name of the provider and the beneficiary are changed. Indeed, members of the Coalition have noted that some hearing officer decisions contained exactly the same language -- including the same grammatical and typographical errors -- despite the fact that the beneficiaries have very different clinical conditions.¹⁴

Finally, several of the decisions issued by hearing officers contain blatantly incorrect statements of Medicare law. For example, one fair hearing officer decision refers to Section 1862(a)(1) of the Act as relating to inherent reasonableness. The hearing officer's decision states:

Furthermore, inherent reasonableness under Section 1862(a)(1) of Title XVIII states that it is more reasonable to pay for a less costly alternative unless the more costly method has been tried and failed.¹⁵

As you are well aware, Section 1862(a)(1) of the Act has nothing to do with inherent reasonableness, let alone any mention of less costly alternatives. Rather, this section pertains to the general Medicare requirement that items and services be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Section 1862(a)(1)(A) of the Act, 42 U.S.C. § 1395y(a)(1)(A). IDPN therapy provided to beneficiaries meeting the medical necessity criteria established in the Coverage Issues Manual is clearly reasonable and necessary for the diagnosis or treatment of illness or to improve the functioning of a malformed body member (i.e., the nonfunction of the gastrointestinal tract). Such clear misstatements of the Medicare law and the absence

¹⁴ Two examples of such form decisions are attached at Tabs D and I, respectively.

¹⁵ Copy attached at Tab J.

of independent review determination significantly undermine the purported value of the DMERC's appeals process for denied claims.

In sum, the DMERCs' IDPN claims denials, and the approval of those denials upon reconsideration and at the fair hearing level, show a concerted, systematic effort to deny coverage for IDPN therapy without regard to the patient's underlying medical condition or established Medicare coverage policy. Contrary to the well-established Medicare coverage criteria for IDPN therapy and the DMERCs' own written medical policies, the DMERCs have established barriers to IDPN coverage -- through front-end claims edits, unnecessary and clinically contraindicated additional requirements, and essentially form fair hearing decisions. This situation has resulted in virtually universal denial of Medicare coverage for IDPN therapy.

Malnutrition in the Dialysis Patient*

Malnutrition is recognized to be a primary determinant of increased morbidity and mortality in ESRD patients [1,2,3,4,5]. The National Cooperative Dialysis Study [NCDS] was one of the first large scale studies to indicate that protein malnutrition, identified by a low protein catabolic rate, was second only to inadequate dialysis in predicting poor outcomes for dialysis patients [2]. The U.S. Renal Data Systems [USRDS] also indicated that low serum albumin was a major predictor of mortality in new dialysis patients [6,7].

Consistent with these findings, Lowrie et al [5] reported results of an extensive retrospective study of the effect of hypoalbuminemia on mortality in dialysis patients. They demonstrated that serum albumin was the most important laboratory predictor for death in this patient population. In this study, as serum albumin declined, the mortality rate dramatically increased. For patients whose serum albumin ranged between 3.0 - 3.5 gm/dl their mortality increased five fold. Mortality at one year of dialysis for patients with a serum albumin between 2.0 - 2.5 gm/dl approached 100 per cent in this study.

Dialysis patients are predisposed to developing malnutrition due to many contributing factors. These include: metabolic changes [such as altered protein metabolism, carbohydrate intolerance and nutrient loss during dialysis]; inadequate dietary intake due to dietary restrictions, nausea and vomiting; interactions between medications and food; and blood loss. In addition, the dialysis procedure is considered to be a catabolic procedure causing endogenous release of cytokines with subsequent increased protein breakdown, and loss of amino acids across the dialyzer [8,9]. Severe cachexia often exacerbates the problem as uremia and concurrent disease can frequently induce abnormalities of the intestinal mucosa and also impair appetite.

While these abnormalities clearly add to the obstacle of providing adequate nutrition to the dialysis patient, they are especially significant for those patients who also develop a concurrent chronic disease which results in partial to complete malabsorption. When this clinical circumstance develops, it is generally impossible for the patient to maintain weight and strength through oral nutrition intake even when such nutrition is fortified with nutritional supplementation.

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A. Partial Gastrointestinal Malfunction

Gastroenterologists and nutritional support specialists recognize the clinical concept that there are a substantial number of disease entities that result in partial, albeit clinically significant gastrointestinal malfunction. This malfunction is clinically important when it is of sufficient severity to prevent an individual from being able to absorb enough from consuming caloric dense foods to sustain or achieve desired weight and strength. Examples of such diseases include:

- **diabetic gastrointestinal neuropathy and enteropathy**
- **ischemic vascular disease of the intestine**
- **chronic pancreatitis**
- **uremic autonomic dysfunction**
- **inflammatory bowel disease [Crohn's]**
- **radiation enteritis**
- **short bowel syndrome**
- **intestinal obstruction**

It is also generally accepted that these diseases may result in the need to provide 50 - 80 grams of protein in 1000 - 2000 kcal of parenteral nutrition three or four times per week with the clinical goal of bridging the caloric and protein gap created by the patient's gut failure. The most appropriate therapeutic modality for these patients would be one that could provide sufficient total protein and calories to meet the protein/calorie deficit while introducing the least amount of added risk to the patient. It has been estimated that approximately four per cent of the dialysis population will develop one of the aforementioned conditions resulting in substantial gut failure at some point in their life [unpublished data from Lowrie, surveying 56,139 ESRD patients].

B. Treatment Options

1. Enteral Supplementation

Enteral nutritional support is the preferred mode of repletion in most patients. As such, this route is **always** the first approach and is often successful in achieving the desired outcome. Every dialysis center in the United States has a renal dietician experienced in treating the nutritional needs of dialysis patients. In addition, nephrologists are generally aware of the interplay between dialysis and nutrition. As such, it must be recognized that exhaustive attempts to help the patient improve his or her nutritional status through aggressive dietary counseling and the use of oral nutritional supplements is routinely done. However, when substantial malfunction of the gastrointestinal tract exists, adequate oral intake will be impossible to achieve in this group of patients. When dietary counseling, adequate dialysis, and enteral nutrition cannot overcome severe gastrointestinal malfunction, another form of nutrition support therapy is generally necessary.

2. Tube Feedings

Daily tube feeding should be considered whenever the patient's gastrointestinal function is limited by the inability to swallow oral nutrition. However, daily tube feedings often are contraindicated in the dialysis patient population. Because these patients frequently have upper gastrointestinal motility abnormalities characterized as gastroparesis, prepyloric feeding [gastrostomy] may induce vomiting and possible aspiration pneumonia. Gastrostomy tubes placed across the pylorus into the small bowel render the pylorus incompetent and still subject the patient to the risk of aspiration pneumonia. Further, postpyloric feedings via a surgically placed jejunostomy tube represents an invasive procedure with increased morbidity in a malnourished dialysis patient which should only be considered when the patient's gastrointestinal abnormality is limited to a swallowing disorder. ESRD patients also have unique problems handling fluid loads. Tube feedings can cause unacceptable problems with recurrent congestive heart failure in this patient population. Additionally, and equally important, the use of either a nasogastric tube or a surgical feeding tube is psychologically and emotionally unacceptable to many of these ambulatory dialysis patients who can continue to lead a reasonably active life.

3. Daily Total Parenteral Nutrition

After all reasonable enteral methods of treating malnutrition in dialysis patients have either failed or been clinically ruled out, total parenteral nutrition (TPN) therapy can be a potentially lifesaving alternative. Daily TPN therapy can provide all of the nutrients needed to sustain a patient's health and well being. Because nutrients are administered directly into the patient's central venous circulation via an indwelling catheter, this method of treatment effectively circumvents the patient's malfunctioning gastrointestinal tract, allowing the patient to sustain weight and strength. Use of this therapy option should be considered when the patient's gastrointestinal disease results in a caloric deficit which can only be overcome by this approach.

However, daily TPN also has inherent risks, some particularly significant to the renal failure patient. In many cases, the risks of this therapy diminish the potential value of this treatment. These risks may be mechanical, infectious, cardiac or metabolic. Home TPN requires the surgical placement of a subcutaneously tunneled silicone or polyurethane catheter. Such catheters may damage central veins causing venous thrombosis or stenosis, jeopardizing the patient's current dialysis access and rendering that entire side of the patient unavailable for any new dialysis access creation. The latter is a particularly unacceptable complication, as the vascular access is the individual's lifeline needed for hemodialysis therapy.

Infectious complications, including blood-borne septicemia, are a particular concern in the uremic immuno-compromised state. Many dialysis patients are skin carriers of potential pathogens for infection, especially *Staph aureus* [10]. Many of the life threatening infections encountered by dialysis patients result from bacterial colonization of the arteriovenous fistula or graft. Use of an external catheter, as would be needed for daily parenteral nutrition, can be expected to have an even greater potential for infection.

Fluid overload and electrolyte abnormalities are the most commonly encountered severe complications of daily TPN. Since ESRD patients cannot eliminate the infused fluid between dialysis treatments, they may develop congestive heart failure or acute pulmonary edema. Hyperglycemia and electrolyte abnormalities are some of the metabolic complications of daily TPN.

In summary, daily TPN clearly will increase the risk of sepsis, threaten the viability of the patient's current and future dialysis access sites, and expose the patient to potentially lethal cardiac complications, and fluid and electrolyte abnormalities.

4. Intradialytic Parenteral Nutrition [IDPN]

IDPN has been employed over the past ten years for malnourished hemodialysis patients who had failed attempts at dietary and pharmacologic management, including enteral supplements. IDPN is administered during the dialysis procedure, through the patient's vascular access, which obviates many of the problems associated with daily TPN. The risks of vascular thrombosis and sepsis posed by a central TPN catheter are eliminated, and the dialysis procedure removes the excess fluids, minimizing the likelihood of congestive heart failure.

