To - Jen Klein
From: Joan Baker
(Mill. Alston's
office

THE WHITE HOUSE

October 7, 1994

1) Ok to w/ thanks
2) pass to Jen to review his letter

Mr. O. Glenn Stahl
3600 North Piedmont Street
Arlington, Virginia 22207

Dear Mr. Stahl:

Thank you for your letter and the enclosed statement on health care reform you recently submitted to the Washington Post.

I appreciate your kind words of support regarding my efforts to promote health care reform. I am optimistic that next year the Congress will approve legislation providing comprehensive, affordable health care for all our citizens. I hope you will continue to speak out on this important issue.

With best wishes, I am

Sincerely yours,

THE WHITE HOUSE

May 25, 1995

Mr. O. Glenn Stahl
3600 North Piedmont Street
Arlington, Virginia 22207

Dear Mr. Stahl:

Thank you for your letter and the enclosed copy of a statement on health care reform you submitted to the Washington Post.

I appreciate your kind words of support regarding my efforts to promote health care reform. I remain optimistic that Congress will eventually approve legislation providing comprehensive, affordable health care for all our citizens. I hope you will continue to speak out on this important issue.

With best wishes, I am

Sincerely yours,

Hillary Rodham Clinton

Hillary Rodham Clinton

I appreciated your article and wish it had been printed!

O. GLENN STAHL
3600 NORTH PIEDMONT STREET
ARLINGTON, VIRGINIA 22207

September 23, 1994

Mrs. Hillary Rodham Clinton
The White House
1600 Pennsylvania Ave., N.W.
Washington, D.C.

PERSONAL ATTENTION, PLEASE!

Dear Mrs. Clinton:

The enclosed statement defending your efforts in health care reform was submitted recently to the WASHINGTON POST in response to a bizarre piece of reasoning published on September 11 by one of the POST's professional writers. So far, the POST has not used my rejoinder; I have found on several occasions that the POST is very protective of its own staff's exclusive access to its pages, even on very controversial matters.

You may not immediately recall my name, but I am the author of the little book, STANDING UP FOR GOVERNMENT, that was presented to you some three years ago by our mutual friends in Arkansas, Elizabeth and Kenneth Warner. You were kind enough to make generous comments about the book in a letter to Ken (April 30, 1991). Does this trigger your memory?

I just wanted you to know that there are many of us out here who greatly admire your dedication and energy on behalf of good causes, in spite of the mean-spirited attacks by misguided groups deliberately spreading "big lies" about everything you and the President are trying to do for the public welfare.

Sincerely,

O. Glenn Stahl

Telephone: (703) 528-0761

COPY

September 12, 1994

MORE ON APPLYING DARWIN'S THEORY TO HEALTH CARE

by: O. Glenn Stahl

It was shocking to see a piece of sophistry in OUTLOOK for September 11 (C-1 & C-4)trying to promote resistance to health care reform by resort to poor old Charles Darwin. Dr. David Brown's "Darwin's Advice to Hillary" doesn't speak well for the quality of "scientific" thought when it misrepresents what health care reformers are trying to achieve.

The article leaves the impression that reform of the system is intended to ration care to many in order to provide for others, as if there is only a certain amount of care available, concentrated heavily on lucky segments of the population. That isn't the issue at all.

Right now, and for the past quarter century, any person needing and wanting care can get it. Medicare and Medicaid, through general taxation, have seen to that. And Dr. Brown says nothing about whether he would abolish or have a substitute for them, even though their costs are skyrocketing.

He ignores the real issue: emergency rooms are filled up all over America with patients seeking primary care (from baby colic to common colds) in an environment not efficient for that service and costing too much for what it spends most of its time on.

It is absurd to claim that we can't afford universal insurance coverage when so many nations not as rich as ours and even one of our own states (Hawaii) thrive on it - and at less cost! Facts simply don't support the assumption that those societies sacrifice quality for universality. Most of them have longer life expectancy, lower infant death rates, and other more favorable health indices than the United States - and at lower cost. And most of them provide a wide choice of forms of care.

The basic insurance principle, invented many years ago, has been that the wider coverage is spread the cheaper the insurance. If this principle were

wrong, we would have discovered it in our life insurance plans many years ago. Our health care system is the most expensive primarily because we do not have everyone contributing to it through universal insurance.

Negative scare tactics like Dr. Brown's were employed fifty years ago to fight pre-paid health maintenance organizations, but HMOs have expanded rapidly and are now major distributors of health care to millions. My wife and I joined one of the first such enterprises, and it has provided us with at least as sound and plentiful care as anyone could get by shopping around for all the specialists they find they need through life - and with far less hassle and more convenience. Military personnel have been provided life-long family care for many decades, and I hear no complaints from retirees or active-duty people about the quality or extent of their coverage.

