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August 11, 1999

VIA FEDERAL EXPRESS
Dockets Management Branch
FDA
Room 12A-16
5600 Fishers Lane
Rockville, MD 20857

Docket No. 96-0417

Dear Dockets Management Branch:

Enclosed please find an original and one copy of Joint Commenters comments in response to FDA's proposed rule published on February 6, 1997. We have also enclosed a third copy. Please date-stamp the third copy and return it to us in the self-addressed UPS envelope.

If you have any questions, please do not hesitate to contact us at the phone number above.

Sincerely,

Jonathan W. Emord
Claudia A. Lewis-Eng

Attachment

96N-0417 C 91

Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD

5701 '99 AUG 13 A8:36

ORIGINAL

In re: FDA Advance Notice of Proposed Rule Making, 62 Fed. Reg. 5700 (Feb. 6, 1997); Current Good Manufacturing Practice in Manufacturing Packing, or Holding Dietary Supplements	)))))	Docket No. 96-0417

SUPPLEMENTAL
COMMENTS OF PURE ENCAPSULATIONS, INC.; DURK PEARSON AND SANDY SHAW; WEIDER NUTRITION INTERNATIONAL, INC.; AND AMERICAN NUTRITION CORPORATION

Pure Encapsulations, Inc.; Durk Pearson and Sandy Shaw; Weider Nutrition International, Inc., and American Nutrition Corporation ("Joint Commenters"), by counsel, pursuant to 21 C.F.R. § 10.20, and in response to 64 Fed. Reg. 32830 (June 18, 1999) submits these supplemental comments in further response to the FDA's advance notice of proposed rulemaking in the above referenced proceeding. These comments supplement those originally filed by the Joint Commenters on May 7, 1997.

The Joint Commenters oppose adoption of the proposed CGMPs. The proposed CGMPs will economically harm small dietary supplement companies by substantially increasing costs of production without increasing the safety and quality of dietary supplements. Additionally, the proposed CGMPs are impractical because they seek to impose one uniform regulation on a marketplace that is as diverse as the market for foods generally. As with foods in common form, the preferable regime for ensuring safety lies in the use of Hazard Analysis and Critical Control Points ("HACCPs") in the first instance.

There is no sound justification to impose CGMPs on the entire dietary supplement marketplace when instances of harm have been isolated and rare, involving specific ingredients not all supplements. This situation is most analogous to the food context in which this agency has elected to require HACCPs as a rule and CGMPs as a specific product exception based on direct evidence of harm derived from that product.

In the advanced notice of Proposed Rulemaking published in the Federal Register on February 6, 1997, FDA proposed to promulgate regulations that would mandate that dietary supplement manufacturers (1) hire certain personnel; (2) construct and maintain certain manufacturing plants and surrounding grounds; (3) develop and implement quality assurance and adverse incident reporting systems; (4) develop and implement sanitation procedures; and (5) develop certain procedures to house and distribute the dietary supplements.

Those mandates will serve only to increase the overhead of all dietary supplement companies but will not increase the safety and quality of dietary supplements. Unfortunately, the economic impact will most affect small and mid-level sized companies that have relatively lower production output than larger dietary supplement companies. In the original submission, the Joint Commenters provided FDA with an economic impact analysis of the proposed CGMPs on small and mid-level dietary supplement companies. The economic analysis was conducted by Drs. Steve H. Hanke, Professor of Applied Economics at the Johns Hopkins University, and Stephen J. Walters, Professor of Economics at Loyola College in Maryland. Dr. Hanke is the former Senior Economist on the President's Council of Economic Advisors and specializes in making

these kinds of market assessments of the impact of regulations. In their report Drs. Hanke and Walters explain:

> The proposed regulations will have unambiguous and negative effects on industry structure and conduct. Since regulatory compliance costs will add to firms' fixed or overhead costs, they will impose a greater relative burden on small firms, which produce smaller volumes over which to spread these costs. Thus, the regulations will cause average costs to rise for all, but the increase will be proportionately greater for small firms. As a result, the proposed regulations undoubtedly will tilt the competitive playing field in this industry toward larger firms.

See Exhibit A at 6-7.

Inevitably, the new regulations will increase costs and will drive out small and mid-sized companies making the market less competitive, raising barriers to market entry, and increasing product prices. Drs. Hanke and Walters explain:

> The result will be that the number of competitors in this industry will fall, because smaller firms will be forced out of this market by larger firms which will now have a competitive advantage and because the regulations will raise new barriers to market entry over time. In consequence, this market will move away from its current atomistic structure and will become significantly more concentrated and less competitive; thus, prices and margins will rise and the gains from exchange in this market will be significantly reduced.

See Exhibit A at 7.

Moreover, the proposed regulations will force smaller companies to direct funds that were previously dedicated to research and development to compliance mandates. See Exhibit A at page 8. Instead of funding clinical trials and scientific research for their products, small companies will be forced to expend their limited resources on additional personnel, expensive manufacturing equipment, and various kinds of product testing to ensure compliance with FDA regulations.

The increased costs that small companies will be forced to absorb will not ensure FDA the safety and quality it seeks. To the contrary, because dietary supplements are already generally safe and of high quality[1], FDA's proposed rule serves only to harm the public by unnecessarily increasing costs, decreasing the availability of dietary supplements and increasing barriers to entry. Congress has expressly found it an essential purpose of the Dietary Supplement Health and Education Act to avoid the removal of dietary supplements from the market that are otherwise safe and effective. 21 U.S.C. § 321 note. The effect of the Proposed Rule would be to achieve that end, wiping out as much as 1/3 of the current market. See Exhibit A at 2.

Instead of imposing CGMPs, FDA should review the evidence that demonstrates the relative safety of dietary supplements compared to food and drugs. Indeed, the incidences of threat to public health connected with the consumption of dietary supplements have been relatively isolated. See Exhibit B at 2-3. Moreover, the adulteration, misbranding and penalties provisions of the Food, Drug and Cosmetic Act provide FDA with adequate enforcement authority to take adverse action against companies that distribute products that pose a threat to public health. See 21 U.S.C. §§ 342, 343, and 333.

The dietary supplement industry is too diverse to be regulated by a single manufacturing regulation. Dietary supplements are marketed in a wide range of product forms such as powders, capsules, tablets, liquids, and gelcaps; they may also be marketed in common food form provided that they are labeled as dietary supplements. Dietary

[1] The original comments submitted by Joint Commenters provided the Expert Report of Dr. Harry G. Preuss, Professor of Medicine and Pathology at Georgetown Medical Center. In that Report Dr. Preuss confirmed that the dietary supplement market is characterized by a degree of safety far superior to the food and drug markets. See Exhibit B.

supplements range from herbal extracts to simple vitamin and mineral formulas to complex herbal, vitamin and mineral forms to even more complex forms including new dietary ingredients. Some dietary supplement manufacturers simply finish and bottle supplements from bulk ingredients while others grow, harvest and produce herbal extracts that are treated then finished for consumption. Because dietary supplements are marketed in various forms and with varying ingredients, the nature and production of each dietary supplement varies greatly. Requiring each dietary supplement company to operate under the same manufacturing regulations is therefore an impractical solution that will burden some greatly, without justification, and others less so, inequitably. With such diversity it is most appropriate to adopt regulations that permit manufacturers to develop HACCPs that are tailored to address the company's specific safety concerns. This approach favored for foods, is likewise the best method for dietary supplements.

The Joint Commenters request that FDA adopt HACCP regulations in lieu of the proposed CGMPs for another central reason. Scientific evidence concerning the best means to produce the diverse array of supplements is incomplete. USP standards cover but a small subset of the universe. Thus, the agency lacks a sufficient scientific basis upon which to ground CGMPs for the entire industry. Rather, as with foods generally, the company is in the best position to identify its own production risks and best countermeasures. HACCPs are thus the only reasonable alternative. The proposed CGMPs would require extensive testing to determine the purity of herbs and botanicals. That requirement is illogical in light of the fact that laboratories lack the analytical procedures to establish the purity of many of the herbs and botanicals that are used as dietary ingredients. In cases where there are analytical procedures available, the

techniques that must be used are so expensive that small companies would not be able to afford the testing as often as is required in the proposed CGMPs. Moreover, safe, less expensive alternatives should be available to the companies.

In short, promulgating a single regulation to govern such a diverse industry serves to impose unnecessary costs on certain manufacturers in the industry and fails to take into account the limits of testing technology. Accordingly, the Joint Commenters recommend that FDA adopt regulations that would permit each company to develop HACCPs that are tailored to the company's specific safety concerns.

For the foregoing reasons, the Joint Commenters respectfully request that the FDA not adopt the proposed CGMPs and, instead, adopt narrowly tailored regulations that permit companies to develop HACCPs. The HACCP system is the least likely to harm the dietary supplement industry and is most likely to provide the greatest chance of enhancing consumer safety.

Respectfully submitted,

PURE ENCAPSULATIONS, INC.;
DURK PEARSON and SANDY SHAW;
WEIDER NUTRITION INTERNATIONAL;
and AMERICAN NUTRITION CORPORATION,

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Dated: August 11, 1999

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PERSONAL

Born December 20, 1953, Salem, MA. Married, two children.

EDUCATION

1982: Ph.D., Economics, University of California, Los Angeles
1977: M.A., Economics, University of California, Los Angeles
1975: B.A., Economics, University of Pennsylvania

EMPLOYMENT HISTORY

1993- :	Professor and Economics Department Chair, Loyola College in Maryland.
1986-93:	Associate Professor of Economics, Loyola College in Maryland.
1981-86:	Assistant Professor of Economics, Loyola College in Maryland.
1980-81:	Lecturer in Economics, California State University, Northridge.
1979-80:	Lecturer in Economics, Santa Monica College.
1979-80:	Research Analyst, Kotin & Regan, Inc., Economic Consultants, Los Angeles.
1977-79:	Teaching Associate in Economics, University of California, Los Angeles.
1975-76:	Senior Research Assistant, Dept. of Research, Federal Reserve Bank of Philadelphia.