One IDPN treatment can provide 60 - 75 grams of intravenous protein, or an average of 1 - 1.4 grams per Kg per treatment. It also provides approximately 1100 total calories per treatment of 3300 calories per week, which is sufficient to overcome the caloric deficit of most patients with clinically significant malfunction of their gastrointestinal tract.

Multiple studies document that IDPN, in appropriately selected patients, promotes weight gain, increases functional status, improves serum albumin and improves survival in malnourished dialysis patients [11, 12, 13, 14, 15, 16]. Olshan et al [11] administered IDPN to ten patients who had failed six months of dietary counseling and enteral supplements. The patients had lost an average of 13 per cent of their usual body weight and were at 88.6 per cent of ideal body weight at the start of IDPN. After two months of IDPN, the patients gained weight, improved their functional status and had a significant increase in their serum albumin. Bilbrey et al [12] from a population of 204 long term dialysis patients, identified 20 patients with moderate to severe malnutrition. After 3 months of IDPN, these patients had a significant improvement in their baseline malnutrition index. Cano et al [13] in a controlled study, administered IDPN in a random fashion to 12 of 26 malnourished dialysis patients. Compared to control patients, IDPN patients showed significant improvement in body weight, arm-muscle circumference, serum albumin and skin test reactivity. Foulks et al [14] described reduced mortality and hospitalization rate in a selected subset of malnourished ESRD patients that were IDPN "responders".

Capelli et al [15] identified 81 ESRD patients with depressed albumin levels [<3.5 gm/dl] and a body weight at least 10 per cent below ideal body weight or a loss of 10

per cent of their usual body weight over two months. All the patients had previously received nutritional counseling by certified dieticians, and dialysis to ensure KT/V of 1 to 1.2 or greater. 50 patients received IDPN and 31 did not for an average length of treatment of 9 months. Using the Cox proportional hazards survival analysis, a significantly increased survival rate was observed with the use of IDPN [relative risk = 1.34, p<0.01]. No other covariant followed [age, diabetes, weight, change in weight, albumin, KT/V, protein catabolic rate, length of time on dialysis, sex, race] significantly affected survival rate.

Chertow et al [16] analyzed data on 24,196 ESRD patients on dialysis during 1991. 22,517 patients who received dialysis on 1/1/91 and were still on dialysis or who had died by 12/31/91 served as controls. The IDPN treatment sample consisted of 1,679 patients who received one or more infusions of IDPN during 1991. Control and IDPN patients were analyzed for age, sex, race, presence of diabetes, baseline renal diagnosis, urea reduction ration [URR], and serum concentrations of albumin and creatinine. Survival in the two groups were then compared. Initial analysis indicated that patients treated with IDPN were older [p<0.01] than controls, and were more likely to be white or diabetic [p<0.01]. At the start of therapy, serum albumin and creatinine were also significantly lower among IDPN treated patients compared to controls [p<0.01].

An analysis of the odds ratio of death at different serum albumin levels indicated significantly improved survival in the IDPN group at all albumins ≤ 3.3 gm/dl.

<u>Serum albumin (gm/dl)</u>	<u>Odds Ratio of Death</u> <u>Comparing IDPN Treatment</u>	
	<u>Group With Controls</u>	<u>P Value</u>
≤ 3.4	0.87	P<0.10 (NS)
≤ 3.3	0.73	P<0.01
≤ 3.2	0.62	P<0.01
≤ 3.1	0.62	P<0.01
≤ 3.0	0.58	P<0.01

The improved survival of IDPN treated patients also approached significance at serum albumin ≤ 3.4 gm/dl [p<0.1]. This was despite the fact that both controls and IDPN patients had equivalent dialysis [URR>60 per cent]. The improved survival with IDPN in patients with albumin ≤ 3.4 gm/dl became even more significant in patients with a concomitant creatinine <8.0 mg/dl, a sign of somatic protein depletion. Time trends for serum albumin and creatinine showed progressive decline in these parameters pre IDPN.

However, patients started on IDPN with pre-treatment serum albumins ≤ 3.4 gm/dl showed a progressive increase in serum albumin and creatinine over the 12 month study period. The analyzed data showed a survival disadvantage when IDPN was administered to patients with a serum albumin ≥ 3.5 m/dl, particularly in association with a serum creatinine > 8.0 gm/dl. Thus IDPN is not appropriate for dialysis patients "failing" for circumstances other than nutritional failure.

In summary, this study, involving large numbers of dialysis patients carefully followed for one year, indicate that IDPN can be life saving when administered to appropriately selected, malnourished dialysis patients. Signs of visceral protein depletion [serum albumin ≤ 3.4 gm/dl], and to a lesser extent signs of somatic protein depletion [serum creatinine < 8.0 mg/dl] identified dialysis patients that would have improved one year survivals if given infusions of IDPN.

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Intradialytic Parenteral Nutrition Administration During Outpatient Hemodialysis

Ten ESRD patients who continued to lose weight over six months, despite aggressive dietary counseling and oral nutritional supplements, were selected for intradialytic parenteral nutrition (IDPN). A one-liter solution of IDPN was infused into the venous drip chamber during a four-hour hemodialysis treatment three times per week. Two months of IDPN led to a positive weight gain and improved appetite in eight patients, and a significant increase in serum albumin among all 10 patients.

Protein-calorie malnutrition and weight loss associated with anorexia remain serious problems in end-stage renal disease patients.¹⁻⁴ Weight loss may relate to non-renal systemic disease, gastrointestinal tract pathology, and negative nitrogen balance from glucose and amino acid losses during hemodialysis.⁵ We selected 10 ESRD patients from the St. Agnes Medical Center outpatient dialysis unit who continued to lose weight over a six-month period despite aggressive dietary counseling and oral nutritional supplements. They then received intradialytic parenteral nutrition (IDPN) for two months with monitoring of changes in weight, appetite, and serum albumin.

PROCEDURE

The 10 ESRD patients to receive IDPN were selected by the dialysis unit nutritionist (J.B.). Their mean age was 65 years

(range 46-85 years). Seven were females, three males. Causes of renal failure were diabetic nephropathy in two patients, renal artery stenosis and accelerated hypertension in two patients, hereditary nephritis in one patient, multiple myeloma with amyloidosis in one patient, chronic glomerulonephritis in two patients, and nephrosclerosis in two patients. Weights were obtained postdialysis when the patient was as edema-free as possible. Ideal body weight was assessed from standard tables as 100 lbs in a 60"-tall female plus five pounds for each extra inch in height, and 105 lbs in a 60"-tall male plus six pounds for each extra inch in height (weight statistics prior to initiation of IDPN are listed in Table I). All patients received hollow fiber hemodialysis treatments for four hours three times per week. IDPN consisted of one-liter solution of 500 ml 8.5% crystalline amino acids without

electrolytes, 250 ml 50% dextrose (diabetic patients) or 70% dextrose (nondiabetic patients), and 250 ml 20% Intralipid. IDPN was administered by an infusion pump into the drip chamber of the venous outflow tubing from the dialyzer. The infusion was performed over the four-hour hemodialysis treatment three times per week for two months. The average amount of IDPN actually administered to each patient per treatment was 886 ml (range 700-1,000 ml).

RESULTS

Nine of 10 patients were below ideal body weight at the initiation of IDPN (Table I). The one patient (R.S.) still at ideal weight had lost 25 lbs or 17% of her usual body weight over the six months prior to initiation of IDPN. After two months of IDPN, eight patients gained an average of 5.1 lbs (range 2-9 lbs) and had improved appetites (Table II). One patient with multiple myeloma and amyloidosis on polydrug chemotherapy lost two pounds. One patient with multiple hospital admissions for upper gastrointestinal bleeding and amputation of a gangrenous leg lost six pounds. Part of this patient's weight loss reflects the below-the-knee amputation (Table III). Two

Table I: Study population.

Patient	Weight lost over 6 mo. prior to IDPN lb.	Percent of usual body weight lost over 6 mo. prior to IDPN	Percent of ideal body weight at initiation of IDPN
HA	6	7	79
JC	8	8	92
JG	27	18	86
MW	7	9	97
SF	10	13	95
RS	25	17	100
AG	12	11	88
HG	9	11	85
MR	19	17	80
CH	25	19	84
Average	14.8	13	88.8
Range	6-27	7-19	79-100

Table II: Weight-gain group (8 patients).

Patient	Weight gain over 2 mo. of IDPN lb.	Change in appetite*
HA	6	↑
JC	7	↑
JG	9	↑
SF	2	↑
RS	2	↑
HG	5	↑
MR	4	↑
CH	6	↑
Average	5.1	
Range	2-9	

*Evaluated by renal dietitian (JB).

Table III: Weight-loss group (2 patients).

Patient	Weight loss over 2 mo. of IDPN lb.	Change in appetite	
MW	2	↓	Multiple myeloma and amyloidosis on polydrug chemotherapy
AG	6	↓	Multiple hospital admissions for upper gastrointestinal bleeding and amputation of a gangrenous leg

months of IDPN resulted in a statistically significant (paired *t*-test) increase in serum albumin (Table IV). The four patients with subnormal serum albumin (<3.5 g/dl) prior to initiation of IDPN had normal serum albumin after two months of IDPN (average albumin pre-IDPN 3.1 g/dl and post-IDPN 3.7 g/dl). No patient experienced symptomatic hypoglycemia postinfusion of IDPN. Some patients experienced nausea and flushing related to Intralipid infusion. Subsequent to this pilot study, we have adopted a policy of initiating IDPN with amino acids and dextrose and adding Intralipid two weeks later.