The simple fact is that we have the highest-cost system because we do not require all potential users to contribute through insurance, whether currently healthy or not. All the reformers want to do is have the healthy as well as the unhealthy subscribe, to have all employers and all employees kick in like our most progressive employers and most enlightened workers. Arguments ######## about not being able to "afford" such concepts are exactly like those made against every progressive social reform during the past two centuries -- child labor abolition, food and drug inspection, minimum wages, maximum hours, equal rights and pay for women, occupational safety measures, social security itself, and all the other ########## steps forward that made us richer, not poorer.

Curiously, Dr. Brown says not a word about availability of health insurance now only to those who pose little risk to the insurer; not a word about the loss of insurance when jobs change or disappear; not a word about the odious legal practices that thrive on lack of restraints on malpractice suits - all factors that drive up health care costs and are conditions that would be ameliorated by even the most modest reforms under consideration.

Dr. Brown would do well to study the spurious arguments and scare tactics of reactionaries who opposed every one of the great social advances in our nation. Far from violating Darwin's "survival of the fittest", they illustrate it. The capacity to conceive of change and to accept progress is part of mankind's continuing fitness to survive.

Our advances demonstrate that both as individuals and as a society we have achieved conditions that have improved our lives and contributed mightily to our survival. And they came from those elements in our population who had the vision and the intestinal fortitude to stand up for what was best for us, both as individuals and and as a society. The word for all this is: CIVILIZATION!

THE WHITE HOUSE

WASHINGTON

May 12, 1995

MEMORANDUM TO BRUCE LINDSEY

FROM: Jennifer Klein J.K.

RE: Federal Insurance Reform

Attached please find a letter from Ray Bourhis, a lawyer from San Francisco who knows Mrs. Clinton. As you can see, we have been hearing from him for quite a while. He strongly believes that the President should take on the issue of unfair insurance practices. While I have assured him that we remain committed to health insurance reform, he continues to urge us to propose legislation to reform the entire insurance market. I have spoken with the Justice Department and the Department of Labor about this idea. Justice, Labor and I don't think that now is the time to address this at the federal level, but I wanted to pass this letter on to you in case you are interested.

Please feel free to call me at 6-2599 if you would like any additional information.

RAY
BOURHIS
&
ASSOCIATES

Law Offices
1050 BATTERY STREET
SAN FRANCISCO, CA 94111
415/392-4660
FAX 415/421-0259

January 31, 1995

First Lady Mrs. Clinton
The White House
1600 Pennsylvania Ave.
Washington, DC 20001

Dear Mrs. Clinton:

Following your letter of November 2, I spoke with Jennifer Kline. We briefly discussed my suggestion that a Presidential Commission be appointed to study the possibility of proposing enactment of a Federal Unfair Insurance Practices Act.

Because of the fact that no uniform standards currently exist, policyholder protections vary dramatically from state to state. Insurers are able to wrongfully deny or grossly undersettle legitimate claims; or to engage in misrepresentation, cancellation and non-renewal activities with virtual impunity. Because such facts affect homeowners, business, disability, health, life and all other lines of insurance, the need for reform is great.

Jennifer told me that you feel this should be dealt with by the Civil Justice Reform Project. I strongly disagree. I believe that this is a matter that President Clinton should approach directly. Americans are quite upset with insurance companies and how they do business. It seems that every day one hears, yet another horror story, about an insurance company wrongfully denying chemotherapy to a breast cancer victim or dragging out flood and earthquake claims for years before offering to pay for only a small fraction of the covered loss.

Unlike with the complex issue of health care reform, insurance reform would require only a two or three page piece of legislation. Furthermore, it would be unnecessary for some government bureaucracy to prosecute violations because the victims of unfair insurance practices would be empowered to enforce their rights under the Act directly. In fact, if the Act contains sufficiently effective deterrent mechanisms it would be largely self-policing.

Beyond the above, as reflected by the positive response to President Clinton's reference to insurance reform in his State of The Union Address, I believe that this proposal would have broad and bipartisan public appeal.

As you know, I have been urging this course of action for over two years. I would be very happy to come to Washington to discuss this in greater detail with whomever you would deem appropriate, but I really hope that you find this effort sufficiently important to get behind it personally. I believe that the results would be very positive in all respects.

Thank you for your continuing interest in this matter.