FIELDS OF SPECIALIZATION

Research: Industrial organization and regulation; economic analysis of law; public policy analysis; privatization; corporate valuation; pricing strategy.

Teaching: Microeconomics (introductory and intermediate); industrial organization; business and government; American economic history; managerial economics.

PUBLISHED ARTICLES

[1] "Reciprocity, Rebating, and Regulation," *Southern Economic Journal*, v. 51, no.

3 (January 1985), pp. 766-75.

[2] "Reciprocity Reexamined: The Consolidated Foods Case," *Journal of Law & Economics*, v. 29, no. 2 (October 1986), pp. 423-38.

[3] "Privatization and Natural Monopoly: The Case of Waterworks," *Privatization Review*, v. 3, no. 1 (Spring 1987), pp. 24-31 (with Steve H. Hanke).

[4] "Effects of Department Size and Organization on the Research Productivity of Academic Economists," *Economics of Education Review*, v. 7, no. 2 (1988), pp. 251-55 (with John M. Jordan and Mark Meador).

[5] "Recent Controversies in the Valuation of Utility Property," *Public Utilities Fortnightly*, v. 122, no. 2 (July 21, 1988), pp. 22-26 (with Steve H. Hanke). Reprinted in *Valuation*, v. 35, no. 1 (January 1990), pp. 28-34.

[6] "Is the NFL an Illegal Monopoly?" *University of Detroit Law Review*, v. 66, no. 1 (Fall 1988), pp. 5-32 (with John A. Gray).

[7] "How Plaintiffs' Experts Can Exaggerate Salary Losses," *The Practical Lawyer*, v. 35, no. 6 (September 1989), pp. 17-29 (with Steve H. Hanke).

[8] "Academic Research Productivity, Department Size, and Organization: Further Results," *Economics of Education Review*, v. 8, no. 4 (1989), pp. 345-52 (with John M. Jordan and Mark Meador).

[9] "Business Climate and Measured Poverty: The Evidence Across States," *Atlantic Economic Journal*, v. 18, no. 1 (March 1990), pp. 20-26.

[10] "Social Regulation: A Report Card," *Journal of Regulation and Social Costs*, v. 1, no. 1 (September 1990), pp. 5-34 (with Steve H. Hanke).

[11] "Academic Research Productivity: Reply, Still Further Results," *Economics of Education Review*, v. 11, no. 2 (1992), pp. 161-67 (with John M. Jordan and Mark Meador).

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"Privatization and Public Choice: Lessons for the LDCs," in Dennis Gayle and Jonathan Goodrich, eds., *Privatization and Deregulation in Global Perspective*, Westport, CT: Greenwood Press (1990), pp. 97-108 (with Steve H. Hanke).

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BOOK REVIEWS

Review of: Thomas J. Trebat, *Brazil's State-Owned Enterprises: A Case Study of the State as Entrepreneur*, *Southern Economic Journal*, v. 52, no. 2 (October 1985), pp. 593-94.

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Review of: Alan Ehrenhalt, *The Lost City: Discovering the Forgotten Virtues of Community in the Chicago of the 1950s*, *The Freeman*, v. 46, no. 7 (July 1996), pp. 530-31.

UNPUBLISHED WORKING PAPERS, MANUSCRIPTS

"Vertical Market Division: Notes and Cases." Working Paper 87-1, Sellinger School of Business and Management, Loyola College in Maryland.

"Free Agent Sports Franchises and Antitrust: The Raiders Case." Working Paper 88-3, Sellinger School of Business and Management, Loyola College in Maryland.

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"U.S. labor faces tough decisions," Baltimore *Evening Sun*, Feb. 28, 1983.

"Protectionists are coming! Protectionists are coming!" Baltimore *Evening Sun*, Apr. 5, 1983.

"Baltimore becomes one of the '10 poorest'; what went wrong?" Baltimore *Evening Sun*, Apr. 19, 1983.

"We don't need a 'hostile takeover' law," Baltimore *Evening Sun*, June 21, 1983.

"A Baltimore Catholic challenges the bishops' letter," Baltimore *Evening Sun*, Sept. 23, 1983.

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"Behind bus strike: deregulation," Baltimore *Evening Sun*, Nov. 8, 1983.

"A tale with many morals, but not a moral tale," Baltimore *News American*, Nov. 29, 1983.

"'Equal pay for equal work' isn't that simple," Baltimore *Evening Sun*, Nov. 30, 1983.

"Does the UMW forget its own jobless?" Baltimore *Evening Sun*, Jan. 17, 1984.

"Subminimum wage for Maryland teenagers?" Baltimore *Evening Sun*, Feb. 20, 1984.

"Hostility to teen subminimum wage keeps young people jobless," Baltimore *Evening Sun*, May 23, 1984.

"Reagan's tax cuts successfully defy Mondale's logic," Baltimore *News American*, Sept. 21, 1984.

"Why has Maryland lost 71,000 industrial jobs since '69?" Baltimore *Evening Sun*, Oct. 23, 1984.

"The Bishops on the Economy," *Loyola* Magazine, Spring 1985; *Catholic Review*, July 17, 1985.

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"'Limousine liberals' fight to keep tax deduction," Baltimore *Evening Sun*, June 13, 1985.

"Let consumer's skepticism be his protection," *Catholic Review*, Aug. 21, 1985.

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"Baltimore's renaissance: Figures distorted picture," Baltimore *Sun*, Sunday, Aug. 17, 1986.

"Congress will bilk consumers to serve special interests," Baltimore *Evening Sun*, Dec. 3, 1986.

"What Schaefer has to do for Maryland's economy," Baltimore *Evening Sun*, Jan. 15, 1987.

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"Why is gas so high?" Baltimore *Evening Sun*, Aug. 10, 1990.

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"Maryland Will Rise Again," Loyola Institute for Business and Economic Research *Executive Business Outlook*, June 1992.

"Making Cal Ripken richer will not make the rest of us poorer," Baltimore *Evening Sun*, Aug. 28, 1992.

"Though it may be a case of dumb luck, Clinton's plan looks like a winner," Baltimore *Evening Sun*, March 31, 1993.

"Is BUILD trying to tear down?" Baltimore *Evening Sun*, June 22, 1994.

"The NFL: Have money? Will travel," San Diego *Union Tribune*, November 16, 1995; *Newsday*, November 24, 1995; Cincinnati *Post*, December 15, 1995.

Author of over 50 additional articles in metropolitan weekly newspapers.

HONORS, AWARDS, MEMBERSHIPS, APPOINTMENTS

Inducted as Honorary Member, Alpha Sigma Nu (National Jesuit Honor Society), 1987; awarded Loyola College Faculty Research Grants, 1985-87, 1989-90, 1992, and Sellinger School, Board of Sponsors Research Grant, 1988; awarded Smith-Richardson Fellowship in Political Economy, 1980, and California Regents Fellowship in Economics, 1976-77.

Appointed to Maryland Governor's Advisory Council on Unemployment Compensation, 1990; member, American Economic Association and American Law and Economics Association.

SERVICE AS REFEREE

The Journal of Legal Economics
The Cato Journal
The Dryden Press

EXHIBIT B

RELATIVE SAFETY OF DRUGS, FOOD, AND SUPPLEMENTS: A COMPARATIVE REVIEW

BY

HARRY G. PREUSS, M.D., F.A.C.N.

RELATIVE SAFETY OF DRUGS, FOOD, AND SUPPLEMENTS: A COMPARATIVE REVIEW

Harry G. Preuss, M.D., F.A.C.N.

Less adverse reactions may occur from use of supplements than pharmaceuticals and foods. I base this on evidence to date which indicates considerably less potential for toxicity from supplements compared to the other two groups, i.e., the risk/benefit ratios for various types of supplements are quite good. This assumption will be defended below.

Many consumers take dietary supplements. These can be composed of single agents or of a broad spectrum of product forms and ingredients; the latter may include vitamins, minerals, herbs and other botanicals, amino acids, etc. One estimate reveals that 40% of Americans use supplements – a conservative guess is that at least 135 million people take a vitamin supplement each day. Focusing on vitamins, they are extremely safe based on various surveys carried out by the American Association of Poison Control Centers (AAPCC), the physician reporting service of the American Medial Association, and the U.S. Public Health's Center for Disease Control. The AAPCC published reviews for the years 1983 to 1990 which showed no deaths directly attributed to vitamins unlike results for pharmaceuticals among over 10 million cases of poisonings using a population base of over 190 million Americans (Tables 1 & 2).

Table 1.

Fatalities Resulting From Poisonings by Vitamin Supplements in USA*

First Eight Annual Reports of the American Association of Poison Control Centers

	1983	1984	1985	1986	1987	1988	1989	1990
# Centers Reporting Data	16	47	56	57	63	64	70	72
Multiple Vitamins-Adult	00	00	00	00	00	00	00	00
Multiple Vitamins-Children	00	00	00	00	00	00	00	00
Vitamin A	00	00	00	00	00	00	00	00
Niacin	00	00	00	00	00	00	00	00
Pyridoxine	00	00	00	00	00	00	00	00
Other B Complex	00	00	00	00	00	00	00	00
Vitamin C	00	00	00	00	00	00	00	00
Vitamin D	00	00	00	00	00	00	00	00
Vitamin E	00	00	00	00	00	00	00	00
TOTALS	**00**	**00**	**00**	**00**	**00**	**00**	**00**	**00**

Table 2

Fatalities Resulting From Poisonings by Pharmaceuticals in USA*

Category of Drugs	1983	1984	1985	1986	1987	1988	1989	1990
Analgesics	22	53	87	82	93	118	126	134
Antidepressants	19	57	90	100	105	35	140	159
Asthma Therapies	04	10	11	21	16	27	34	37
Cardiovascular Meds	05	18	21	50	52	65	70	79
Sedatives/Hypnotics	11	51	62	61	48	77	78	72
Amphetamines	01	04	06	11	11	12	05	06
TOTALS	**62**	**193**	**227**	**325**	**325**	**434**	**453**	**487**

*From the Towsend Letter for Doctors, April 1992

In contrast to the reports on nutritional supplements (Table 1), the total number of fatalities from pharmaceuticals in the above categories equals 2446 over 8 years (Table 2). Obviously, figures of adverse reactions from supplements approaching those give above for the pharmaceuticals do not exist. Sure, there will be cases of overdose of an ingredient from a supplement when the individual does not follow label instructions or the advice of a health-care provider. However, these occur much more frequently with pharmaceuticals and foods. For example, cases of sodium and potassium overload from foods and pharmaceuticals are not uncommon in diabetics and other listed categories. In the case of supplements, there were recent reports of eosinophilia myalgia syndrome due to L-tryptophan usage. This was later found to emanate from a contaminated batch of the amino acid from one manufacture – in other words, the injuries were produced by a contaminant, not the natural product itself. Suffice it to say these happenings are rare with supplements.