DISCUSSION

Malnutrition is not uncommon in the hemodialysis population. Richards et al evaluated the nutritional status of 37 hemodialysis patients by measuring percentage of ideal and usual body weight, triceps skinfold thickness, muscle mass, serum albumin, transferrin, and total lymphocyte count.² Abnormal parameters were found one or more times in 97%, two or more times in 89%, and three or more times in 59% of these patients. Wolfson and Kopple evaluated the nutritional status of 13 middle-class male hemodialysis patients.³ Four were home hemodialysis patients, and 11 had not been hospitalized for one year. Despite this, comparison with 60 normal con-

trols revealed that the dialysis patients had significant decreases in triceps skinfold thickness, body weight, and serum transferrin. Eight of 13 dialysis patients had serum transferrin and albumin levels more than two standard deviations below the mean value for normals. Miller et al demonstrated that, at the time of renal transplantation, 42% of 24 diabetic dialysis patients and 29% of 21 nondiabetic dialysis patients had midarm muscle circumferences under the fifth percentile, indicative of significant protein-calorie malnutrition.⁴

Wolfson and Kopple infused 39.5 g amino acids and 200 g dextrose during hemodialysis in eight stable ESRD patients.⁶ Taking into account usual dialysate amino acid losses, they estimated that 90% of infused amino acids were retained by the patients. Based on this study, we selected a population of 10 ESRD patients with protein-calorie malnutrition and continued weight loss despite aggressive nutritional counseling for IDPN. All patients received 42.5 g amino acids plus 925 non-nitrogen calories (diabetic patients) or 1,095 non-nitrogen calories (nondiabetic patients) infused during each four-hour hemodialysis. Two months of IDPN led to positive weight gain and improved appetites in eight patients. Moreover, there was a statistically significant increase in serum albumin among the 10 patients.

Table IV: Change in serum albumin after IDPN.

Patient	Serum albumin at initiation of IDPN g/dl	Serum albumin after 2 mo. of IDPN g/dl
HA	3.2	4.0
JC	3.8	4.1
JG	4.1	4.5
MW	4.4	4.1
SF	4.0	4.3
RS	3.9	4.5
AG	3.3	3.8
HG	4.0	4.8
MR	2.9	3.8
CH	3.1	3.5
Average	3.7	4.1*
± Standard deviation	± 1.4	± 1.0

*P <0.01.

CONCLUSION

IDPN is beneficial for those ESRD patients not responding to several months of nutritional counseling and maximum oral dietary supplements. We recommend a two-month trial of IDPN for the subset of hemodialysis patients with refractory anorexia and progressive weight loss. Nutritional benefit to the patients is demonstrated as positive weight gain, improved appetite and significant increase in serum albumin.

REFERENCES

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- 2. Richards V, Hobbs C, Murray T, et al. Incidence and sequelae of malnutrition in chronic hemodialysis patients (Abstract). *Kidney Int* 14:683, 1978.
- 3. Wolfson M, Kopple JD. Nutritional status in apparently healthy hemodialysis patients (Abstract). *Kidney Int* 19(1):161, 1981.
- 4. Miller DG, Levine SE, Delia JA, et al. Nutritional status of diabetic and nondiabetic patients after renal transplantation. *Am J Clin Nutr* 44:66-69, 1986.
- 5. Borah M, Scoenfeld P, Gotch F, et al. Nitrogen balance during intermittent dialysis therapy in uremia. *Kidney Int* 14:491-500, 1978.
- 6. Wolfson M, Jones M, Kopple JD. Amino acid losses during hemodialysis with infusion of amino acids and glucose. *Kidney Int* 21:500-506, 1982.
- 2. Rose BD. Acute renal failure. In *Pathophysiology of Renal Disease*, ed. BD Rose, pp. 55-95. New York: McGraw-Hill, 1981.
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- 10. Wolfson M, Jones R, et al. Amino acid losses during hemodialysis with infusion of amino acids and glucose. *Kidney Int* 21:501-506, 1982.
- 11. Kopple JD. Nutritional therapy in kidney failure. *Nutr Rev* 39:193-214, 1981.

THE WHITE HOUSE
WASHINGTON

August 10, 1995

Ms. Nancy Chupp
Church Women United
Washington Office, Box 16
110 Maryland Avenue, NE
Washington, DC 20002

Dear Ms. Chupp:

Enclosed please find copies of the letters that were sent to the women who submitted questions at your Forum on Women's Health last year. The questions were forwarded to the Office of the First Lady by Barbara Woolley.

Because the legislative environment surrounding health care has changed so dramatically since the forum was held, we responded to the questions by providing an update on the President's health care reform efforts. Thank you for your patience in awaiting a response.

Sincerely,



Jennifer Klein
Senior Policy Analyst

cc: Barbara Woolley

THE WHITE HOUSE

WASHINGTON

August 2, 1995

Ms. Gail Nicholas Magruder
Director
Health Ministries
M Division
5007 Sangamore Road
Bethesda, Maryland 20816

Dear Ms. Magruder:

I very much enjoyed the opportunity to meet with you last year to discuss health care reform at the Church Women United's Forum on Women's Health.

I am writing to give you an update on the President's health care reform efforts. Recently, the President announced a proposal to reach a balanced budget in ten years. The President's proposal takes the first steps toward health care reform by assuring that an individual who loses his or her job will be able to pay for family health insurance; by helping elderly or disabled Americans get long-term care; and by reforming the insurance market so that Americans will not lose their coverage if they change jobs, lose a job or get sick. The proposal will also make coverage more available and affordable for small businesses and the self-employed.

The President's plan improves Medicare by expanding choice, offering new benefits, and extending the solvency of the Medicare Trust Fund without imposing new cost increases on Medicare beneficiaries. The plan will preserve Medicaid as a safety net by protecting coverage while reforming it to make it work more efficiently.

Measures such as these will make a difference in the lives and health of American families. Once again, I thank you for your interest in women's health, and I appreciate your patience in awaiting a response. I encourage you to remain informed and active in important issues like health care reform.

Sincerely yours,



Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

August 2, 1995

Ms. Helen H. Mitchell
The BFM Group
Human Resource Development
38 Hawthorne Court, N.E.
Washington, D.C. 20017

Dear Ms. Mitchell:

I very much enjoyed the opportunity to meet with you last year to discuss health care reform at the Church Women United's Forum on Women's Health.

I am writing to give you an update on the President's health care reform efforts. Recently, the President announced a proposal to reach a balanced budget in ten years. The President's proposal takes the first steps toward health care reform by assuring that an individual who loses his or her job will be able to pay for family health insurance; by helping elderly or disabled Americans get long-term care; and by reforming the insurance market so that Americans will not lose their coverage if they change jobs, lose a job or get sick. The proposal will also make coverage more available and affordable for small businesses and the self-employed.

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Sincerely yours,



Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

August 2, 1995

Ms. Kristina Peterson
114 High
Mannington, West Virginia 26582

Dear Ms. Peterson:

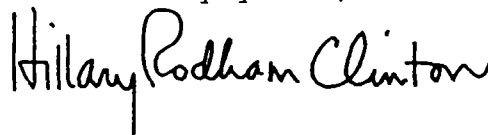
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Sincerely yours,



Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

August 2, 1995

Ms. Peggy Halsey
Apartment 306
34 Plaza Street
Brooklyn, New York 11238

Dear Ms. Halsey:

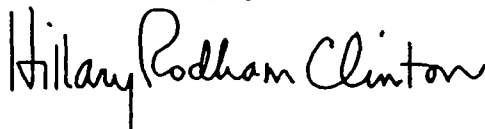
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Sincerely yours,

A handwritten signature in black ink that reads "Hillary Rodham Clinton". The signature is written in a cursive style with a large initial "H".

Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

August 2, 1995

The Reverend Betsy Z. Halsey
3261 Chestnut Avenue
Baltimore, Maryland 21211

Dear Reverend Halsey:

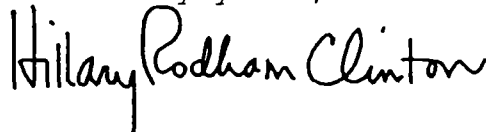
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Sincerely yours,

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Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

August 2, 1995

Ms. Nirmala Abraham
1758 Mendenhill
Hockessin, Delaware 19707

Dear Ms. Abraham:

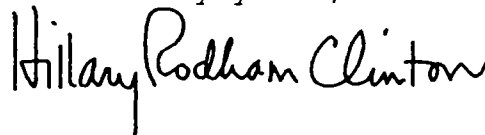
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Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

August 2, 1995

Ms. Laia S. Katz
3550 Raymoor Road
Kensington, Maryland 20895

Dear Ms. Katz:

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I am writing to give you an update on the President's health care reform efforts. Recently, the President announced a proposal to reach a balanced budget in ten years. The President's proposal takes the first steps toward health care reform by assuring that an individual who loses his or her job will be able to pay for family health insurance; by helping elderly or disabled Americans get long-term care; and by reforming the insurance market so that Americans will not lose their coverage if they change jobs, lose a job or get sick. The proposal will also make coverage more available and affordable for small businesses and the self-employed.

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Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

August 2, 1995

Ms. Carolyn Chupp
8645 West 250 N.
Shipshewana, Indiana 46565

Dear Ms. Chupp:

I very much enjoyed the opportunity to meet with you last year to discuss health care reform at the Church Women United's Forum on Women's Health.

I am writing to give you an update on the President's health care reform efforts. Recently, the President announced a proposal to reach a balanced budget in ten years. The President's proposal takes the first steps toward health care reform by assuring that an individual who loses his or her job will be able to pay for family health insurance; by helping elderly or disabled Americans get long-term care; and by reforming the insurance market so that Americans will not lose their coverage if they change jobs, lose a job or get sick. The proposal will also make coverage more available and affordable for small businesses and the self-employed.