Very truly yours,

RAY BOURHIS & ASSOCIATES

Ray Bourhis

RB:ap

cc: President Clinton
Ms. Jennifer Kline, Via Facsimile Transmission
No. (202) 456-2878

ray.hc127

U.S. Department of Labor

Assistant Secretary for
Pension and Welfare Benefits
Washington, D.C. 20210

DATE: 3/17/95

TO: Jennifer Klein

AGENCY:

TELEPHONE NUMBER: ***FAX:*** 456-2878

FROM: ***MEREDITH A. MILLER***
Deputy Assistant Secretary for Policy
Pension and Welfare Benefits Administration
U. S. Department of Labor
200 Constitution Avenue, NW, Room S-2524
Washington, DC 20210

COMMENTS:

NUMBER OF PAGES INCLUDING COVER SHEET 2

Should you experience any problems receiving this transmission, please call (202) 219-8233.

U.S. Department of Labor

Pension and Welfare Benefits Administration
Washington, D.C. 20210

March 17, 1995

MEMORANDUM FOR JENNIFER KLEIN

FROM: MEREDITH MILLER

SUBJECT: Bourhis Letter

My apologies for getting these points to you so late. I'm not sure if you received my message that we were unable to respond to his concerns about the Civil Justice Reform Project because we are unfamiliar with it. Nevertheless, here is our reaction to his ideas:

1. The Administration's focus on insurance market reform has thus far been focused in the area of health as opposed to other lines of business (to my knowledge). We would agree with Mr. Bourhis that consumer protections are uneven across states and ideally, as in the President's bill, federal standards would level the playing field between states as well as set a minimum floor of protections for consumers. You might add here the President's stratgy to work with Congress on this. We also are cautious that new federal standards should not dilute adequate state standards and set consumers back even further.

2. Mr. Bourhis suggests in his letter that insurance reform would only require a few pages of legislation. He also suggests a minimal role for "some government bureaucracy to prosecute violations because the victims of unfair insurance practices would be empowered to enforce their rights under the Act directly." His letter describes the Act as establishing deterrent mechanisms that would allow for consumer self-policing. These are the set of comments I am assuming you are asking us to respond to. Mr. Bourhis' references to empowerment and self-policing could be interpreted to mean that a federal law would preempt all state regulation of the benefit claims grievance, notification and appeal process, including expanded remedies. He may have more areas for reform in mind than this list. Nevertheless, Mr. Bourhis may be suggesting unlimited damages that could be recovered in wrongful benefit denial cases which would explain the empowerment and deterrents referenced in his letter. Of course,this would also put all claimants into a federal court system.

3. Bourhis' suggestions appear to be going in the opposite direction of policy debates on the current tort reform and other similar considerations on the Hill.

4. Lastly, I would add that, with respect to the brevity of potential legislation in this area, it would be hard to address the issues of consumer protection currently under discussion in policy circles in such a short piece unless Bourhis is limiting reform to the grievance process and remedies within unlimited damages.

Good Luck!

THE WHITE HOUSE

WASHINGTON

January 24, 1994

Arthur Curtis, M.D.
448 East Ontario Street, Suite 200
Chicago, Illinois 60611

Dear Art:

Thank you for your letter and the enclosed materials. I'm grateful that you took the time to share your invaluable experience. The Health Security Act addresses many of the issues you raised in an effort to bring health care costs under control, preserve quality of care and give all Americans the security they deserve.

As you outlined in your paper, the current health care system gives physicians every incentive to perform excessive, and even unnecessary, tests and procedures. We believe that the Health Security Act changes those incentives by allowing health plans to compete for consumers seeking high quality health care at reasonable prices.

You also noted that practice guidelines produced by professional societies are essential tools in making treatment decisions and should be made more available to practicing physicians. The Act provides for coordination of the development and dissemination of clinical practice guidelines at the federal level. The Act requires that practice guidelines be based on the best available research and professional judgment, include clinical guidance on particular treatments and conditions, and provide information on the risks, benefits and costs of alternative treatments.

The Act also includes malpractice reforms that begin to relieve physicians of the threat of litigation that may lead to the practice of defensive medicine and increased medical costs. Among other reforms, a pilot program is established under which evidence that a physician has followed appropriate practice guidelines is a complete defense in malpractice actions.

Thank you again for sharing your support and ideas. I will pass your letter and the information you enclosed to the Administration staff members who are working on national health care reform. I have also asked Lynn Margherio, who coordinates our physician outreach group, to contact you.