Although the above example of supplement safety (Table1) includes only vitamins, other supplements such as minerals, herbs, botanicals, amino acids, etc. when taken properly are equally safe. Certainly, the safety record of supplements is far superior to over-the-counter drugs, e.g., Tylenol, which are frequently associated with abnormalities of liver function, especially in alcoholics.

The fact that supplements, for the most part, are natural products that have been taken by humans over many years (and in many countries) assures that their safety has been tested adequately. Pharmaceuticals undergo testing in four phases. In Phase 1, the toxicity study is usually performed on normal volunteers – in many cases, on less than 10 individuals. Phase 2 efficacy studies may be carried out on less than 100 patients. Phase 3 studies may be multi-centered and performed on thousands of patients. If a severe adverse reaction occurs at a frequency of 1/10,000, it could be missed in Phase 1-3, since it may not have occurred or the single occurrence may be attributed to something else. Accordingly, following the marketing of pharmaceuticals in Phase 4 when a large proportion of the public is using the preparation, could reveal the toxic reactions. In the

case of the majority of natural products, these have been tested by huge numbers of individuals over the centuries. One might say that supplements have already undergone "phase 4 trials."

Vitamins in large doses have been used in the 90s – vitamin A derivatives for treating acne and age-related skin damage: vitamin D3 for treatment and prevention of psoriasis, and niacin to reduce neural tube defects during the preconception time of pregnancy. For the most part, these are being prescribed and usage directed by licensed health-care professionals, who are able to weigh the risk/benefits of the therapy. Nonetheless, the problems with their usage arise from using higher than usual doses, not from the basic elements themselves.

Foods provide an adverse reaction rarely found in pharmaceuticals and supplements. Many foods, unlike pharmaceuticals and supplements, provide an excellent media for the growth of pathogens. Food poisoning can be caused by eating foods contaminated with bacteria or bacteria-produced toxins. It can also result from eating foods that contain a naturally occurring poison such as certain types of mushrooms and fish. A recent five-year report from the Centers for Disease Control and Prevention (CDC) identifies Salmonella as the leading cause of food-borne illness and death. Concerning food poisoning, 79% were traced to bacterial pathogens in outbreaks where a cause was determined. While the load of bacterial pathogens can be diminished considerably by good manufacturing practices, as well as good sanitary procedures in nursing homes, hospitals, cafeterias, and at home, it cannot be eliminated completely. Thus, proper cooking procedures must be carried out on eggs and poultry. Recent reports from Japan concerning food poisoning report 29,513 cases in 1994 and 22,329 in 1995 (surpassing 19,089 in 1993). It is estimated that from 2-4 million cases of salmonella poisoning occur in the U.S. annually.

Staphylococci grow in dairy products and in poorly cooked meat and fish. In contrast to a slower onset of salmonella toxicity, symptoms begin two to six hours after the food contaminated with staphylococcus is eaten and include nausea, vomiting, stomach cramps, and diarrhea. Botulism is rare, but is an extremely severe form of food poisoning caused by foods that have not been properly canned or preserved. Botulism can be fatal. Other maladies caused by food result from trichinosis in pork, E coli and salmonella from beef, cynotoxins and hepatitis from seafood, aflatoxins from peanuts, and toxins from mushrooms. Suffice it to say onset of food poisoning from supplements comparable to poisoning from foods is extremely rare if it occurs at all.

The excellent record showing little risk in using supplements suggests a rationale for their usage. They have far fewer adverse side effects compared to pharmaceuticals and have shown little penchant to harbor bacteria or bacteria-produced toxins. Admittedly, therapeutic benefits must be proven more definitively in most cases. Huge multi-center trials of these agents, unlike pharmaceuticals, have not been carried out. However, the risks are so negligible that supplemental use for prevention may be warranted prior to "state-of-the-art," multi-center, double-blinded, placebo controlled

investigations. Even though the data concerning benefits are not conclusive, I supplement with chromium. In the case of chromium supplementation (the second leading supplement sold), the risks are virtually nonexistent. Data from animal and human studies show no known toxicity, but indicate a potential to overcome cardiovascular risk factors, ameliorate diabetes, and even augment healthful life span. It is possible that some adverse reaction may take place 20 years from now, but this is true of pharmaceuticals as well. Accordingly, the risks are so unlikely, that it is worth taking with the potential for the benefits.

In summary, when comparing pharmaceuticals and foods with supplements, the potential for toxicity of the later is far less than for the two former categories. Toxicity is rare with supplements – Vitamin A toxicity is unlikely, Vitamin C renal stones are extremely rare, and there should be no problems from vitamin D when taken as directed. With little risk involved, it is worth allowing these products on the market in an unencumbered fashion, because there may be a connection between dietary supplement use, reduced health-care expenses, and disease prevention.

EXHIBIT A

MEMORANDUM

To: Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., rm. 1-23
Rockville, MD 20857

From: Steve H. Hanke, Ph.D.
Professor of Applied Economics
The Johns Hopkins University
Baltimore, MD 21218

and Stephen J.K. Walters, Ph.D.
Professor of Economics
Loyola College in Maryland
Baltimore, MD 21210

Re: "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements"--Comments
[Docket No. 96N-0417]
RIN 0910-AA59

Date: May 7, 1997

1. Introduction

The FDA is considering whether to institute rulemaking to develop current good manufacturing practice (CGMP) regulations for dietary supplements and dietary supplement ingredients. This economic assessment is offered in support of comments to be filed with the Food and Drug Administration.

We conclude that the proposed regulations will not produce an increase in public safety--and may even reduce it. In addition, such regulations will lead to a more concentrated, less competitive industry; this will raise prices to consumers and significantly reduce the gains from exchange in this market. Finally, such regulations will significantly reduce research productivity and the rate of innovation in this dynamic industry. In sum, consumers will pay more for a restricted array of products, and in return will receive no greater level of safety from product defects than they currently enjoy. Clearly, regulatory resources are limited; there must be many higher-valued uses of the resources which would be consumed should the proposed CGMP regulations be implemented.

In the remaining sections of this memorandum, we will discuss the anticipated effects of

the CGMP regulations in more detail, supporting our analysis with references to authoritative research. Section 2 briefly discusses the current status of the dietary supplement industry. Section 3 describes the ways in which consumers are protected from unsafe or low-quality goods in unregulated markets. Section 4 summarizes some evidence on how regulation (or, in some cases, deregulation) has affected consumer safety, and offers some forecasts about safety should regulation come to the dietary supplement industry. Section 5 assesses the competitive impact of regulation on market structure and firm conduct (e.g., pricing). Section 6 discusses the impact of regulation on the rate of innovation. Section 7 contains concluding remarks.

2. Brief Overview of the Industry

In its current form, the natural products industry (of which the dietary supplements industry is a part) approaches what economists might call a "competitive ideal." There are many producers, all acting independently, and none exercising appreciable market dominance or monopoly power. There are no artificial barriers to entry. Pricing is very competitive, and the rate of product innovation is admirably high.

Though the natural products industry is large in absolute dollar terms, with natural product sales exceeding $11 billion in 1996, it accounts for only about 2% of the overall grocery market. Nevertheless, sales growth has been a very robust 22% per year since 1991. Dietary supplements (a designation which encompasses vitamins, supplements, natural medicines, and herbs) make up almost 80% of dollar sales at the average small, supplement-focused store, and about 20% of sales at large, natural-products supermarkets; there are currently 6,600 natural/health food retail outlets, about half of which are small (under 2,000 square feet).[1]

The market is expanding rapidly not just in terms of dollar sales, but in the variety of products available to consumers. By one estimate, there were 4,000 to 5,000 new product introductions in the natural products industry in 1995. One major distributor currently carries an average of 15,000 items in its warehouses, and estimates it will need to increase this number by about one-third within the next few years.[2]

Despite the industry's rapid growth and extraordinary rate of innovation, there is no evidence that consumer safety has been compromised. To our knowledge, the only supplement-related public health problem in recent years involved the development of eosinophilia-myalgia (EMS) in association with the ingestion of supplements containing the amino acid tryptophan in

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[1]See: "Market Overview, 1995" and "Market Overview Preview, 1996," *Natural Foods Merchandiser*.

[2]*Ibid.*

1989.[3] EMS resulted in 38 deaths and about 1,500 cases of illness. By contrast, there are approximately 9,000 deaths annually from contaminated foods.

In sum, the market for natural products and dietary supplements appears to be functioning about as well as any real-world market can. The gains from exchange in this market are large and growing rapidly; this growth signals a high level of consumer satisfaction that appears to be a direct function of competitive pricing, strong service, and a most impressive rate of innovation. If it is possible to improve performance in this market--from the standpoint of consumer welfare--it would be very difficult indeed to describe how.

3. Market-Based Safety and Quality-Assurance Mechanisms

It is common to suppose that, absent some sort of regulatory mechanism, consumers will be vulnerable to unscrupulous producers of unsafe or merely shoddy products. It is certainly true that consumers are vulnerable; there are virtually no products about which consumers are as well-informed as are the goods' producers. What is often overlooked, however, is that consumers are aware of their informational disadvantage vis-a-vis sellers, and commonly take steps to assure that sellers have strong incentives not to take advantage of them.