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Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

August 2, 1995

Ms. Vera S. Frasier
Post Office Box 447
Nokesville, Virginia 22123-0447

Dear Ms. Frasier:

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Sincerely yours,



Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

August 2, 1995

Ms. Rebecca Erwin
9405 Chimney Way
Gaithersburg, Maryland 20879

Dear Ms. Erwin:

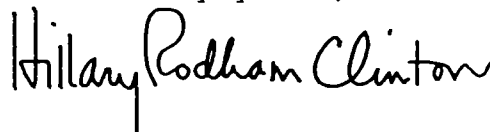
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Hillary Rodham Clinton



Church Women United

Washington Office, Box 16
110 Maryland Avenue NE, Washington, D.C. 20002
Telephone: (202) 544-8747 Fax #: (202) 543-1297

President
Ann B. Garvin
General Director
Patricia Rumer

Supporting Organizations of Church Women United

African Methodist Episcopal Church
(Women's Missionary Society)
African Methodist Episcopal Zion Church
(Women's Home and Overseas Missionary Society)
American Baptist Churches in the USA
(American Baptist Women's Ministries)
Christian Church (Disciples of Christ)
(International Christian Women's Fellowship)
Christian Methodist Episcopal Church
(Women's Missionary Council)
Church of God
(Women of the Church of God)
Council of the Brethren
(Program for Women)
Council of Hispanic American Ministers (Evangelical)
(Women's Department of CONAM)
Cumberland Presbyterian Church
(Cumberland Presbyterian Women)
The Episcopal Church
(Episcopal Church Women)
The Evangelical Lutheran Church in America
(Women of the Evangelical Lutheran Church in America)
General Convention of the New Jerusalem (Swedenborgian)
(Alliance of New Church Women)
Greek Orthodox Church of North and South America
(Greek Philanthropic Society)
International Council of Community Churches
(Women's Christian Fellowship)
Eastern American Church Women United
(Evangelical Women's Fellowship)
Methodist Church in America
(Women's Boards - Northern and Southern Jurisdictions)
National Baptist Convention of America
(Senior Women's Assembly)
National Baptist Convention, USA, Inc.
(Women's Commission)
Presbyterian Church/USA
(Presbyterian Women)
Progressive National Baptist Convention, Inc.
(Women's Department)
Reformed Church in America
(Reformed Church Women)
Religious Society of Friends
(United Society of Friends Women International)
Reorganized Church of Jesus Christ of Latter Day Saints
(Women's Ministerial Convocation)
United Church of Christ
(Coordinating Center for Women in Church and Society)
The United Methodist Church
(Women's Division)

February 27, 1995

To: Barbara Wooley
From: Nancy Chupp

I left a message on your phone machine this morning. My apologies if it sounded garbled.

It was good to see you last week at the meeting with Council of Presidents. Congratulations on your increased role as liaison on women's issues. Let us know if we can do anything.

Last April Church Women United sponsored a televised forum on women's health with the First Lady. Many of our members were able to ask questions. Due to lack of time, some were unable. During the hour taping, the First Lady invited people in the audience who didn't get to ask questions to send them to the White House. I collected them and sent them last April, but they were never responded to, probably due to the overwhelming demands on the White House on this issue last year.

Although the health care issue has changed dramatically and the Administration's plan is no longer on the table, would it be possible to have these questions responded to? As an organization, we constantly try to empower our members politically and to combat the growing cynicism that "my voice doesn't count anyway." It would help tremendously if the questions askers received some kind of response from the White House.

As always, it's a pleasure working with you. Thanks for your consideration to this issue.



Church Women United

Washington Office, Box 16
110 Maryland Avenue NE, Washington, D.C. 20002
Telephone: (202) 544-8747 Fax #: (202) 543-1297

President
Ann B. Garvin
General Director
Peppicia Rumer

Supporting Organizations of Church Women United

- African Methodist Episcopal Church
(Women's Missionary Society)
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- The Episcopal Church
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- The Evangelical Lutheran Church in America
(Women of the Evangelical Lutheran Church in America)
- General Convention of the New Jerusalem (Baptists)
- Alliance of New Church Women
- Greek Orthodox Church of North and South America
(Ladies Philanthropic Society)
- International Council of Community Churches
(Women's Christian Fellowship)
- Korean American Church Women United
(Evangelical Women's Fellowship)
- Methodist Church in America
(Women's Boards-Northern and Southern Provinces)
- National Baptist Convention of America
(Senior Women's Auxiliary)
- National Baptist Convention, USA, Inc.
(Women's Convention)
- Presbyterian Church/USA
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- Progressive National Baptist Convention, Inc.
(Women's Department)
- Reformed Church in America
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- Religious Society of Friends
(United Society of Friends Women International)
- Reorganized Church of Jesus Christ of Latter Day Saints
(Women's Ministerial Commission)
- United Church of Christ
(Coordinating Center for Women in Church and Society)
- The United Methodist Church
(Women's Division)

April 26, 1994

Mrs. Hillary Rodham Clinton
Office of the First Lady
The White House
Washington D.C. 20500

Dear Mrs. Clinton

Thanks again for participating in our national televised forum on women's health on April 15. Your presentation and answers to our many questions were very clear and easily understood. Many women commented afterward that you illustrated an amazing ability to make a very complex issue, accessible and understandable.

As you noted, there were many more questions than time allowed. In response to your invitation that questions be sent to the White House for a written response, Church Women United's Washington Office has been collecting questions for the last week. I now turn them over to you with names and addresses.

Thanks again for your participation in our health care dialogue as well as taking time to answer these follow up questions.

Sincerely,

Nancy Chupp
Legislative Director

02/27/1995 15:35 282666666 NCC WASHINGTON PAGE 03

QUESTIONS FROM WOMEN'S FORUM ON HEALTH CARE - APRIL 15, 1994

1. Gail Nicholas Magruder, M.Div., Director, Health ministries, 5007 Sangamore Road, Bethesda, MD 20816.

QUESTION: *Part of preventive care means paid access to acupuncture, Chiropractic "touch for Health," nutrition advice by trained people (not M.D.'s) who receive little or no medical school training re: nutrition. Are you going to guarantee these?*

2. Helen H. Mitchell, The BFM Group - Human Resource Development, (202) 387-0213.

QUESTION: *Was consideration given to dealing only with those who do not have health care?*

3. Kristina Peterson, 114 High, Mannington, WV 26582. (Member of Presbyterian Health Network).

QUESTION: *Regarding highly rural, low population areas with citizens of high risk population...there are no doctors. There is no incentive even with full payment of patient care since there are not a lot of patients due to low population. Can there be other incentives like government subsidy for a full salary to those who will go to underserved areas and also the paying off of medical school bills?" Also critical to rural areas is preventative education and health care - what can you do?*

4. Peggy Halsey, 34 Plaza St., Apt. 306, Brooklyn, NY 11238.

QUESTION: *How will the Administration's plan guarantee that adequate research is funded and proper oversight given on specific issues of women's health?*

5. Rev. Betsy Z. Halsey, 3261 Chestnut Ave., Baltimore, MD 21211.

QUESTION: *I am encouraged by the Administration's emphasis on preventative care. Would you please explain how this applies to mental health care. Will there be caps on this particular health care service?*

6. Nirmala Abraham, (Mar Thoma Church), home address: 1758 Mendenhill, Hockessin, Delaware 19707.

QUESTION: *Malnutrition is prevalent among elderly. As more and more people, especially women are living longer, malnutrition has an impact on the health care dollars. Malnutrition results in increased infection and disease. My question is: Will the President's health care reform plan have coverage for nutrition counseling?*

7. Laia S. Katz, Vice President, Women of Reform Judaism. Home address: 3550 Raymoor Road, Kensington, MD 20895.

QUESTION: *You spoke to the need for a broad range of services for women - pre-natal, etc. Will a*

bottom line be the right to choose not to need pre-natal services as part of the right to a guaranteed package of benefits, or can this right be lost to the give and take of legislation given up by the Administration in return for others benefits?

8. Carolyn Chupp, 8645 W. 250 N. Shipshewana, Indiana 46565.

QUESTION: *Thank you for an excellent presentation on April 15 and your commitment to universal health care. My question about Health Care Reform: Will every citizen be required to join a health care plan? For example, the Amish and other conservative groups do not believe in insurance coverage because of being too closely tied with the government. As a group, they cover each other's medical expenses.*

QUESTION: *My husband owns a small bakery (of 22 employees in a rural area) and employs mostly Amish employees. Would he be required to take out insurance for each of them even if they do not want it? Since he does not currently pay for health coverage, I am not sure he could continue to keep the business open. How does your plan guarantee that small businesses, such as my husband's, would not be forced to close because of the extra high expense?*

9. Vera S. Frasier, P.O. Box 447, Nokesville VA 22123-0447.

QUESTION: *Will HMO be good only in the state where the policy card is issued or will it be valid across the border? Will it be valid in states and the U.S. Territories outside the Continental USA?*

10. Rebecca Erwin, 9405 Chimney Way, Gaithersburg, MD 20879 (301) 926-1694.

QUESTION: *I ask from the perspective of a mother of a handicapped child: Will medical-related services be provided that are not life and death health issues, but will improve quality of life and productivity of handicapped individuals? Services like intensive speech therapy and physical therapy are not fully covered under the Federal Laws pertaining to the education of handicapped children. Will the pools of health care providers include a plan for these services that is fair in cost or will those individuals with extensive needs end up paying more for much needed services than a "healthy" individual? The choice of health provider pools could result in people who use medical services at a greater frequency being forced to buy a more expensive plan, thus the neediest will pay more than the healthiest. How ethical is this method? How does it address the needs of handicapped people?*

THE WHITE HOUSE

WASHINGTON

July 20, 1995

Jack Kushner, M.D., M.G.A.
20 Ridgely Avenue
Annapolis, Maryland 21401

Dear Dr. Kushner:

Thank you for sending your health care plan. Carol Rasco, Assistant to the President for Domestic Policy, received it from Leon Panetta and asked me to respond.