With warm personal regards, I remain

Sincerely yours,

Hillary

Hillary Rodham Clinton

ARTHUR W. CURTIS, M.D.
448 EAST ONTARIO STREET, SUITE 200
CHICAGO, ILLINOIS 60611
TELEPHONE (312) 944-7441

November 17, 1993

Hillary Rodham Clinton
1600 Pennsylvania Avenue NW
Washington, DC 20500-2000

Dear Hillary:

I was at a reception at Rick Ricketts' restaurant for Mary Lou Kearns a few days ago. As you may know, she is running for Secretary of State of Illinois. Betsy Ebeling was at the meeting and was kind enough to give me the zip code plus four that she said would give a letter a good chance of reaching you. I have written you at the White House before, but I suspect that my letter did not reach you. I am sending the same thoughts that I sent before. They may help "make the numbers work" for your new health plan by helping to cut costs. I also wanted to give you a few thoughts on how specialists like myself might be used to advantage without having to be re-trained as generalists.

Let me first digress and tell you how pleased and impressed I am with all that you and Bill have done. The NAFTA victory was stunning. Your administration is clearly going to accomplish more than any in the past. I like the decisions that have been made. I even think that I will like the health plan. What really impresses me, however, is your husband's willingness to openly utilize the abilities of you and the Vice President and to give the Vice President chances to look good, something that is unprecedented in American politics and is a clear sign of outstanding leadership!

To get to my unabashedly self-serving point, I think that our present abundance of specialists can be used cost-effectively in your health care system. The present generation of primary care doctors have not been trained to be as versatile in medicine as they probably should have been. If a specialist uses his greater knowledge and experience in his field to assess even a minor problem, he can, by avoiding unnecessary tests and inappropriate treatments, usually arrive at the proper diagnosis and treatment faster and more cheaply than a family doctor. Wouldn't you really want to see a dermatologist for your rash or an orthopedist for your sore knee rather than your internist or your gynecologist? Perhaps patients could be allowed to go straight to a specialist in certain situations, at least for a few years until the mix of physicians changes.

The problem with care by specialists is that the specialists have often been taught that all patients that they see need to be tested and treated as if they had a tertiary-care type of problem. I have given examples of this in the enclosed essay. Bill has said that your plan will include guidelines. If specialists can be constrained by guidelines that spell out the indications for tests and procedures, the expertise of the specialists can be used to maintain high quality health care without such great expense.

My thoughts should give you a different slant from what you might have heard from other doctors, especially from those who are tied to the medical and medical education establishments. Many major medical centers are currently making previously-unheard-of profits, in part from treating simple problems as major problems, and have become extremely profit-oriented. I have made the mistake of speaking out on this issue, and I and my family have paid dearly for my outspokenness.

ARTHUR W. CURTIS, M.D.
448 EAST ONTARIO STREET, SUITE 200
CHICAGO, ILLINOIS 60611
TELEPHONE (312) 944-7441

I am as close as the telephone for you or any of your staff wanting an explanation of anything regarding my field. I am good at explaining medical things to lay people. I am a generalist in my field, but I could refer you to people with special expertise as needed. I am sorry to say that I was not first in my class in medical school, but I did have the highest score on the written half of the American Board of Otolaryngology Examination in 1976. I was the Consultant for Otolaryngology for the *AMA Encyclopedia of Medicine*. I have written several papers, have been an officer in a national otolaryngology society and the Vice Chief of Staff of the Rehabilitation Institute of Chicago, have maintained an academic affiliation, have diligently kept up with the literature in my field and have made some important people very angry at me. I have practiced otolaryngology for the last seventeen years, mostly solo private practice on Chicago's Near North Side, but also for two years in the Army in Oklahoma, three years teaching half-time at Cook County Hospital when I came back from the Army in 1978 and a few hours a week at a closed panel HMO in the past year and a half.

Knowing you and following your activities give me tremendous pleasure. Thank you so much for providing me this vicarious enjoyment. Keep up the good work!

Sincerely,

Arthur W. Curtis, M.D.

AWC/kf

EXPENSIVE MEDICINE

American doctors tend to practice expensive medicine--often to the great benefit of their patients, but not always. Expensive medicine costs American jobs by making our manufactured goods expensive in world markets; and unnecessary medical tests, procedures, and visits expose patients to possible complications and take them away from their jobs and school. There are many motivations for practicing needlessly expensive medicine--greed, fear of lawsuits, premature introduction of unproven techniques, pressures from patients, customary academic approaches, previous training and, in the case of tests, as a substitute for thinking or for a careful history and physical examination. Sometimes, third-party reimbursement policies result in the choice of an overall more expensive approach to a problem to allow the patient to incur less out-of-pocket expense. If Bill's administration can find ways to eliminate the unnecessary in medicine, medical care can almost certainly be expanded to include all of the people presently not getting adequate care without an increase in medicine's share of the GNP; and the quality of the care would be improved at the same time! I will give you examples of needlessly expensive medicine and suggest that sets of guidelines be established to steer doctors away from such practices.