The most important mechanism in this regard is consumer reliance on brand-names.[4] Simply put, a firm's brand-name or reputation serves as collateral--more formally, as a *forfeitable collateral bond*--that will depreciate if consumers are disappointed in the quality of the product the firm provides. Before risking their money (or safety) on the purchase of a product about which they know relatively little (compared to the seller, who likely knows whether the product has actually been produced using "good practice" or not), consumers want to know that the seller has something to lose if the product proves to be of lower-than-anticipated quality. Thus, consumers rationally resist buying the products of "unknown" sellers. Sellers' brand-names or reputations are useful to consumers because, once a name or reputation has been created--often at considerable expense--it is an asset that depends for its value on consumers' continued favorable opinion of the firm. In seeking to maintain the value of their brand-name assets, firms will have very strong incentives to satisfy consumers expectations about product quality and safety.

Many studies have documented that this mechanism works extraordinarily well. For example, in the airline industry, carriers which are responsible for crashes are punished with

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[3]See: Belongia, *et al.*, "An Investigation of the Cause of the Eosinophilia-Myalgia Syndrome Associated with Tryptophan Use," *New England Journal of Medicine*, (August 9, 1990), pp. 357-65, and Kamb, *et al.*, "Eosinophilia-Myalgia Syndrome or Fibromyalgia with Eosinophilia -- A Reply," *Journal of the American Medical Association*, (June 23-30, 1993), pp. 3108-09.

[4]For a more detailed summary of this mechanism, see: Stephen J.K. Walters, *Enterprise, Government, and the Public*, McGraw-Hill Book Co. (1993), New York, pp. 309-312.

significantly reduced patronage and huge equity losses, while crashes which are not the airlines' fault (resulting from, e.g., climatic conditions) suffer no reputational losses.[5] Airlines' brand-name assets are so important to their performance that airline deregulation has not led to compromises in consumer safety.[6] And in the over-the-counter drug market, the tremendous amount of brand-name capital that the Johnson & Johnson Co. had at risk with its *Tylenol* brands led the firm to take strong measures to protect public safety in the aftermath of the 1982 and 1986 poisonings.[7] Of course, the best evidence that the market mechanism is effective at providing safe, high-quality products is the relative scarcity of such events.

Reinforcing and supplementing this quality- and safety-assurance mechanism are private certification agencies and the courts. Private certification agencies, including producers' insurance carriers and a variety of independent information-gathering and bonding agencies (e.g., Underwriters' Laboratories--the familiar "UL" label), help to reassure consumers that firms have "posted a bond" in markets where traditional means of creating brand awareness (commonly, mass advertising) are less useful. And, of course, tort law exists to ensure that firms which sell products that result in harm to consumers will suffer large losses.

The key question which must be answered prior to implementing any new safety regulations is whether the regulations will add anything to these pre-existing quality- and safety-assuring mechanisms. Regulatory resources are scarce; we certainly do not want to squander them where there will be little incremental benefit to the public. And, as a review of the evidence on regulatory performance shows, regulation sometimes has the capacity actually to reduce consumer safety.

4. Regulation and Safety: Retrospect and Prospect

Safety regulation has produced some notable triumphs. For example, if we had done nothing to tighten auto safety standards, it is possible that the number of annual highway fatalities would be about 60,000 rather than 40,000-45,000.[8] But a careful review of the literature on health and safety regulation cannot help but leave one disappointed with overall

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[5]Mark L. Mitchell and Michael T. Maloney, "Crisis in the Cockpit? The Role of Market Forces in Promoting Air Travel Safety," *Journal of Law and Economics*, 32 (October 1989), pp. 329-55.

[6]Steven Morrison and Cliff Winston, "Enhancing the Performance of the Deregulated Air Transport System," *Brookings Papers: Microeconomics*, The Brookings Institution (1989), Washington, DC, pp. 84-99.

[7]Mark L. Mitchell, "The Impact of External Parties on Brand-Name Capital: The 1982 *Tylenol* Poisonings and Subsequent Cases," *Economic Inquiry*, 27 (October 1989), pp. 601-18.

[8]Robert W. Crandall, *et al.*, *Regulating the Automobile*, The Brookings Institution, Washington, DC, 1986.

performance in this area.[9] For example, most studies of the effects of Occupational Safety and Health Administration regulations on occupational illness and injury rates have found *no* favorable effects--though more recent studies have found small improvements in the incidence of minor injuries.[10] Other studies have found no safety benefits of the Consumer Product Safety Commission's mattress flammability[11] and bicycle safety[12] standards.

Most vexing, however, are the studies documenting *negative* effects of safety regulation. One study of the CPSC's "childproof safety cap" regulation found that total poisoning rates were higher than would have been the case absent the regulations.[13] The CPSC's flammability standards for carpets have actually been associated with a doubling of carpet-related injury rates.[14] And an international comparison of mortality data from drug consumption has found that, all else constant, there are more poisoning deaths in countries that rigorously enforce prescription regulation.[15]

The culprit here is what appears to be "offsetting behavior" by consumers. Simply put, consumers--feeling that regulators have "solved" safety problems for them--are less vigilant than they otherwise would be, or modify their behavior in potentially risky ways. The safety cap regulations, for example, led some parents to be less careful about where they stored potentially harmful products, or the caps' inconvenience caused some to leave the caps off entirely; absence of safety caps on some products led some consumers to (erroneously) conclude the products were totally safe. Even where there are net positive effects of regulation on safety,

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[9]See, e.g., Steve H. Hanke and Stephen J.K. Walters, *Social Regulation: A Report Card*, National Chamber Foundation (1990), Washington, DC.

[10]W. Kip Viscusi, "The Impact of Occupational Safety and Health Regulation, 1973-83," *Rand Journal of Economics*, 17 (Winter 1986), pp. 567-80.

[11]Peter Linneman, "The Effects of Consumer Safety Standards: The 1973 Mattress Flammability Standard," *Journal of Law and Economics*, 23 (October 1980), pp. 461-79.

[12]Ross D. Petty, "The Consumer Product Safety Commission's Promulgation of a Bicycle Safety Standard," *Journal of Products Liability*, 10 (1987), pp. 25-50.

[13]W. Kip Viscusi, "The Lulling Effect: The Impact of Child Resistant Packaging on Analgesic Ingestions," *American Economic Review*, 74 (May 1984), pp. 324-27.

[14]W. Kip Viscusi, "Consumer Behavior and the Safety Effects of Product Safety Regulation," *Journal of Law and Economics*, 28 (October 1985), pp. 527-53.

[15]Sam Peltzman, "The Health Effects of Mandatory Prescriptions," *Journal of Law and Economics*, 30 (October 1987), pp. 207-38.

there is evidence of some partially-offsetting behavior by consumers.[16]

The key question in this case is whether the proposed CGMP regulations pose the risk of some offsetting behavior by consumers. We believe they do.

Note first that the dietary supplement industry is one where consumers are generally skeptical of the efficacy and safety claims of sellers; as a result, consumers rely heavily on brand-name capital and the reputations of firms and trusted experts in the field when making their consumption choices. Given the extraordinarily low accidental death rate in this industry, it is fair to say that this safety- and quality-assurance mechanism has worked well.

The proposed regulations, however, are likely to upset this equilibrium. Under regulation, consumers may be more apt to risk purchasing "unbranded" products or the products of "unknown" producers. The idea that "the government wouldn't let them sell it if it wasn't safe and effective" will take root. Of course, regulatory enforcement resources are limited; it will be essentially impossible for regulators to authenticate the claims of all producers. Nevertheless, the *appearance* of oversight by regulators will give a boost to "fly-by-night" sellers; they will no longer need to make heavy investments in brand-name or reputation in order to induce trials by consumers.

Unless the regulatory authority is willing to commit massive resources to enforcement, then, the safety implications of the proposed regulations are, at best, ambiguous. Replacing the market-based safety- and quality-assurance mechanism with a regulatory system that is enforced with less than perfect efficiency may reduce the probability that the products of an established seller are unsafe or ineffective, but will also certainly increase the probability that a consumer will buy the product of an unscrupulous seller.[17] We believe there is a great probability that the latter effect will dominate, and that regulation will have a negative net effect on safety in this market--as it has in several others.

5. Regulatory Effects on Industry Structure and Conduct

The proposed regulations will have unambiguous and negative effects on industry structure and conduct. Since regulatory compliance costs will add to firms' fixed or overhead costs, they will impose a greater relative burden on small firms, which produce smaller volumes

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[16]Sam Peltzman, "The Effects of Automobile Safety Regulation," *Journal of Political Economy*, 83 (July-August 1975), pp. 667-725; Robert W. Crandall and John D. Graham, "Automobile Safety Regulation and Offsetting Behavior: Some New Empirical Estimates," *American Economic Review*, 74 (May 1984), pp. 328-31.

[17]This is because the seller is (a) indifferent to the long-run implications of consumer dissatisfaction when he has little or no brand-name capital at risk, and (b) aware that regulatory enforcement is imperfect, and so the probability of paying a penalty for defying the regulations is less than 1.0.

over which to spread these costs. Thus, the regulations will cause average costs to rise for all, but the increase will be proportionately greater for small firms. As a result, the proposed regulations undoubtedly will tilt the competitive playing field in this industry toward larger firms.

The result will be that the number of competitors in this industry will fall, because smaller firms will be forced out of this market by larger firms which will now have a competitive advantage and because the regulations will raise new barriers to market entry over time. In consequence, this market will move away from its current atomistic structure and will become significantly more concentrated and less competitive; thus, prices and margins will rise and the gains from exchange in this market will be significantly reduced.[18]

Given that the proposed CGMP regulations actually were submitted by "representatives of the dietary industry,"[19] it is quite likely that these effects are well understood by industry insiders--and, indeed, may have motivated the proposals. There is ample empirical research showing that firms sometimes embrace regulation as a competitive tactic. The key here is what economists have dubbed *enforcement asymmetries*, in which regulatory requirements or costs have a disproportionate impact on a subset of firms, leaving remaining firms to enjoy enhanced market demand, diminished competition, and competitive advantage.