Your plan includes many features that are important to the President. As you know, the President supports your goal of universal coverage. You will be pleased to know that some of the insurance problems you identified were addressed by the President in the health reform initiative that he announced as part of his recent budget proposal. Specifically, the proposal would reform the insurance market to ensure that Americans can keep their coverage if they change jobs and will not lose or be denied coverage if they have a pre-existing condition. It would add important consumer protections by requiring insurers to provide consumers with specific information on their plans as well as to establish grievance and appeals procedures. In addition, the initiative would subsidize insurance for working families for six months after a job loss and improve the availability and affordability of coverage for small businesses.

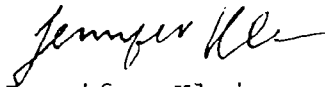
However, your plan includes several elements that the Clinton Administration would not support. The Administration does not promote ending tax deductibility of insurance. In fact, as you may know, the Administration has recently proposed to extend the tax deductibility of health insurance for individuals who are self-employed. Nor would the Administration support the abolition of Medicare. The Administration seeks to preserve and strengthen Medicare while making it more efficient.

Additionally, while assessing the financial implications of the proposal is impossible without more details, your proposed premium of \$4,500 per couple is low. Currently, the average cost per Medicare couple is about \$9,500 and per Medicaid couple is \$7,400. The cost for a federal employee and his or her family in the Blue Cross/Blue Shield standard plan is \$4,710. Given these costs and the generous subsidies you described, it seems as though your proposal would be difficult to fund.

Jack Kushner, M.D., M.G.A.
July 20, 1995
Page two

Thank you again for sharing your suggestions with us. We will keep them in mind as the Administration continues to work toward health care reform in the coming months.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jennifer Klein".

Jennifer Klein
Senior Policy Analyst

cc: The Honorable Carol Rasco .

THE WHITE HOUSE
WASHINGTON

JUN 22 1995

June 5, 1995

Dr. Jack Kushner
20 Ridgely Avenue
Annapolis, Maryland 21401

Dear Dr. Kushner:

Thank you for your letter submitting a health care plan for the United States. I appreciate your contacting me concerning this important issue.

In order to give your health care plan the appropriate attention, I have forwarded your letter and the plan to Carol Rasco, Assistant to the President for Domestic Policy, and asked that she or a member of her staff respond to you directly. Please be assured that your health care plan will receive the proper review.

Once again, thank you for writing.

Sincerely,



Leon E. Panetta
Chief of Staff

cc: The Honorable Carol Rasco

LEP/tab

NEUROSURGERY

JACK KUSHNER, M.D., P.A.

DIPLOMATE AMERICAN BOARD OF NEUROSURGERY
FELLOW AMERICAN COLLEGE OF SURGEONS
FELLOW INTERNATIONAL COLLEGE OF SURGEONS
MASTER GENERAL ADMINISTRATION - FINANCE

May 2, 1995

Mr. Leon Panetta
The White House
1600 Pennsylvania Avenue
Washington, DC 20500


RE: Health Care Plan for the
United States

Dear Mr. Panetta:

I would like to submit to you a health care plan for the United States which was written by Dr. Rose Rubin, Professor of Economics at the University of Memphis and me. We feel that this represents a compromise between the Republicans and Democrats on an issue that is so important to everyone in our country. I have already sent this to numerous Republicans in Congress and thus far I have not received an answer from anyone except for Nancy Kassenbaum and Wayne Gilchrist who stated that they could not support the plan.

Please review the plan and see whether or not there are any elements in it which you find supportable. If you have any additional ideas as to where I should send this plan for consideration, please let me know. Best regards.

Sincerely,


Jack Kushner, M.D., M.G.A.

JK/lis

A Health Care Plan for the United States

Jack Kushner, M.D.

and

Rose Rubin, Ph.D.

Most Americans and politicians would agree that the United States has the best health care in the world and also would agree that something has to be done to change the way it is financed. None of the health care reforms thus far proposed has proved to be politically viable. Now that we have a new Congress, perhaps some sort of compromise arrangements can be realized. We propose a new and different health financing system that would provide coverage for all Americans and would still allow them flexibility and choice.

Our proposed health care system combines Republican and Democratic tenets. It is based on a continued private-public mix of ownership and control of health care resources and delivery, which could continue to be for profit or not for profit; and it features diverse sources of health care financing. This is a universal coverage plan, which would entitle every American citizen and legal resident to a universal health care card. It would settle divisive issues such as pre-existing illnesses, portability, employer mandates, and preferential tax deductions. This plan would be utilitarian in that the government could finance care for the poor, and yet it would be libertarian in that those households which choose to do so could purchase additional health care.

This health plan starts with removal of the tax deductions for employer purchased health insurance. Members of Congress are currently discussing proposals to modify the Internal Revenue Code. This change would also disembarass employers of paying for health insurance, which interferes with American competitiveness in the international economy. The national health insurance plan would give participants a choice of either an indemnity insurance carrier or a managed care HMO. Furthermore, participants would know that all services are supplied by participating providers at pre-negotiated rates. As opposed to health insurance in the private sector, the national health insurance plan would rebate a prorated amount of their premium if their benefits were not fully utilized. It would settle the issue of insurance portability, because workers could purchase insurance themselves and retain it when they change jobs. Households would have a choice of ways

to finance their health care. They could pay out of pocket, purchase private indemnity insurance or obtain managed care coverage. Rather than having predominantly employment based group private insurance or only government financing we recommend the following changes:

*Health insurance payments would not be tax deductible and would be based on reported household income.

*Pre-existing diseases, community and experience ratings, and portability would no longer be factors since there would be universal coverage.

*Payment for the health care credit card would be based on household income level and size. Whereas a husband and wife without children would pay \$4500 per year (\$375 per month) for this health care, a family with children would pay more and a single person would pay less.

*All citizens and legal residents would receive a health insurance credit card. For example, a household with a husband and wife would use the card to receive health care purchased with the annual \$4500 (\$375 per month) health insurance premium, as well as the major medical insurance benefits with limits up to \$100,000.

*A husband and wife with an income of \$35,000 or more could purchase private insurance, either indemnity or managed care, and indicate this choice on their tax return with proof. Alternatively, they could participate in the government-sponsored health insurance program and receive a prorated rebate if they did not fully utilize their benefits. This rebate could take the form of cash or the credit could be applied toward their income taxes the following year. The household would get the rebate rather than each person.

A husband and wife with an income less than \$35,000 would pay only \$2500 per year (\$208 per month) for their \$4500 policy and a \$100,000 major medical insurance policy. This group could also choose whether it wanted its care provided by indemnity insurance or the managed care system that participates with the government plan. Although the husband and wife would still receive \$4500 of health insurance benefits and the \$100,000 major medical insurance policy, their rebate would be prorated based on the \$2500 payment.

The third tier of the system would provide health coverage for households that have income below the federal poverty level. These households would be insured under the government sponsored managed care system and would not be eligible for any rebate.

Importantly, this plan would separate health care financing from welfare payments for low income households providing motivation to enter the job market while retaining health care financing.

Although any universal health care plan will incur increased costs, the government could increase its revenues and finance this plan by:

- 1) Eliminating the tax deductibility of employer purchased health insurance.
- 2) Receiving increased taxes from the wage increases that many employees would receive from their employers in lieu of health insurance.
- 3) Receiving revenues from premium payments for government sponsored health insurance policies.
- 4) Abolishing Medicare and the acute part of Medicaid. (However, one area of government revenue would be reduced, as there would no longer be a Medicare supplemental tax of 1.25% on income).
- 5) Abolishing other federal and state health programs for specific conditions, such as end-stage renal disease.
- 6) Transforming the Veteran's Administration Hospital system could be transformed into geriatric acute care facilities and into long term health care centers for the anticipated increased number of people receiving these services.

This health care plan would save the American public and businesses millions of dollars. For example, individuals would no longer need medical insurance as part of their automobile insurance policy. The medical care component of workman's compensation insurance could be deleted, reducing another cost of employment to business. In addition, medical malpractice awards would be reduced.

This broad health financing plan provides universal coverage and allows more Americans to participate in their health decision making with positive, rather than perverse, incentives for rational cost consciousness. Many households will opt out of the national health insurance plan. Some will choose to stay in the government-sponsored plan, with increased information regarding the cost of their health care decisions and with the ability to select an indemnity or a managed care system. While the issue of health care is still in the mind of America, we feel there is room for compromise with this plan.

THE WHITE HOUSE

WASHINGTON

July 6, 1995

Ms. Sandy Isenberg
President
Board of County Commissioners
County of Lucas
One Government Center
Suite 800
Toledo, Ohio 43604-2259

Dear Ms. Isenberg:

Erskine Bowles asked me to respond to your letter of June 8. Thank you for your support of the First Lady's breast cancer awareness campaign and for your interest in the Food and Drug Administration's (FDA) efforts to ensure the timely commercial availability of devices used in the detection of breast cancer.

The Clinton Administration, including the FDA, shares your goal of facilitating early diagnosis of breast cancer. Under the Mammography Quality Standards Act of 1992, the FDA is charged with ensuring high quality mammographic examinations and has certified over 10,000 U.S. mammography facilities as meeting federally-developed standards.

We also agree that women should have access to every safe medical device that will aid in the early detection of breast cancer. That is why the FDA works to expedite product development and agency review of innovative products intended for the treatment or diagnosis of life-threatening or seriously debilitating diseases. You will be pleased to learn that in September 1994, the FDA's Obstetrics and Gynecology devices Advisory Panel, a group of outside experts, recommended that studies be performed to ascertain whether medical devices, such as the Sensor Pad, add benefit to conventional breast self-examination. The FDA has been working closely with the manufacturer to determine the kind of scientific data necessary to judge the safety and effectiveness of the Sensor Pad device.