I think that doctors need more guidelines on how to practice. These could come from consensus panels within already-existing societies. As an example, the American Heart Association periodically releases guidelines on antibiotic prophylaxis for patients with valvular heart disease undergoing various medical and dental procedures. Similarly, there are officially established guidelines for childhood immunizations. These guidelines, although arbitrary, are based on the thoughts of the best minds in the field, are handy to use and offer protection from litigation if followed.

A helpful, new guideline would be one defining the need for blood clotting tests prior to surgery. Numerous studies have demonstrated that such testing is not worthwhile except in limited situations based on the patient's history. Nevertheless, fear of litigation and possibly a lack of interest in or ignorance concerning taking an appropriate history, leads most surgeons, including myself, to frequently order these tests. Many surgery departments require them, possibly under the influence of hospital administrators who want to increase revenues. If the American College of Surgeons set up guidelines on who needs these tests and which ones, surgeons would be glad to comply; patient care would not be compromised; and money could be saved.

I have enclosed a copy of a recent article from the *British Medical Journal* (304:740-743,1992) that reports on the success of a project to cut down on the number of X-rays performed at a group of British hospitals and clinics. (See attachment 1.) Using rather extensive guidelines and a system to educate and monitor physicians, a modest eight or nine per cent reduction in X-rays occurred. The authors thought that ultimately a 20% reduction would be obtained. Since there are stronger incentives in America than in England to over-order X-rays, an even greater reduction could be hoped for here, where doctors are influenced by greed, fear of litigation and pressure from their hospitals and clinics. (As a physician, your hospital usually keeps track of how many tests you do at their facility, how may patients you admit and how much surgery you do; and your ability to get favorable treatment from the institution is influenced by this information.)

Testing is one of the most expensive aspects of modern medicine, and the most expensive approach to testing is ordering a "battery of tests." This approach was quite reasonable when patients were hospitalized for testing. It is also a practical approach in a tertiary care setting when a patient has come from a long distance and must leave soon. A standardized battery of tests for a given complaint or condition, if set up as a protocol in an experiment with carefully designed objectives, can be a way to get useful data and to find out what tests are most helpful in making a diagnosis.

There are much better and cheaper ways, however, to arrive at a diagnosis. The history and physical examination, especially the history, will allow a good doctor to arrive at a diagnosis most of the time. The importance of the patient's history is too often underemphasized in modern medical education. Some tests may be done initially to rule out any serious illnesses suggested by the symptoms. On many occasions, however, one can simply treat a suspected common, easily treated condition and do tests to rule out serious disease if the patient does not get better. Tests can usually be done in a sequence rather than in a battery. First do the test most likely to give you your diagnosis and proceed to the next test only if the first does not give you the answer.

A therapeutic trial is often safer and cheaper than a test, can give you just as useful information and can get the patient better right away; but doctors often feel that they have to document a disease with a test before they can treat it, mostly because of fears of lawsuits. If you think a patient's nocturnal cough is caused by gastro-esophageal reflux, you can treat the patient with Maalox or Tagamet and see what happens. Many doctors, however, will always do a test first, such as an esophagram or even esophagoscopy, before initiating treatment. These tests, however, may be falsely positive or negative.

I want to talk for a while about how some common diagnoses in or related to my specialty, otolaryngology, are handled. Middle ear infection is the most frequent diagnosis for which a child sees his or her pediatrician or family doctor. How this disease is handled, therefore, has a great impact on the cost of medicine. These infections may be asymptomatic but usually present with ear pain. Once the painful stage has passed, the ear will be filled for a while with a fluid that has a lower level of bacteria than the original pus in the middle ear. Adults find this stage quite distressing, but children will almost never complain about it. There is good evidence that this stage, with its associated mild hearing loss, will slow a child's acquisition of language skills if it goes on for months. Most of the pediatric and otolaryngologic literature suggests that a child with an acute middle ear infection

should be treated with a ten-day course of antibiotics and followed up at six weeks to be sure that the fluid has cleared.

What is usually done, however, is quite different, at least where I practice. A child will usually be seen every seven to ten days until the last of the fluid is gone. The visits may include a tympanogram and will usually conclude with the prescribing of a new antibiotic, the cost of which may be over $50.00. It has never been proven that this approach gets the child better any sooner. I suspect that it does but that the difference is not enough to have an impact on a child's ultimate acquisition of language skills. And think of the cost and the time that parents lose from work! The American Academy of Pediatrics should look at this question and publish reasonable guidelines. The public as well as physicians should be made aware of these guidelines since some parents would otherwise be concerned that their children were not getting proper treatment.