The best-known example has to do with the 1977 amendments to the Clean Air Act, in which environmentalists lobbying for regulations to force western public utilities to install smokestack scrubbers found they had some unexpected allies: eastern coal mining companies (and their legislators). The reason was that eastern coal contains about 16 times as much sulfur as western coal; eastern producers knew if they could get Congress to require installation of sulfur dioxide *scrubbers* rather than merely specifying how much sulfur dioxide could be *emitted* from stacks, their cheaper, higher-sulfur coal would be easier to sell. Despite an EPA report noting that *compliance costs and sulfur emissions levels would be higher* under a scrubbing requirement than under a feasible alternative, the requirement passed.[20]

In other industries, EPA and OSHA regulations have been used to protect older, unionized firms in northeastern states from the competition of younger, non-unionized firms in

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[18]For a review of the evidence on the relationship of market concentration to prices and profits, see Walters, *op. cit.*, pp. 186-89.

[19]See "Memorandum of Meeting, Center for Food Safety and Applied Nutrition, Food and Drug Administration," Washington, DC, November 30, 1995.

[20]Bruce A. Ackerman and William T. Hassler, *Clean Coal/Dirty Air, or How the Clean Air Act Became a Multi-Billion Dollar Bail-Out for High-Sulfur Coal Producers and What Should Be Done About It*, Yale University Press (1981), New Haven, CT.

southern states.[21] In some cases, CPSC regulations have been used to protect domestic firms from foreign competition.[22]

Such unwholesome use of the regulatory process--dubbed "predation through regulation" or "predatory use of government" by some economists[23]--damages consumer welfare in two ways. First, as has already been noted, it reduces the gains from exchange in affected markets by raising prices and reducing quantity demanded. Second, it diverts regulatory enforcement resources from activities where they may have a high return to where they have a low or negative return. In this case, there is a very real likelihood that regulatory resources which have the capacity to significantly improve safety levels in food and pharmaceutical markets will be misallocated toward markets where they will, in effect, be used to prop up a cartel rather than enhance public safety.

6. Regulatory Effects on Innovation

There is a wealth of evidence that regulation can have a large negative impact on the rate and timing of product innovations.[24] Such "regulatory lag" has been especially important in the pharmaceutical industry, where, for example, the 1962 amendments to the Food, Drug, and Cosmetic Act have been blamed for a stunning reduction in the rate of introduction of new drugs in the U.S.

Of course, reducing the rate of introduction of new chemical entities was the *goal* of the 1962 amendments; it is commonly assumed that the drugs kept off the market by these regulations were of dubious safety and efficacy, and that, on net, the regulations enhanced welfare. Yet a variety of studies have shown that, in fact, the regulations did not significantly reduce the proportion of new drugs that proved ineffective, and that the absolute reduction in

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[21]Ann P. Bartel and Lacy Glenn Thomas, "Predation through Regulation: The Wage and Profit Effects of the Occupational Safety and Health Administration and the Environmental Protection Agency," *Journal of Law and Economics*, 30 (October 1987), pp. 239-64; B. Peter Pashigian, "Environmental Regulation: Whose Self Interests Are Being Protected?" *Economic Inquiry*, 23 (October 1985), pp. 551-84.

[22]Nina Cornell, *et al.*, "Safety Regulation," in H. Owen and C.L. Schultze, *Setting National Priorities: The Next Ten Years* (1976), pp. 457-504.

[23]See Bartel and Thomas, *op. cit.*, and William J. Baumol and Janusz Ordover, "Use of Antitrust to Subvert Competition," *Journal of Law and Economics*, 28 (May 1985), pp. 247-65.

[24]There is also ample evidence that regulation has contributed to the productivity slowdown in the U.S. For a review of this empirical evidence, see Hanke and Walters, *op. cit.*, pp. 21-23.

the number of effective drugs introduced has significantly reduced consumer welfare.[25]

More recently, research has shown that FDA regulations have differential impacts on pharmaceutical firms of various sizes. Specifically, smaller U.S. pharmaceutical firms had suffered devastating reductions in research productivity as a result of FDA regulations; research productivity also declined for large firms, but the revenue effects of this decline were more than offset by sales gains resulting from reduced competition in this industry.[26] In sum, large firms are willing to pay slightly higher R&D costs as a result of regulation because they know their smaller rivals' R&D costs will skyrocket; thus, the larger firms' profits will be enhanced. The problem is that, in the drug market, consumers will suffer not only from higher prices but reduced availability of therapies. We anticipate that the proposed CGMP regulations would produce similar effects in the dietary supplements industry.

7. Concluding Remarks

We conclude that the proposed CGMP regulations are unnecessary and undesirable. Existing regulatory practice appears to be consistent with an equilibrium in the dietary supplements industry that involves a high level of safety, competitive prices, and a very rapid pace of innovation.

The proposed regulations have, in our view, a very high probability of damaging consumer safety rather than enhancing it. Replacing market-based quality- and safety-assurance mechanisms with apparent regulatory oversight poses significant risks of offsetting behavior by consumers; such behavior could well lead to lower levels of safety and product satisfaction than currently prevails in this industry. In addition, the regulations will undoubtedly tilt the playing field in the industry in favor of large firms, putting smaller firms at a severe competitive disadvantage; this will lead to higher prices, reduced sales volumes, higher profits, and reduced rates of innovation as the larger firms exercise their market power. This will significantly reduce consumer welfare.

Ultimately, we believe this is the hidden motive of the industry insiders who have proposed the regulations. As in many other cases, these regulations have been offered not to enhance the public interest, but to advance the interests of a subset of firms in the an industry where competition is currently very vigorous. Regulatory resources are extremely valuable and have the capacity to significantly improve welfare; it would be an unconscionable waste of these resources to use them to limit competition in this dynamic market.

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[25]Sam Peltzman, "An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments," *Journal of Political Economy*, 81 (September 1973), pp. 1049-91; Henry G. Grabowski and John M. Vernon, *The Regulation of Pharmaceuticals: Balancing the Benefits and the Risks*, American Enterprise Institute (1983), Washington, DC.

[26]Lacy Glenn Thomas, "Regulation and Firm Size: FDA Impacts on Innovation," *Rand Journal of Economics*, 21 (Winter 1990), pp. 497-517.

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- RESUME -

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EDUCATION

1964	B.S.	University of Colorado Boulder, Colorado
1969	Ph.D.	University of Colorado Boulder, Colorado

PROFESSIONAL EXPERIENCE

Academic Appointments

1966 - 1969	Assistant Professor (1968-69) and Instructor (1966-68) Colorado School of Mines Golden, Colorado
1974 - 1975	Visiting Associate Professor Graduate School of Public Policy University of California Berkeley, California
1969 - Present	Professor of Applied Economics (1975-Present) [formerly Assistant Professor (1969-73) and Associate Professor (1973-75)] The Johns Hopkins University Baltimore, Maryland 21218

Private Sector Appointments

1985 - 1995	Vice President and Chief Economist FCMI Financial Corporation Toronto, Canada
1993 - Present	Columnist Forbes New York, New York

1995 - Present	Vice Chairman Friedberg Mercantile Group, Inc. New York, New York
1995 - Present	President Toronto Trust Buenos Aires, Argentina
1997 - Present	President FCMI NZ Financial Corporation, Ltd. Auckland, New Zealand

Public Sector Appointments

1976 - 1980	Member Governor's Council of Economic Advisors Annapolis, Maryland
1981 - 1982	Senior Economist President's Council of Economic Advisors Washington, D.C.
1984 - 1986	Senior Advisor Joint Economic Committee U.S. Congress Washington, D.C.
1985 - 1987	Member Presidential Task Force on Project Economic Justice Washington, D.C.
1990 - 1991	Personal Economic Advisor Deputy Prime Minister The Socialist Federal Republic of Yugoslavia Belgrade
1991 - 1992	Special Adviser on Currency Reform Deputy Prime Minister The Republic of Albania Tirana, Albania
1994 - 1996	State Counselor on Monetary and Financial Issues Republic of Lithuania Vilnius, Lithuania
1994 - 1995	Economic Adviser Office of the President Republic of Kazakhstan Alma Ata, Kazakhstan
1995 - 1996	Adviser to The Minister Ministry of Economy and Public Works and Services Republic of Argentina Buenos Aires

1995 - 1996	Adviser Fundo de Inversiones de Venezuela Caracas
1997 - Present	Adviser to the President Republic of Bulgaria Sofia, Bulgaria

Research Appointments

1972	Research Associate National Museums of Kenya Nairobi, Kenya
1978	Visiting Scholar Centre de formation internationale a la gestion des resources en eau Sophia Antipolis, France
1979 - 1980	Associate Research Scholar International Institute for Applied Systems Analysis Schloss Laxenburg, Austria
1981	Distinguished Visiting Scholar Lund Institute of Technology University of Lund Lund, Sweden
1983	Senior Fellow The Heritage Foundation Washington, D.C.