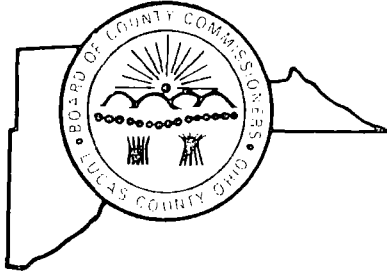
Thank you again for writing.

Sincerely,



Jennifer Klein
Senior Policy Analyst

cc: The Honorable Erskine Bowles



COUNTY OF LUCAS

June 8, 1995

BOARD OF COUNTY COMMISSIONERS

SANDY ISENBERG
President

BILL COPELAND
MARK L. PIETRYKOWSKI

EDWARD J. CIECKA
Administrator

NANCY POSKAR
Clerk

Mr. Erskine Bowles, Assistant to the President
and Deputy Chief of Staff
Executive Office of the President, 1st Floor, West Wing
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

*Sono to
DPC
Gentry
Parker*

Dear Mr. Bowles,

The new cancer awareness program headed by Hillary Clinton is commendable. However, I feel this program will have no true significance or impact without the support of the Food and Drug Administration (FDA).

As a female with a family history of breast cancer, I know first hand the emotional devastation of this terrible disease. There continues to be an overwhelming need for products and devices designed to aid women in the early detection of breast cancer. It is my hope that Dr. Kessler will realize the importance of these life saving devices. The FDA needs to re-evaluate its laboratory and clinical process and promote the marketing of these products, including the sensor pad.

The FDA needs to get back on track and function as part of the White House team.

Sincerely,

Sandy Isenberg, President
Board of County Commissioners
Lucas County, Ohio

THE WHITE HOUSE

WASHINGTON

July 6, 1995

John H. Olwin, M.D.
9631 Gross Point Road
Skokie, Illinois 60076

Dear Dr. Olwin:

I am writing in response to your letter to Leon Panetta about chelation therapy.


The National Heart, Lung, and Blood Institute (NHLBI) has followed the scientific literature on chelation for the treatment of heart and vascular disease for more than 25 years. There are proponents of chelation therapy who have made very strong claims for its effectiveness. However, the only scientifically sound research on chelation therapy for the treatment of atherosclerosis has demonstrated no beneficial effects when compared to dummy or placebo therapy.

I have enclosed a copy of the NHLBI's informational summary on chelation therapy. Since the date of that report, another scientifically sound study of patients with atherosclerosis involving arteries of the lower extremities found no differences in outcomes between patients who received active drug and those who received placebo.

As you point out, it is possible that existing studies have been inadequate and the National Institutes of Health (NIH) would welcome grant applications for chelation therapy research. The vast majority of research sponsored by the NIH is investigator-proposed and since the NHLBI began following chelation therapy only two of 40,000 proposals have focused on it.

I have taken the liberty of forwarding your letter to Dr. Peter L. Frommer, Deputy Director of the NHLBI. If you have further questions or are interested in submitting a research grant application, please feel free to contact Dr. Frommer at (301) 496-1078.

Sincerely,


Jennifer Klein
Senior Policy Analyst

cc: Leon E. Panetta



National Institutes of Health
National Heart, Lung, and
Blood Institute
Bethesda, Maryland 20892

CHELATION THERAPY - AN INFORMAL SUMMARY

The goal of chelation therapy for treating arteriosclerosis (or atherosclerosis) is decreasing the narrowing of arteries by the removal of calcium. Calcium is present in some arteriosclerotic lesions. The drug used, disodium EDTA (disodium edetate, Endrate) grasps or binds calcium, and the hope is that it will grasp calcium from these areas of arterial obstruction.

Such "chelation therapy" is commonly accompanied by other therapies, such as trace element "supplements," large doses of vitamins and dietary modifications. Nevertheless, the central element of "chelation therapy" is repeated intravenous infusions of disodium EDTA.

There is no sound evidence that chelation therapy works -- that it is effective or has clinical benefit.

There is also an important fallacy in this underlying idea. When disodium EDTA is administered intravenously, it encounters calcium everywhere in the blood and it binds calcium from the blood, not from the tiny deposits of calcium that may exist in arteriosclerotic lesions. The bound calcium is removed from the body through the kidneys. The calcium in blood is replenished by calcium from the bone, which is easily accessible to the blood stream, or by calcium from the gut.

The advocates of "chelation therapy" have testimonials from people who feel that their symptoms have been relieved. However, there is no clinical trial or clinical study with scientific merit that has shown the purported beneficial effects. Until August, 1991, the best study was published in 1963. It concluded that "we believe that chelation as used in this study did not benefit patients more than other commonly used therapeutic methods. It is not a useful clinical tool in the treatment of coronary artery disease at the present time". By today's standards, that study has some shortcomings but there is no subsequent study to contradict those results. In August, 1991 and early 1992, reports were published of a large, scientifically sound clinical trial that carefully documents that chelation therapy does not work. Symptoms, clinical findings, x-rays, and other measurements were compared in patients who received the chelation therapy and compared to similar measurements in patients who received a "dummy" therapy instead of chelation. The results were identical; chelation therapy was shown to be of no value.

2 CHELATION THERAPY - AN INFORMAL SUMMARY

What about people who have felt better following chelation therapy? In the objective assessment of a variety of medical therapies, including some for arteriosclerotic disease, people have often felt much better in response to sham therapy or "placebos." Indeed, the more dramatic the intervention, the more likely the effect. The more someone has invested in feeling better -- and a course of chelation therapy may be on the order of 30 to 50 intravenous infusions over several months and costs thousands of dollars -- the more likely a person is to be convinced that there has been a benefit.

It might be noted that "chelation" is a chemical term meaning that a compound grasps a metallic element to form a ringed structure. In that sense, some forms of chelation are accepted and appropriate forms of therapy. For example, deferoxamine is a validated therapy in the management of iron overload following repeated blood transfusion and EDTA, similar to that used in chelation therapy of arteriosclerosis, is appropriate and accepted for the treatment of lead poisoning.

This has nothing to do with the alleged benefits of chelation in the management of arteriosclerosis. There is no reason to expect benefit from chelation in the management of arteriosclerosis. More importantly, there has been no scientific evidence of such benefit -- and now there is scientific evidence of no benefit.

June 1992

THE WHITE HOUSE
WASHINGTON

JENNIFER
PLEASE ACKNOWLEDGE
receipt directly.
Thanks,
J.

May 24, 1995

Dr. John H. Olwin
9631 Gross Point Road
Skokie, Illinois 60076

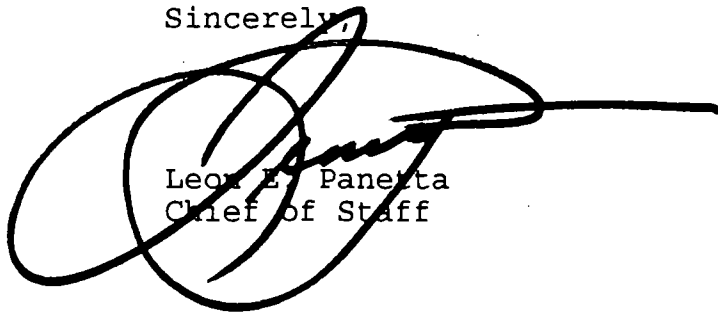
Dear Dr. Olwin:

Thank you for writing and sharing your suggestions regarding a way to "bypass" health care costs accrued due to heart disease. This Administration remains determined to fulfill the fundamental principle of reform -- guaranteed private health care coverage for all Americans.

To give your ideas the proper attention, I have taken the liberty of forwarding your letter to the appropriate health policy staff at the Office of Domestic Policy. I can assure you that your thoughts will receive careful consideration.

Thank you again for taking the time to write. I will keep your views in mind.

Sincerely,



Leon E. Panetta
Chief of Staff

cc: Office of Domestic Policy

LEP/tab

JK

John H. Olwin, M.D.
9631 Gross Point Road
Skokie, Illinois 60076
1-708-676-4030

MAR 13 1995

March 7, 1995

Mr. Leon Panetta
Chief of Staff
The White House
Washington D.C.
20500

Dear Mr. Panetta:

I very much enjoyed your interview Sunday on the David Brinckley program and thought you handled the questions from Sam Donaldson particularly well.

You have probably one of the most difficult positions in the Administration and are probably better qualified for the job than anyone who has tried it in this century. Quite a statement, but many of my friends would agree.

Certainly, one of your most difficult problems at present is that of Health Care. There is no easy solution to it, but having been a part of it for sixty years I have a few suggestions about one of the most pressing and costly problems in the field today... that of coronary artery "bypass". As you well know, most of these operations are done on patients over 60 years of age and each costs \$65,000 or more. Some individuals have gone through the procedure two, three and more times, at the above or greater cost.

There is a procedure that will almost surely prevent or materially reduce the development of atherosclerotic obstruction of the coronary arteries in most if not all individuals. It has been neglected and or scorned by most of the medical profession, largely because it has not been given an acceptable trial. The accompanying material may answer questions as to its possible efficacy and cost.

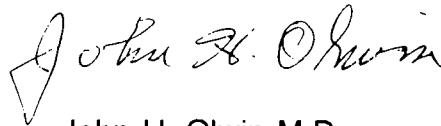
I would suggest that two committees composed of competent physicians be chosen. One committee would organize a controlled

clinical study of patients who are candidates for coronary by-pass. Half of those candidates would proceed with the by-pass. The other half will be given infusions of EDTA (ethylene diamine tetra acetic acid). The second committee would judge the results of the two procedures. Within one year following the completion of the two procedures the comparative benefits of them should be apparent.