One of the disorders that I see most frequently is chronic rhinitis. It occurs year-round and, in most individuals, usually has a combination of allergic and non-allergic triggers. Patients with chronic rhinitis often also have seasonal allergic rhinitis, a somewhat more common disease. Patients with seasonal allergic and/or chronic rhinitis probably amount to 20 to 25% of the American population. How these diseases are treated would, therefore, have a considerable impact on the cost of medicine. I have enclosed the three handouts that I give to my new chronic rhinitis patients after verbally giving them the same information. (See attachments 2, 3 and 4.) A lot of them will use the non-prescription medicines described, either regularly or on an as-needed basis. If they need (and can afford) the prescription medicines, I will prescribe and renew them by telephone and generally see the patient only once. My lower middle class patients who do not do well with non-prescription medicines and alterations of their environment and do not have prescription cards usually prefer to tolerate the symptoms rather than pay for the expensive prescription drugs.

The proper role of allergy shots in the treatment of rhinitis is not the same in every practitioner's mind, in part because allergic desensitization has an amazing lack of scientific study to guide its usage. It has been proven that injections for several seasonal pollen allergens, given singly, can diminish a patient's allergic symptoms for the season in which they are given. Studies have shown that there is no carry-over effect into the next season as would be expected if injections could "cure" the allergy. Shots will, of course, seem to produce a cure in cases of spontaneous remission, which, for example, will occur in approximately 7% of hay fever patients each year. There have not been good studies to my knowledge demonstrating even short-term benefit from treating the year-round allergens with shots or proving that any shots can cure allergies. Furthermore, most people are given shots for multiple allergens at once, and a recent study suggests that giving allergy shots this way does not work. (See attachment 5.)

Mainstream thinking in the field of allergy is that shots are a treatment, not a cure, and that shots should be reserved for people whose allergic manifestations cannot be well controlled with appropriate medicines and changes in their environment. Nevertheless, there are allergists who believe that shots are curative and, therefore, should be the first-line treatment for chronic rhinitis. These people cost society a lot of money and cause complications that might not otherwise occur.

There clearly are a significant number of chronic rhinitis patients whose symptoms are triggered solely or predominantly by non-allergic triggers--weather changes, air conditioning, tobacco smoke, gasoline fumes, spicy food, etc. Nevertheless, there are approaches that one can utilize to treat almost every chronic rhinitis patient with allergy shots. Most allergists will not try to desensitize people with very low and therefore questionable levels of allergic reactivity, such as people with a score of 1 or 2 on a RAST-type test that will have a scale of 0 to 5 or 0 to 7. Some allergists do. Since allergy tests have a false positive rate of 5% or more, you will almost certainly get a positive if you do enough tests. (To avoid this problem, many allergists will do a panel of 6 common allergens, such as ragweed, on the first visit to see if the patient is allergic at all before proceeding with a battery of tests for the less common local allergens.) More research and some guidelines are needed in the field of allergy.

The term sinusitis refers to a bacterial infection in the paranasal sinuses, which are small air-filled spaces in the facial bones connected to the nose by small air passages. During an infection, the sinuses involved will fill up with pus. Usually the infections are triggered by the common cold and are short-lived (one to three weeks), but they may become chronic or be recurrent. These infections occur almost exclusively in people with chronic rhinitis. A careful history and physical examination will usually enable an otolaryngologist to pick out the smaller number of patients with possible chronic sinusitis from the larger number with chronic rhinitis. Treatment normally consists of a minimum of two weeks of antibiotics and decongestants and many weeks more for resistant cases. The antibiotics can be very expensive, and occasionally an expensive and somewhat dangerous surgical procedure will be resorted to prematurely because it is covered by a patients' insurance and the medicines are not.

The diagnosis of sinusitis has recently been greatly facilitated by the use of the CT scan,. which has helped us better see and evaluate the ethmoid sinuses. The ethmoid sinuses are between the eyes, are composed of multiple small cells and do not show up well on traditional sinus x-rays. We now know that in many patients the ethmoid sinuses are an important site of sinus disease and, not uncommonly, are the sole site. We also have learned that a large number of healthy, asymptomatic patients have a presumably insignificant thickening of the lining (mucosa) of their ethmoid sinuses. It is not surprising that this can happen because it has long been known that many patients without sinusitis have abnormalities in their more-easily-visualized (on x-ray) maxillary sinuses, either thickening of the sinus lining or cysts. Overall, about half of asymptomatic patients without a history of significant nasal problems will have one of these findings. An MRI scan will pick up even more of the sinus lining thickening than a CT scan. Radiologists, probably at the prodding of a surgically aggressive otolaryngologists, will usually read all cases of sinus mucosal thickening as sinusitis even though there is no scientific basis for such a reading except in cases of extreme thickening.