Other Professional Activities

1975 - 1985	Member Editorial Board Land Economics
1976 - 1979 1985 - 1987	Associate Editor Water Resources Research
1980 - 1982	Economics Editor Water Engineering and Management (formerly Water and Sewage Works)
1981 - 1982	Member Editorial Board Water Resources Bulletin
1982-Present	Member Advisory Board Reason Foundation Los Angeles, California
1982-Present	Fellow The Institute for Humane Studies George Mason University Fairfax, Virginia

1982-Present	Adjunct Scholar The Heritage Foundation Washington, D.C.
1982-Present	Adjunct Scholar The Cato Institute Washington, D.C.
1983-1987	Associate Editor Water Resources Bulletin
1983-Present	Member Editorial Board The Cato Journal
1985-Present	Senior Fellow The Ludwig von Mises Institute Auburn University Auburn, Alabama
1985-Present	Contributing Editor Friedberg's Commodity and Currency Comments
1985-Present	Associate Editor Review of Austrian Economics
1985-Present	Member Academic Advisory Board Atlas Economic Research Foundation Fairfax, Virginia
1985-Present	Member Board of Advisors Pacific Institute for Public Policy San Francisco, California
1988-Present	Senior Fellow Institute for Advanced Strategic and Political Studies Jerusalem, Israel
1988-1993	Member Economic Policy Committee U.S. Chamber of Commerce Washington, D.C.
1988-Present	Member National Advisory Board National Center for Privatization Wichita, Kansas
1988-Present	Member Editorial Advisory Board Privatization
1989-Present	Member International Board of Advisors Carl Menger Institut Vienna, Austria

1989-Present	Principal and Associated Person (Registered) National Futures Association Chicago, Illinois

Other Professional Activities (continued)

1989-1992	Member Board of Review Journal of Economic Growth
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1989-Present	Co-Editor Policy Studies Institute for Advanced Strategic and Political Studies Jerusalem, Israel
1990-1993	Consulting Editor and Member of the Board of Review Journal of Regulation and Social Costs
1990-1995	Member Board of Directors Acton Institute Grand Rapids, Michigan
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1990-Present	Member Academic Advisory Committee Institute for Research on the Economics of Taxation Washington, D. C.
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1991-Present	Member Advisory Council Centre for Research Into Communist Economies London
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1991-Present	Contributing Editor and Member of the Editorial Board of Advisors The International Economy
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TRAINING AND ACADEMIC POSITIONS

1959 - 1960 Internship (Straight Medicine)
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1960 - 1962 Resident (Straight Medicine)
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1964 - 1966 Fellowship Nephrology (Clinical & Research) under Dr. George E. Schreiner Georgetown University

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1966 - 1970	Assistant Professor of Medicine University of Pittsburgh School of Medicine Pittsburgh, PA, under Dr. Jack Meyers, Chairman
1970 - 1971	Associate Professor of Medicine University of Pittsburgh, Pittsburgh, PA, under Dr. Jack Meyers, Chairman
1971 - 1976	Associate Professor of Medicine & Pathology Georgetown University School of Medicine Washington,D.C. under Dr. Dudley Jackson, Chairman
1971 - 1994	Director of Research Renal Division Head, Dr. George E. Schreiner
1974 - 1978	Consultant Lecturer to Nephrology Branch National Naval Medical Center Bethesda, MD
1976 -	Professor of Medicine & Pathology Georgetown University School of Medicine Washington, D.C.
1993-1994	Sabbatical in Molecular Biology Kidney Laboratory, NHLBI, NIH Bethesda MD Maurice Burg, Arlyn Garcia-Perez, David Sheikh-Hamad

AWARDS & HONORS

1962 - 1965	NIH Postdoctoral Fellowship
1966	NIH Special Research Fellow
1967 - 1972	Established Investigatorship American Heart Association
1968	Interstate Postgraduate Medical Association Research Prize
1977 - 1978	Consulting Editor American Journal of Medicine
1978 -	Beta Chapter, AOA Washington, D.C.
1978 -	Consulting Editor, Nephron
1979 - 1982	Consulting Editor, Nephrology Review
1979 - 1981	Clinical Science 3, NIH Study Section (member)
1981	Guest editor, Nephron Festschrift for George E. Schreiner, MD

1981 - 1985	Research Committee, Peer Review Virginia Chapter of American Heart Association
1982	Guest editor, "Compensatory Renal Growth" Symposium Kidney International
1982	Research Task Force, Northern Virginia Chapter American Heart Association
1983 - 1987	Member, National Advisory Council on Aging Data Planning Committee, NIA Program Committee, NIA
1984	Ad Hoc Member, Biochemistry Study Section N I H
1984 - 1986	Member, Director's Advisory .Council NIH - NIA Representative
1984 -	Series Editor, Nephrology Today Co-Editor,Geriatric Nephrology Editor ,Management of Common Problems in Renal Disease Editor, The Clinical Practice of Nephrology Editor, Tubulointerstitial Diseases
1985 -1989	American Heart Association, DC Chapter Research Committee, Peer Review
1989	Editorial Board - Clinical Nephrology
1989 -	Editorial Board - Geriatric Nephrology and Urology
1990 -	Chairman Nephrology-Hypertension Council, Am College Nutrition
1991 -	Coordinator Cardiovascular-Nephrology-Hypertension Section of the Am College Nutrition
1992	Co-Chairman Program Committee for the ACN Symposium concerning "Nutrition in Diseases of Women" - San Diego, CA
1992	Editor- Primer on Clinical Nephrology, Norton Publishing Co, New York NY
1992	Editor- Laboratory Evaluation of Renal Function Saunders Co, Philadelphia PA
1992	Advisory Editor- Kidney
1992	Advisory Editor Journal of the American College of Nutrition
1992	Elected Board of Directors American College of Nutrition
1993	Co-chairman of Symposium on Nutrition and Cardiovascular Diseases and Hypertension - Chicago, IL

1993	American College of Nutrition Secretary-Treasurer Chairman Finance Committee By-Laws Committee
1994	American College of Nutrition Program Committee
	ACN representative ILSI meeting: Sodium and Health, Washington; DC
1995	Chairmen: Washington Welcoming Committee ACN Meeting
	ACN Representative: ASTHOS meeting on Prevention of Cardiovascular Diseases, Washington DC
	Co Chairmen: Interaction of Nutrition and Genetics on Chronic Diseases. ACN Meeting in Washington DC
	Consultant or expert witness InterHealth Concord CA Electromedical Products, Mineral Wells Texas
1996	Co-Chairmen Symposium Nutritional Factors Affecting the Glucose-Insulin System: Role in Chronic Diseases and Aging
	Co-Chairmen Symposium Controversies in the Nutritional Management of Chronic Fatigue Syndrome
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MEMBERSHIP IN PROFESSIONAL SOCIETIES.

1966 -	American Federation for Clinical Research
1967 -	International Society of Nephrology
1968 -	American Society of Nephrology
1968 - 1982	Central Society for Clinical Research
1969 - 1970 -	American Society of Physiology Society for Experimental Biology & Medicine
1974 -	American Society for Clinical Investigation
1979 - 1982	New York State Academy of Science
1983 - 1985	American Association for the Advancement of Science
1984 -	American Society of Renal Biochemistry
1985 -	Association of Clinical Scientists
1985 -	American Society of Hypertension

1988 - Fellow, American College of Nutrition

UNIVERSITY COMMITTEES AND DUTIES

1971 - Georgetown Representative to Washington VA Research Board

1978 - 1979 Committee to Review Pharmacology Department

1979 - 1980 Chairman, Committee to Review Biochemistry Department

1979 - Subcommittee on Scientific Merit (IRB)
Chairman, 1986 -

1979 - 1985 Member, Student's Financial Appeals Board Chairman, 1981 - 1985

1981 - 1982 Member, Search Committee
Biochemistry Department Chairman

1981 - 1983 Member, Graduate Committee
Department of Pathology

1981 Member, Ad Hoc Committee on Teaching Department of Pathology

1984 Interdepartmental Research Group Georgetown University Medical Center
Chairman

1984 - 1986 Animal Welfare Committee

1984 - 1985 Georgetown University Committee on Aging Subcommittee on Research

1984 - 1987 Georgetown University Research Committee (Chairman, 1984 - 1985) (Vice Chairman,(1985 - 1986)

1985-Present Director, Student's Research Day - GUMC

1986-Present GUMC Internal Review Board (Vice Chairman)

1987-Present Member, Gertrude Maengwyn-Davis Award Committee

1987-Present Ad Hoc, Student Academic Appeals Committee

1987 - 1988 Dean's Task Force on Incentives for Obtaining Extramural Funds (Chairman)

1997 JSHS - Judge

OTHER ACTIVITIES

1971 Member, Site Visit Team
Cincinnati Veterans Administration Hospital Cincinnati, Ohio
Core Research Grant

1972 - 1976 National Kidney Foundation, Washington, DC Peer Review Board

1975 Visiting Professor
University of Michigan Medical Center Ann Arbor, Michigan

1978	Visiting Professor Loyola University Medical Center, Chicago, IL
1978	Invited Lecturer First International Workshop on Renal Ammoniagenesis, Montreal, Canada
1981	Visiting Professor, St. Louis University School of Medicine St. Louis, MO
1981	Invited Lecturer Second International Workshop on Ammoniagenesis, Athens, Greece
1984	Invited Lecturer Third International Workshop on Ammoniagenesis, Carmel, CA
1985	Visiting Professor, Nagasaki University Medical Center Nagasaki, Japan
1986	Invited Lecturer Biochemistry of Systemic Acid-Base Balance Titisee, Germany
1986	Invited Lecturer 8th Annual European Renal Biochemistry Meeting Dubrovnic, Yugoslavia
1986	Member, NIH Site Visit Team Polycystic Kidney Disease Program Grant Albuquerque, New Mexico
1987	Invited Lecturer New York Academy of Medicine Geriatric Nephrology Symposium
1987	Faculty (Invited Lectureship) 2nd Annual Meeting The American Society of Hypertension
1987	Invited Lecturer, Session Chairman 4th International Workshop on Ammoniagenesis Cadarache, France
1987	Faculty, Seminar on Geriatric Nephrology Lenox Hill Hospital, New York NY
1987-1988	Expert Witness-Patent Infringement Moduretic Patent Merck, Sharp & Dome vs Biocraft
1988-	Invited Lecture, Seventh Annual St Louis GRECC Symposium: Endocrine Function and Aging
1988-1990	AHA, Nation's Capital Affiliate Development Committee
1990	Visiting Professor Loyola University Medical Center
1991	Co-Course Leader PMA Symposium- Hypertension January 1991
1991	Invited Guest Editor for Clinics on Laboratory Evaluation: Renal Function, Electrolytes and Acid-Base Homeostasis