I have no doubt as to the outcome of the trial. And I believe that the resulting changes in our methods of treatment of patients with *any* type of atherosclerosis will result in at least an eighty-five (85) per cent reduction in the present cost of such treatment.

Thank you for giving your time and attention to this letter. So that your advisors in the fields of Health Care may have some basis for judging my competence to write on such matters I am taking the liberty of enclosing my Resumé.

Most respectfully,

A handwritten signature in cursive script that reads "John H. Olwin". The signature is written in dark ink and is positioned above the printed name.

John H. Olwin M.D.

RESUME

John H. Olwin

Fields of competence:

Trace metals; blood coagulation;
general and vascular surgery,
thrombo-embolism;
atherosclerosis

Professional Experiences:

Private practice of sclerotherapy for varicosities and venous blemishes 1978 to present.

Private practice of General and Vascular surgery 1939 to 1984.

Founder and Director of Clinical Coagulation Laboratory and of Coagulation Research Laboratory, Presbyterian, and then Presbyterian-St. Luke's Hospital, Chicago, Illinois, 1946 and 1947 respectively to 1969. Attending Surgeon, Presbyterian-St. Luke's Hospital, 1942 to 1972. Emeritus, General Surgery, Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois 1972 to present. Clinical Professor of Surgery, Rush Medical College, 1942 to present. Consultant in General and Vascular Surgery, Veterans Administration Hospital, Hines Illinois, 1946 to 1962. Special interest in the role of essential and toxic metals and organics in cellular metabolism.

Education: B.A. University of Illinois, 1929. M.D. University of Chicago (Rush Medical College) 1934. Internship, Presbyterian Hospital, Chicago, Illinois 1935 to 1936. Residency (General Surgery) 1937 to 1939. Research Fellow, Rush Medical College 1939-1940. Associate, General Surgery, Cook County Hospital, 1939 and 1940.

Professional Activities American Medical Association, Chicago Surgical Society, American College of Surgeons, Society for Vascular Surgery (Recorder 1960 to 1966), Central Surgical Society, Western Surgical Association, Chicago Medical Society, Illinois State Medical Society, Institute of Medicine of Chicago (Secretary, 1970 to 1972; President, 1973 to 1975), Committee on Thrombosis and Hemorrhage, National Research Council, 1959 to 1964.

Military Service: Extended Active Duty M.C.AUS 1940 to 1946, .Lt.Col. Chief of Surgery, 29th Evacuation Hospital, Bronze Star, three Battle Stars.

Publications: Author or co-author of 151 papers in the areas of General and Vascular Surgery, Blood Coagulation, Trace Metals and Chronobiology.

CHELATION THERAPY

What is chelation therapy? It is the infusion of substances that remove metals from the body. The word is derived from the Greek word *chela*, the pincer claw of the crustean. Early investigators saw a similarity between the way these chemical agents bind metals and the way the crustacean firmly fixes its prey. The metals are so firmly bound that it is difficult for other chemicals to break that bond. Chelating agents have been used in industry for many years to separate metals from ores or from other metals.

The exact nature of the chemical action on the body, other than the binding of metals, is not well understood. There are several theories. The one I hold to is that we are removing toxic metals which have replaced, in the various enzyme systems, the essential metal(s) necessary to the normal functioning of that particular enzyme system.. There are, at the present time, 15 trace metals that are known to be essential to normal enzyme activity. Among these are cobalt, chromium, iron, molybdenum, manganese, nickel, selenium, tin and vanadium. Every cell contains more than 3000 enzymes and of these more than fifty per cent are so-called metallo-enzymes. In these enzymes the metals are structural components of the enzyme system. The remaining enzymes are probably influenced by metals acting as co-enzymes or as catalysts. Thus, almost no process goes on in the body without the aid of metals. If these essential metals are replaced by toxic ones such as lead, cadmium, mercury, aluminum or even an overwhelming amount of some of the other metals, even the essential ones, these enzymes are paralyzed. If we can remove these metals that are acting as poisons, perhaps we can restore the enzyme systems to their normal or near-normal activity and thus reverse the disease processes. In removing the toxic metals, we also remove a number of the essential ones. These, however, can be replaced by the food that we eat and by the addition to our dietary routine of so-called nutrient supplements, i.e. vitamins and minerals.

It would be a happy circumstance if we could feed this chelating agent by mouth. However, when given orally most of it passes through the intestinal tract without being absorbed and, in passing, binds a number of the essential elements that we need. Hence, it becomes necessary to give it either intramuscularly or intravenously. Since the intramuscular route is painful and is less well controlled, we give it intravenously. This is an inconvenience and an expense but it is also painless and, being more easily controlled, is much safer than the intramuscular route. The inconvenience is that the patient must sit with a needle in his/her

vein for a period of three hours for an infusion. Since the material that we use is an acid, even though a weak one --ethylene-diamine-tetra-acetic acid (EDTA)-- it must be given slowly so as not to be painful and so as to allow the body to absorb it more completely rather than excreting it too rapidly. Unlike most drugs, it is not broken down in the body into its component parts, but is excreted just as it is given except that it has firmly bound a number of metals. It is excreted in the urine and can be recovered (almost 100 per cent of it) in a relatively short period of time (hours). When properly given it is entirely safe. Its only toxic effect is on the kidneys and since we give it slowly and monitor each patient's kidney function with each infusion, the hazard is reduced to zero. In fact, we have some patients with badly damaged kidneys who, when given the material cautiously, have been able to accept it and have experienced an improvement in their kidney function.

it has been observed by competent investigators that arteries in human beings obstructed by calcium and lipid (fat) deposits will, over a period of months to years, become patent and will for the most part remain so as long as the EDTA infusions are continued. The artery walls will again be narrowed and the obstruction will recur by similar calcium and lipid deposits if the infusions are discontinued. These findings have been repeated in rabbits fed an atherogenic diet. As stated earlier, one of the principle effects of the infusion of EDTA is the removal of toxic metals such as lead, cadmium, aluminum and mercury from the body, thus restoring normal enzyme function. There is no doubt that all persons and animals living in the cities of western civilization have elevated levels of such metals. Some years ago we did a study of 100 patients in Chicago and suburbs and found an elevated level of lead (the "normal" then being 0 to 80 micrograms per 24 hour specimen of urine) in 87 per cent of them. Sheep grazing near a freeway have been found to have a heavy body-burden of lead. EDTA has been used by the medical profession for years as the best treatment available for lead poisoning. Another study from our laboratory showed that cholesterol and all other blood lipids were significantly lowered following the beginning of chelation therapy and remained lowered as long as the therapy was continued. The lipid levels returned to their former state about three weeks after the infusions were discontinued. Other benefits following the initiation of chelation therapy that I have observed have included the unblocking of atherogenic obstruction in main leg arteries; dissolution, overnight, of freshly lodged emboli; increase in collateral circulation, color and warmth to a limb, and termination of gangrene; observed status-quo of an abdominal aortic aneurysm in a patient on regular chelation therapy over a period of thirty years; improvement in or elimination of claudication; improvement in sexual desire and performance in men and, in a very limited number of adults,

improvement in, or elimination of, the symptoms of Alzheimer's Disease.

Unfortunately, the EDTA infusions must be continued in order to maintain their various benefits. Nobody knows how often treatment must be given. Over the years I have found that, after the initial series of 20, one infusion every two weeks has been adequate. A few patients have seemed to do well on monthly infusions. All of those who have stopped the treatment completely have, within two to three years, developed arterial closures and a return of their previous conditions.

It is interesting to speculate on the possible influence of universal chelation therapy on the health of the nation and on the national health bill. At the current cost, the latter would be in the neighborhood of \$2500 to \$3000 per person, per year, much less with universal utilization. A coronary artery by-pass operation currently costs \$60,000. Other possible benefits of the elimination of toxic metals in the body and the improvement of enzyme function are mind-boggling. Fortunately infusions are easily and simply administered and can be set up in every hamlet in the country.

As with Edward Jenner's claim in his discovery of smallpox vaccination in the late 1770's and that of Louis Pasteur a century later, when he told the doctors and mid-wives they were carrying child-bed fever from patient to patient because they did not wash their hands between cases,original scorn and disbelief, by the medical profession, will eventually turn to the acceptance of EDTA-chelation therapy as a valuable and useful tool in the treatment of a number of clinical abnormalities.

John H. Olwin M.D.
Clinical Professor of Surgery
Rush Medical College

For those who may wish to look further into the scientific bases for, and the benefits of chelation therapy it is recommended that he/she order a copy of a collection of papers by various scientists in the field. It is 'A Textbook on Chelation Therapy' edited by Elmer M. Cranton with a foreword by Linus Pauling. It can be obtained from the American College of Advancement in Medicine, Edward A. Shaw, M.B.A., Ph.D. Executive Director, 23121 Verdugo Drive. Suite 204, Laguna Hills, Ca. 92653 714 583 7666. The cost is approximately \$25.

THE WHITE HOUSE
WASHINGTON

June 19, 1995

Sabrina Mohammed
32 Asbury Place
Mt. Tabor, NJ 07878

Dear Ms. Mohammed:

Thank you for writing to share your ideas about teenage pregnancy. Both the President and the First Lady care deeply about children and are working to ensure that they are born into caring and supportive family environments.

After approximately 30 years of decline, the rate of teen pregnancy has begun to rise. In fact, in 1990 more than one million women between the ages of 15 and 19 became pregnant -- almost 12% of all teenage girls. Sadly, many teenagers who have children are unable to support them financially and therefore must rely on public assistance. As you noted, having children at a young age also makes it difficult for the parents to stay in school or work, especially if they do not have access to affordable child care.