The recent use of CT scans and the introduction of endoscopic sinus surgery has resulted in an explosion of sinus surgery in America. The endoscopic technique utilizes the "arthroscope" used originally by orthopedic surgeons to do joint surgery through tiny incisions and is now also used to remove gallbladders and perform tubal ligations with minimal incisions. The technique has proven to be more dangerous, especially in the hands of less experienced operators, than its early proponents led us to believe. Nevertheless, when done by experienced surgeons for appropriate indications, it is an excellent way to do sinus surgery.

Unfortunately, no person or organization with any standing has ever stated what the indications are for endoscopic sinus surgery. It would seem logical to use it exclusively on patients whose chronic sinusitis has failed to respond to weeks of medical management or on patients whose recurrent sinusitis is greatly interfering with their lives in spite of controlling their chronic rhinitis, treating each infection with early and aggressive antibiotic therapy and, if appropriate, straightening their nasal septum, a significantly safer procedure. What often happens, however, is that sinus surgery is performed on people with sinusitis with little or no attempt at medical management, on people with chronic rhinitis and the sinus mucosal thickening or maxillary sinus cysts that I previously alluded to and on patients with chronic rhinitis and normal scans even though there are no studies that I am aware of that suggest that sinus surgery is an appropriate treatment for chronic rhintis.

To make matters worse (and more expensive), sinus surgeons today will often routinely operate on radiographically and clinically normal sinuses in conjunction with diseased or radiographically "abnormal" sinuses. This is done to save the patient the inconvenience of having a subsequent operation if more sinuses later become diseased, which can happen. (A study on the incidence of later disease in such sinuses would be useful.) This practice, however, exposes a patient to possible serious complications such as blindness and meningitis and will sometimes result in the development of sinusitis in a patient or in a sinus that has never had sinusitis before! I have seen the new developments of sinusitis twice for sure and almost certainly in another patient and have heard of other such patients from other otolaryngologists.

I think that it is important to look carefully at the type of medicine that is being practiced and taught at medical schools since these practices have an important impact on the next generation of doctors. Medical centers have long been known to practice expensive medicine, and there is no sign that this is about to change. When I was a medical student, grants for medical research were easy to come by, and a small cadre of full-time medical educators provided tertiary care almost exclusively. In those days, no academic general surgeon would be interested in doing a hernia repair or a routine gallbladder; but the situtation has since changed considerably. Under Nixon the amount of money available for medical research, except for cancer, sharply declined. Medical school faculty members now have to support their institutions with money made from patient care, and there are academic general surgeons interested in doing hernia repairs and gallbladders. Medical School faculty groups now contract with HMOs, have their own primary care doctors, have large public relations departments and advertise in all available media to reach patients directly, no longer relying so much on doctor referrals.

Unfortunately, the style of tertiary care at medical centers has often persisted even when a doctor is doing primary or secondary care. Tertiary care, of necessity, often involves multiple expensive and/or invasive tests and procedures to diagnose and treat a patient who is no better or perhaps is worse after previous diagnosis and treatment in the hands of other physicians. In primary and secondary care, however, most problems are not serious and can be handled with a careful history and physical examination, suggestions for changes in lifestyle and simple medicines.

A nearby academic group of otolaryngologists does not believe in using antihistamine-decongestant tablets at all or in using the sprays described in my handout on a long-term basis because they are not curative. Every patient with nasal symptoms has a CT scan of the sinuses, a $500.00 RAST-type allergy test, a nasal culture and rhinomanometry, a test of nasal airway resistance. If the patients' nasal symptoms do not go away after a course of an antibiotic and oral and topical corticosteroids, they are treated with allergy injections and/or nasal and sinus surgery. (The usual surgical procedure consists of operations on four sinuses, a straightening of the nasal septum and reduction of the nasal turbinates for a total overall cost of $10,000.00+.) This is mostly inappropriate as well as needlessly expensive treatment for a person with non-allergic rhinitis.

compare to my handouts.

I am in a surgical subspecialty which, traditionally at least, has been responsible for the medical and surgical management of the ear, nose and throat. At one point, consideration was given to making our official name Otolaryngology--Head and Neck Medicine and Surgery rather than what it ultimately became, Otolaryngology--Head and Neck Surgery. Data from the American College of Surgeons reveals what we spend the second greatest amount of time in our offices compared to the other surgical subspecialties that have a medical component--ophthalmology, urology and orthopedic surgery. In my specialty, however, some doctors, especially in academia, think of themselves simply as surgeons. They assume that a patient visiting them, whether referred by another physician or self-referred, is tired of medical treatment and has made a decision to have surgery. If academic otolaryngologists are only surgerons, who will know and teach non-surgical otolaryngology and to whom will it be taught?