1991	Appointed course leader for PMA Symposium on Hypertension to be held October 1991, 1992
1991	Appointed course leader for PMA symposia on Laboratory Evaluation held in December 1991 and 1992
1992	American College of Nutrition. Co-Program Chairman on Nutrition in Women's Disease. San Diego CA
1992	Invited Lecturer-American College of Nutrition. Subject: Lead influence on mentation and the cardiovascular system.
1992	Invited lecturer- Lenox Hill Hospital Exogenous Factors Affecting Blood Pressure
1992	Guest Editor - Symposium on Nutrition and Diseases of Women published in the Journal of the American College of Nutrition
1992	Elected to Board of Directors of the American College of Nutrition
1993	Invited faculty member and speaker Conference on the Inclusion of Women and Minorities in Clinical Research sponsored by PPRR, Georgetown University
1993	Member of Board Human Kurdish Right Committee, Washington DC
1993	Invited speaker "Advances in Perinatal and Pediatric Nutrition" on "Lead Toxicity-Effect on Intellect and Hypertension" Stanford University, Palo Alto CA
1993	Co-chairman of symposium on atherosclerosis and hypertension for the October meeting of the American College of Nutrition and invited speaker on "Role of Macronutrients in Hypertension."
1993	Invited Author "Nutrition" for Encyclopedia Americana
1994	Visiting Professor Lenox Hill Hospital - Sugar and Hypertension
1994	Appointed member Certification Board Nutritional Specialists (CBNS)
1994	Invited Speaker USDA -The Role of Macronutrients in Blood Pressure Regulation
1994	American College of Nutrition Representative to ILSI Conference on Sodium: Health and Disease
1995	Consultant for Ciba-Geigy Pharmaceuticals. Use of Auriculin (Atrial Natriuretic Protein) in Acute Tubular Necrosis.
1995	American College of Nutrition Representative to Partners for Heart Disease and Stroke Prevention. A Vision for Action. sponsored by Assoc of State and Territorial Health Officials.
1995	Advisory Board for Certifying Examination (CBNS)
1995	Invited speaker Washington Area Micronutrient Club, "Insulin Resistant Disorders"
1995	Invited speaker Dairy Council. Interaction of Genetics and Nutrition in Hypertension (Oct 1995)

1995 Invited speaker Expo East Antioxidant conference, Baltimore MD "Effects of chromium on blood pressure and free radical formation (Sept 1995).

1995 Ciba Pharmaceuticals, Special Consultant . Obesity and Type II Diabetes Mellitus"- Use of Bromocriptine

1995 Representative of ACN to National Cholesterol Conference at NIH

1995 Guest speaker Treatment of Hypertension Martinsburg West VA and Patuxant Naval Base MD

1996 Invited speaker Fourth International Conference On Geriatric Nephrology and Urology. "Macronutrients and Trace Elements as They Affect Blood Pressure of the Elderly." Toronto Canada (April, 1996)

1996 Invited Speaker, Japanese Society of Urology, Special Lecture "Aspects of Geriatric Nephrology" Nagasaki, Japan (May 1996).

1996 Invited Speaker. Second International Congress on Alternative and Complementary Medicine, Alexandria VA, "Nutritional Effects on BP Regulation", June 1996

1996 Chairperson and Speaker ACN Annual Meeting San Francisco CA: Insulin Resistance: Nutritional Implications.

1996 Chairperson ACN Annual Meeting San Francisco CA October Controversial Issues in the Management of Chronic Fatigue Syndrome.

1996 Taped Interview on Nutritional and Exogenous Factors Affecting Overall Health Nutrition and Blood Pressure Regulation Preventive Medicine Update, Clinician of the Month(May 1996)

1996 Consultant or Expert Witness:
InterHealth Co, Concord CA- Use of Chromium in Hypertension
Birkmayer Inc, Vienna Austria: Use of NADH in Syndrome X
Effects of NADH on Chronic Fatigue Syndrome
Electromedical Products International, Mineral Wells TX- CES
Emords Associates, Washington DC Role of Fiber in Health
Medical Products Laboratories, Philadelphia PA Benzocaine as Local Anesthetic.
Great Salt Lakes Mineral Corporation, Ogden Utah Toxicity of Armak 1225
Ciba Pharmaceuticals, Summit NJ, ACE inhibitors and renal protection
Richardson Laboratories, Boise ID Saw Palmetto and Ginkgo Biloba

1996 ACN
Elected Vice President 1996, President-Elect 1997, President 1998
Vice Chairman Program Committee 1996

1997 Invited speaker to Chiropractors Meeting, Flagstaff Arizona July 1997 Natural means to control blood pressure.

1997 American College for Advancement of Medicine (ACAM)- Invited speaker to Anaheim CA. Role of antioxidants in aging.

RESEARCH PAPERS

1. Grossman LA, Kaplan, JH, Preuss HG, Harrington, JL: Mesenteric Panniculitis. JAMA 183:318-323, 1963.

2. Denis G, Preuss HG, Pitts RF: The PNH3 of renal tubular cells. J Clin Invest 43:571-582, 1964.

3. Preuss HG, Bise BW, Schreiner GE: The determination of glutamine in plasma and urine. Clin Chem 12:329-337, 1966.

4. Preuss HG, Davis BB, Maher JF, Bise BW, Schreiner GE: Ammonia metabolism in renal failure. Ann Int Med 65:54-61, 1966.

5. Preuss HG, Massry SG, Maher JF, Gilliece M, Schreiner GE: Effects of uremic sera on p-amino hippurate transport. Nephron 3:265-273, 1966.

6. Massry SG, Preuss HG, Maher JF, Schreiner GE: Renal tubular acidosis after cadaver kidney homotransplantation: Studies on mechanism. Am J Med 42:284-292, 1967.

7. Preuss HG, Hammack WJ, Murdaugh HV: The effect of Bence Jones proteins on the in vitro function of rabbit renal cortex. Nephron 5:210-216, 1968.

8. Preuss HG, Murdaugh HV: The toxic effect of ammonia on renal cortical tubule function in vitro. J Lab Clin Med 7:561-572, 1968.

9. Preuss HG, Pyridine nucleotides in renal ammonia metabolism. J Lab Clin Med 72:370-382, 1968.

10. Ciccone JR, Keller AI, Braun SR, Murdaugh HV, Preuss HG: Azotemic inhibition of organic acid transport in liver. Biochem et Biophys Acta 163:108-110, 1968.

11. Ciccone JR, Keller AI, Braun SR, Murdaugh HV, Preuss HG: Azotemic inhibition of hippurate accumulation in vivo. Nephron 6:140-148, 1969.

12. Lipman RL, Raskin P, Preuss HG: Failure of cirrhotic sera to inhibit renal tubule hippurate transport in vitro. Proc Soc Exper Biol Med 131:936-938, 1969.

13. Preuss HG: Renal glutamate metabolism in acute acidosis. Nephron 6:235-246, 1969.

14. Braun SR, Keller AI, Weiss FR, Ciccone RJ, Preuss HG: Evaluation of the renal toxicity of heme proteins and their derivatives: A role in the genesis of acute tubule necrosis. J Exp Med 131:443-460, 1970.

15. Preuss HG, Terryi EF, Keller AI: Renotropic factors in plasma from uninephrectomized rats. Nephron 7:459-470, 1970.

16. Bourke E, Frindt G, Preuss HG, Rose E, Weksler M, Schreiner GE: Studies with uraemic serum on the renal transport of hippurates and tetraethylammonium in the rabbit and rat: Effects of oral neomycin. Clin Sci 38:41-48, 1970.

17. Goldberg VJ, Weiss FR, Preuss HG: Function in hypertrophying kidneys: Organic acid and base transport. Am J Physiol 218:1066-1069, 1970.

18. Weiss FR, Preuss HG: Glutamine synthetase and plasma glutamine in augmented ammoniagenesis in acidosis. Am J Physiol 218:1697-1700, 1970.

19. Weiss FR, Preuss HG: Influence of extracellular and intracellular factors on hippurate uptake by rat kidney cortex: Acid-base effects. Proc Soc Exp Med Biol 135:30-32, 1970.

20. Preuss HG: Ammonia production from glutamine and glutamate in isolated dog renal tubules. Am J Physiol 220:54-58, 1971.

21. Orringer EP, Weiss FR, Preuss HG: Azotaemic inhibition of organic anion transport in the kidney of the rat: Mechanisms and characteristics. Clin Sci 40:159-169, 1971.

22. Preuss HG, Weiss FR, Adler S: Renal ammonia production in the presence of citric acid cycle blockade. Proc Soc Exp Biol Med 136:738-741, 1971.

23. Weiss FR, Preuss HG: Glutamate metabolism and ammonia production in dog kidneys. Nephron 8:344-354, 1971.

24. Preuss HG, Weiss FR: Rate limiting factor in rat kidney slice ammoniagenesis. Am J Physiol 221:458-464, 1971.

25. Preuss HG, Weiss FR: Distribution of glutamate ammoniagenesis in rat kidneys. Nephron 8:408-412, 1972.

26. Preuss HG: Glutamine and glutamate metabolism in guinea pig kidney slices. Am J Physiol 222:1395-1397, 1972.

27. Preuss HG, Weiss FR, Janicki RH, Goldin H: Studies on the mechanisms of folate induced growth in the rat kidneys. J Pharm Exp Therap 180:754-758, 1972.

28. Adler S, Preuss HG: Interrelationship between citrate metabolism, ammoniagenesis, and gluconeogenesis in renal cortex in vitro. J Lab Clin Med 79:505-515, 1972.

29. Manos 0, Roxe DM, Schreiner GE, Preuss HG: #-amino- butyric acid shunt in renal ammoniagenesis: Am J Physiol 224:154-157, 1973.

30. Freed KH, Bowie C, Manos OV, Preuss HG: Oxygen consumption and ammoniagenesis in rat kidney slices. Am J Physiol 224:268-270, 1973.

31. Preuss HG, Weiss FR, Manos 0, Vertuno L, Schreiner GE: Acid-base effects on renal organic cation transport. Proc Soc Exp Biol Med 142:356-358, 1973.

32. Preuss HG, Manos 0, Vertuno L: The effects of glutamine deamination on glutamine deamidation in rat kidney slices. J Clin Invest 52:755-764, 1973.