The President and First Lady have launched a National Campaign Against Teen Pregnancy to prevent unwanted pregnancies. The campaign relies on leaders from all sectors of society -- business, media, entertainment, education, sports, churches, and foundations -- to raise public awareness about the crisis of teen pregnancy and to educate young people about positive life alternatives so that they will abstain from sexual activity or engage in careful family planning by using contraceptives.

I commend you for taking your school work seriously and investigating issues that you care about. I wish you continued success in your endeavors.

Sincerely,



Jennifer Klein
Senior Policy Analyst

Sabrina Mohammed
32 Asbury Pl.
Mt. Tabor, N.J. 07878.
May 1, 1995.

The White House Office
1600 Pennsylvania Avenue.
N. W. Washington, D.C. 20500.

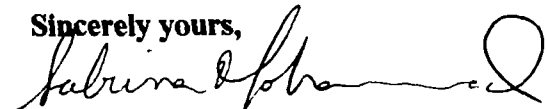
Dear Jennifer Klein:

My name is Sabrina Mohammed and I am seven-teen years of age. I am a junior at Parsippany Hills High School, who is working on a project for my U.S. II History class. This project deals with trying to make a change that I strongly believe in. I believe that teenagers under the age of eight-teen years old who gets pregnant and is not able to show the government that they are mature and will be able to support the child, it should be taken away. The reason I feel this way is because there are so many teenagers getting pregnant at young ages and getting on welfare. These teenagers then stay on welfare for most of there lives and don't even try to better themselves, most likely they will keep getting pregnant and get more money for the kids. Some just stay on welfare because they like getting the checks and don't even try to get jobs. More and more each day I personally see my young friends getting pregnant and having the kids and sometimes never graduating high school.

The government should then decide whether to put the baby up for adoption or return the baby to its parents after they are able to take care of the baby. They are so many bad things happening to babies and so many people going on welfare. Their not doing anything with their lives and are living off of welfare.

In doing much research on this topic, I have learned that about 75% of the people I have talked to about this agrees with me. In a survey that I took about 50% agrees with me on this topic, about 30% is undecided and 20% disagrees. I also put a petition together that many people signed. I learned a lot about how people felt about this subject and I have come to a conclusion that something has to be done about this problem of growing teenage pregnancy. Hopefully you may be able to do something about this or just give me your opinion even if you don't agree. Thank you.

Sincerely yours,



Sabrina Mohammed.

TEEN PREGNANCY (filename: teenpreg.tp)
JANET ABRAMS, 456-2857
3/13/95

TEEN PREGNANCY

"We've got to ask our community leaders and all kinds of organizations to help us stop our most serious social problem: the epidemic of teen pregnancies and births where there is no marriage...Tonight, I call on parents and leaders all across this country to join together in a national campaign against teen pregnancy -- to make a difference."

President Clinton, 1995 State of the Union

BACKGROUND: TEEN PREGNANCY IS OUR MOST SERIOUS SOCIAL PROBLEM

- Twelve Percent of all Teenage Girls Got Pregnant in 1990 -- more than 1 million women between the ages of 15 and 19 -- 12% of all teenage girls.
- The rates are rising From the 1950s through the early 1980s, the rate of births to teens declined steadily, however, between 1986 and 1991, the teen birth rate rose 24%. The U.S. rate of births to teens is now twice as high as in the United Kingdom and six times as high as in France, Italy, and Denmark.
- And teen births are mostly outside marriage In 1960, only 15% of teenage mothers were unmarried. By 1992, that percentage had increased to 71%.
- In all Communities Out-of-wedlock childbearing has increased greatly among both black and white teens. The rate of births outside marriage among black teenagers rose from 64% in 1970 to 93% in 1992. For white teens, the percentage of births out of wedlock more than tripled over the same period, from 18% to 61%.

THE IMPACTS

- Children in Poverty 80% of children of unwed teen mothers who have not completed high school live in poverty. In contrast, of children born to married parents at least 20 years old with a high school degree, only 8% live in poverty.
- Mothers on Welfare More than three-fourths of all unmarried teen mothers will be on AFDC at some point during the 5 years following the birth of their child.
- Other Social Ills Children of teenage parents are more likely to die in their first years, have lower cognitive achievement, repeat a grade in school, be victims of abuse and neglect, and become teen parents than children of older parents.
- Society Pays In 1991, taxpayers spent about \$34 billion to assist families begun by teenagers. 42% of families receiving AFDC were started by teen mothers, age 15-19.

A NATIONAL CAMPAIGN AGAINST TEEN PREGNANCY

We've got to ask our community leaders and all kinds of organizations to help us stop our most serious social problem: the epidemic of teen pregnancies and births where there is no marriage. Tonight, I call on parents and leaders all across this country to join together in a National Campaign against Teen Pregnancy -- to make a difference.

*President Bill Clinton
1995 State of the Union Address*

President Clinton has urged the American people to join together in an effort to stem the epidemic of children having children. He has outlined a plan of action which requires leadership by both the private and public sectors. "Government," the President has said, "can only do so much" to break the debilitating cycle of teen pregnancy and poverty.

Private Sector Initiative ...

As envisioned by the Administration, leaders from all sectors of society -- business, media, entertainment, education, sports, churches, and foundations -- would create an independent, not-for-profit organization to focus the resources and talents of the private sector on the complex problem of teen pregnancy. The organization would wage a nationwide campaign to promote individual responsibility, as well as hope and opportunity, for America's youth.

Specific functions of the organization might include:

- producing a national media campaign to raise public awareness about the crisis of teen pregnancy and promote responsible behavior
- supporting community-based initiatives which stress abstinence and pregnancy prevention and educate young people on positive life alternatives
- setting and monitoring national goals for reducing teen pregnancy and expanding economic opportunities for youth
- offering a forum for discussion of key issues by interested groups across the country
- providing training and technical assistance to local organizations
- sponsoring research and evaluation of prevention programs
- operating a clearinghouse for information on teen pregnancy and effective prevention strategies

Reasons for Optimism:

Private-sector campaigns to influence social behavior have achieved considerable success.

- The grassroots coalition Mothers Against Drunk Driving (MADD) has effectively raised public awareness about the hazards drinking and driving and contributed to significant change in Americans' behavior. Since MADD's inception in 1980, the number of alcohol-related fatalities on U.S. highways has decreased by 39%.
- In 1986, the privately funded National Partnership for a Drug Free America set out to change Americans' attitudes about drugs through targeted media activity. Between 1987 and 1993, the Partnership focused \$1.7 billion in advertising time on the issue. Drug usage declined across all segments of society over that period, and anti-drug sentiment grew significantly.

Numerous community-based initiatives have proven effective in reducing the incidence of teen pregnancy.

- In Atlanta, a program sponsored by Grady Memorial Hospital for eighth-graders provides abstinence training and contraceptive education. Children who entered the program sexually inexperienced were found to be five times less likely to become sexually active by the end of the school year than their non-program peers.
- In New York, the Adolescent Pregnancy Prevention Program (APPP) of the Children's Aid Society takes a holistic approach, offering girls and boys a wide range of services, including Family Life and Sex Education, Medical and Health, Job Club and Career Awareness, and Homework Help. Every participant who graduates from high school or earns a General Equivalency Diploma is guaranteed admission to Hunter College. Of the 250 teenagers who have participated in the Harlem APPP during the past 9 years, only eight girls have become pregnant out of wedlock, and two boys are known to have fathered children.

... In Partnership with Government

In 1992, Bill Clinton made the groundbreaking commitment to "end welfare as we know it." The President's reform plan included several measures to motivate young people to make responsible life choices:

- Teen mothers on welfare would be required to live at home with their parents, stay in school, identify the father, and move into employment within a limited period of time.
- Tough new child support laws would be strictly enforced, so that prospective teen fathers would know they had to provide child support for the next 18 years.
- States would have the flexibility to try innovative ways to encourage responsible behavior, such as rewarding teen recipients who make progress in school and

sanctioning those who drop out.

- School-based teen pregnancy prevention programs in high-risk areas
- A national teen pregnancy clearinghouse to disseminate information on model programs.

A NATIONAL CAMPAIGN AGAINST TEEN PREGNANCY

"We clearly need a national campaign against teen pregnancy that sends a clear message: It is wrong to have a child outside marriage. Nobody should get pregnant or father a child who isn't prepared to raise the child, love the child, and take responsibility for the child's future."

President Clinton, March 7, 1995

President Clinton has urged the American people to join together to stem the epidemic of children having children. He has outlined a plan of action which requires leadership from both the private sector and government.

- ✕ Private Sector Leadership . . . Recognizing that "government can only do so much" in addressing the complex issue of teen pregnancy, the President is inviting leaders of all fields -- business, sports, entertainment, education, churches, foundations -- to contribute their energy and resources to addressing the problem. A private sector campaign waged from boardrooms, t.v. stations, pulpits, and community centers across the country would promote individual responsibility, as well as hope and opportunity, for America's youth.

- In Partnership with Government In 1992, Bill Clinton made the groundbreaking commitment to "end welfare as we know it." The President's reform plan included several measures to motivate young people to make responsible life choices:
 - ✓ Teen mothers on welfare would be required to live at home with their parents, stay in school, identify the father, and move into employment within a limited period of time.
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 - ✕ States would have the flexibility to try innovative ways to encourage responsible behavior, such as rewarding teen recipients who make progress in school and sanctioning those who drop out.
 - ✕ School-based teen pregnancy prevention programs in high-risk areas
 - ✕ A national teen pregnancy clearinghouse to disseminate information on model programs.

UPDATE

The House is marking up welfare reform legislation that takes a more punitive approach to teen pregnancy, cutting off all benefits to mother and child until the mother turns 18. The administration is opposed to this approach. Floor action will occur in late March, and the Senate will take up welfare reform in April or May.

The National Campaign is in the development stages, as people outside the administration talk to leaders in a wide range of fields about taking up the President's challenge.