33. Goldin H, Zmudka M, Tio F, Vasquez A, Preuss HG: Para amino hippurate and tetraethylammonium transport in fragments of rat renal cortex. Proc Soc Exp Biol Med 144:692-696, 1973.

34. Roxe DM, Schreiner GE, Preuss HG,: Regulation of renal gluconeogenesis and ammoniagenesis by physiologic fuels. Am J Physiol 25:908-911, 1973.

35. Vertuno L, Preuss HG, Argy WP, Schreiner GE: Fanconi's syndrome following homotransplantation. Arch Intern Med 133:302-305, 1974.

36. Preuss HG, Weiss FR, Iammarino R, Hammack W, Murdaugh HV: Effects on rat kidney slice function in vitro of proteins from the urine of patients with myelomatosis and nephrosis. Clin Sci Molec Med 46:283-294, 1974.

37. Preuss HG, Grant K, Parris R, Zmudka M: Effects of sera and sera fractions from spontaneously hypertensive rats on renal organic anion and cation transport. Proc Soc Exper Biol Med 145:397-402, 1974.

38. Preuss HG, Manos 0, Vertuno L, Baird K: The effects of pH change on renal ammoniagenesis in vitro. Proc Soc Exper Biol Med 146:803-808, 1974.

39. Preuss HG, Baird K, Goldin H: Oxygen consumption and ammoniagenesis in isolated dog renal tubules. J Lab Clin Med 83:937-946, 1974.

40. Hsu C, Preuss HG, Argy WP, Schreiner GE: Prolonged tubular malfunction following acute oliguric renal failure. Nephron 13:342-348, 1974.

41. Preuss HG, Goldin H: Ammoniagenesis in growing nephrons of uninephrectomized rats. Lab Invest 31:454-457, 1974.

42. Preuss HG, Shim PS, Baird K, Gibbings T, Parris R, Grant K, Schreiner GE: PAH and TEA transport in kidney slices from spontaneously hypertensive Wistar rats. Proc Soc Biol Med 147:839-841, 1974.

43. Preuss HG, Goldin H: Humoral regulation of compensatory renal growth. Med Clin N Am 59:771-780, 1975.

44. Davis BB, Preuss HG, Murdaugh HV: Hypomagnesemia following the diuresis of post-renal obstruction and renal transplant. Nephron 14:275-280, 1975.

45. Preuss HG, Tourkantonis A, Hsu CH, Shim PS, Barzyk P, Tio F, Schreiner GE: Early events in various forms of experimental acute tubular necrosis in rats. Lab Invest 32:286-294, 1975.

46. Hsu CH, Kurtz TW, Preuss HG, Weller JM: Measurement of renal blood flow in the rat. Proc Soc Exp Biol Med 149:470-472, 1975.

47. Preuss HG, Goldin H: A renotropic system in rats. J Clin Invest 57:94-101, 1975.

48. Preuss HG, Byrne D, Shim PS: Effect of paraaminohippurate on renal glutamine metabolism in the rat. J Pharm Exper Therap 197:199-205, 1976.

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52. Preuss HG, Parris R, Goldin H: Effects of sera and liver extracts from partially hepatectomized rats on liver slice DNA synthesis. Experientia 33:630-631, 1977.

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54. Vertuno LL, Rakowski T, McCarthy E, Preuss HG: Effects of metabolic acidosis on renal Na and H20 handling in humans. Nephron 19:278-283, 1977.

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transport in rat kidney fragments. Nephron 30:32-39, 1978.

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57. Sleeper RS, Vertuno LL, Strauss FF, Preuss HG: Effect of acid challenge on in vivo and in vitro rat renal ammoniagenesis. Life Sci 22:1561-1571, 1978.

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59. Preuss HG, Eastman ST, Vavatsi-Manos 0, Baird K, Roxe DM: The regulation of renal ammoniagenesis in the rat by extracellular factors. I. The combined effects of acidosis and physiologic fuels. Metabolism 27:1626-1638, 1978.

60. Preuss HG, Baird K, Eastman ST: The regulation of renal ammoniagenesis in the rat by extracellular factors. II. Ammoniagenesis by rat kidney slices incubating in normal and acidotic sera. Metabolism 27:1639-1647, 1978.

61. Bourke E, Frindt G, Schreiner GE, Preuss HG: Effects of fluorocitrate on renal ammoniagenesis and glutamine metabolism in the intact dog kidney. Kidney Int 15:255-263, 1979.

62. Preuss HG: Goldin H, Shivers M: Further studies on a renotropic system in rats. Yale J Biol Med 51:403-412, 1978.

63. Preuss HG, 'Geoly K, Chester A, Johnson M, Kliger A, Schreiner GE: Renal function in polycystic kidney disease. Nephron 24:198-204, 1979.

64. Castillo 0, Robertson D, Goldin H, Preuss HG: Autoradiographic evidence for the existence of a renotropic system. Nephron 25:202-296, 1980.

65. Preuss HG, Goldin H: Effects of the rat renotropic system on -14 C-uridine incorporation into RNA and RNA precursors. Life Sci 25:497-505, 1979.

66. Hernandez W, Goldin H, Shivers M, Robertson D, Preuss HG: Studies on the tissue specificity of a circulating renotropic factor. Acta Physiol Latino AM 29:117-122, 1979.

67. Belledonne M, Preuss JM, Preuss HG: Acid excretion in young and adult Wistar Kyoto and spontaneously hypertensive rats. Experientia 35:1594-1695, 1979.

68. Preuss HG: The effects of alpha methyl glutamate on ammonium excretion and renal ammonia production in rats. Toxicology and Experimental Therapeutics. 54:454-461, 1980.

69. Preuss MB, Preuss HG: Effects on sucrose on the blood pressure of various strains of Wistar rats. Lab Invest 43:101-107, 1980.

70. Risquez A, Hernandez W, Preuss HG: Effects of acetazolamide of renal ammoniagenesis in dogs. Renal Physiol 2:205-213, 1980.

71. Lee J, Hollyer R, Rodelas R, Preuss HG: Effects of trimethoprim and sulfamethoxazole on PAH and TEA transport. Toxicology and Experimental Therapeutics 58:184-193, 1981.

72. Preuss HG: Regulation of renal ammoniagenesis during acidosis: The pyridine nucleotide hypothesis revisited. Life Sci 27:2293-2302, 1981.

73. Austin H, Goldin H, Preuss HG: Humoral regulation of renal growth: Evidence for and

against the presence of a circulating renotropic factor. Nephron 27:163-170, 1981.

74. Preuss HG, Manos 0, Eastman S, Gaydos D: The correlation between glutamate deamination and glutamine deamidation in rat kidney mitochondria. Nephron 27:244-253, 1981.

75. Preuss HG, Rodelas R, Terlinsky A, Gelfand M: Augmented active chloride transport in the renal diluting segment of man following administration of glipizide. Renal Physiol 4:173-179, 1981.

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77. Kliger AS, Hollyer R, Preuss HG: The mechanisms of acetate stimulation of PAH transport in rat kidney fragments. Renal Physiol 5:18-26, 1982.

78. Zarate A, Gelfand M, Knepshield J, Preuss HG: Propanolol associated hypoglycemia in dialysis patients. J Artif Organs 4:130-134, 1981.

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80. Preuss HG, Fournier RD: Effects of sucrose ingestion on blood pressure. Life Sci 30:878-886, 1982.

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87. Risquez A, Slemmer DS, Preuss HG: Effects of 2-oxoglutarate concentrations on canine slice ammoniagenesis. Renal Physiol 6:218-225, 1983.

88. Bagnasco SM, Slemmer DS, Risquez A, Preuss HG: Effects of substrates on ammoniagenesis of kidney slices from acidotic and control rats. Metabolism 32:900-905, 1983.

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92. Bourke E, Delaney V, Risquez, A, Preuss HG: Effect of inhibitors of the tricarboxylic acid cycle on glutamine utilization in the intact dog. Contrib Nephrol 47:28-35, 1985.

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94. Fournier RD, Chiueh CC, Kopin IJ, Knapka JJ, DiPette D, Preuss HG: The interrelationship between excess CHO ingestion, blood pressure and catecholamine excretion in SHR and WKY. Am J Physiol 250:E381-385, 1986.

95. Palestine AG, Austin III HA, Balow JE, Antonovych TT, Sabnis, SG, Preuss HG, Nusenblatt RB: Renal Histopathologic alterations in Cyclosporin treated uveitis patients. N Engl J Med 314:1293-1298, 1986.

96. More NS, Rao NA, Preuss HG: Early sucrose-induced retinal vascular lesions in SHR and WKY rats. Ann Lab Clin Sci 16:419-426, 1986.

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98. Preuss HG, Fournier RD, Chieuh CC, Kopin RJ, Knapka JJ, DiPette D, More NS, Rao NS: Refined carbohydrates affect blood pressure and retinal vasculature in SHR and WKY. J Hypertension 4:S459-S462, 1986.

99. Areas J, Balian S, Slemmer D, Belledonne M, Preuss HG: Renal ammoniagenesis following glutamine loading in intact dogs during acute metabolic acid-base perturbations. Clin Sci 72:61-69, 1987.

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103. Preuss HG, Slemmer D, Areas J, Conrado J: Renal ammonia production from the nitrogens of glutamine in intact acidotic dogs before and after bicarbonate infusions. J Clin Chem and Clin Biochem 25:401-407, 1987.

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111. Preuss HG, Fournier RD, Preuss J, Zein M, Garcia C, Knapka Effects of different refined carbohydrates on the blood pressure of SH and WKY Rats. J of Clin Biochem and Nutrition. 5:9-20, 1988.

112. Yokum DE, Klippel JH, Wilder RL, Gerber NL, Austin HA, Wahl SM, Leskol, Preuss HG, Yarbord C, Minor JR, Berkebile C, Dougherty S: Randomized trial of cyclosporin A in severe treatment refractory arthritis. Ann Int Med 109:863-869, 1988.

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transport with blood pressure. Clin Nephrol 36:87-92, 1991

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