The difference in remuneration between performing surgery and treating a patient medically is obscene and is a strong disincentive to non-surgical treatment. Furthermore, most surgeons have a prejudice in favor of surgical therapy that goes beyond greed--an ethic with macho overtones that even female surgeons are not immune to. At least one study has shown that a topical steroid spray is just as effective as surgery in allowing patients with nasal polyps to breathe well and is even more effective in allowing them to smell properly. Nevertheless, many nasal surgeons consider a nasal polypectomy or even endoscopic sinus surgery to be the initial treatment of choice for polyps. (The cost of the spray is also a deterrent to using it.) A large series at the Mayo Clinic has demonstrated excellent results using a plastic button to close nasal septal perforations, but most nasal surgeons prefer to do surgery. There is a nice office treatment to close a hole in the eardrum with trichloroacetic acid, but most ear doctors prefer to close perforations surgically with a graft.

Thanks to expert public relations, researchers wanting to promote themselves and their ideas and companies and institutions hoping to make a profit will often bring a new medical technology into widespread usage before its benefits are proven. A good example of this is bone marrow transplants for cancer. People get on TV and into the courts demanding that their medical insurance pay for this procedure. I have enclosed a copy of a recent *Medical Letter* (34:79-80,1992) appraisal of bone marrow transplants. (See attachment 6) They seem to work in only a small subset of the patients on whom they have been tried; and, even for those patients, the transplants have yet to be proven more effective than conventional chemotherapy. This treatment is being performed at great expense at numerous centers throughout the country. At best, it can be considered a promising treatment that has not yet been perfected. Having so many subjects in an experimental cancer treatment does not speed the acquisition of knowledge as much as you would think because cancer

research requires years of follow-up to get useful data, not just large numbers of patients.

New operations and other techniques are developed, published and disseminated all over the country without their efficacy being proven. In the 1970's a technique was developed to re-innervate a paralyzed vocal cord with a nerve-muscle pedicle. This was subsequently performed by otolaryngologists all over the country, including one I did myself. It was ultimately discovered that virtually no one else was getting anything close to the outstanding results reported by the developer, and the procedure has since all but been abandoned. LASER tonsillectomy was highly touted and widely performed but has not lived up to its promise and is being performed less and less. LASER removal of vocal cord nodules was initially even more highly touted and was probably the most significant operation for which otolaryngologists all over the country, including me, asked their hospitals to get them a LASER. Now the predominant thinking, at least among the experts on the professional voice, is that the traditional "cold steel" method of removing nodules is preferable to using the LASER. (Do not let anyone touch Bill's vocal cords with a LASER without talking to me first!)

We need to do all that we can to eliminate the unnecessarily expensive in medicine. Each specialty and sub-specialty of medicine has to be carefully scrutinized. There should be guidelines to steer the minority away from highly expensive (and highly remunerative) approaches that the majority of physicians do not deem necessary. Presently the AMA is developing "practice parameters," or "patient care strategies," with the help of specialty societies. Hopefully, these can become the needed guidelines. They should be carefully scrutinized, however, to be sure that they will eliminate the sorts of practices that I have described. Past guidelines have not. The high rollers in medicine will complain loudly, but the doctors who work hard and play by the rules (unwritten so far) will understand and will be willing to go along.

M.D.
OTOLARYNGOLOGY
HEAD & NECK SURGERY

Attachment # 2

CHRONIC RHINITIS

Chronic rhinitis is one of the most common afflictions of mankind. Literally translated it means a long-term inflammation of the nose. The inflammation can be manifested by various symptoms, including nasal discharge, nasal obstruction, sneezing, postnasal drip, facial pressure and/or pain, headache and nasal crusting. Chronic rhinitis usually begins insidiously for no apparent reason at any time in life. It may last for months or years and then go away equally mysteriously. It can come and go more than once during a person's lifetime. People with a personal or family history of asthma, hay fever, other allergies or nasal polyps are more prone to this condition.

We used to think that there were two distinct types of chronic rhinitis--chronic allergic rhinitis and non-allergic, or vasomotor, rhinitis. Present thinking is that most sufferers have some combination of the two. The year-round allergens that cause rhinitis are house dust, various types of molds, and various feathered or furry creatures, especially cats or dogs. A person with year-round nasal allergies, of course, can also have seasonal allergies to pollens.

Non-allergic factors include, among other things, various irritants and pollutants in the air that the average person can more or less tolerate but the chronic rhinitis patient cannot. The worst of the common irritants is tobacco smoke. Various other chemical dusts and fumes may provoke the symptoms of chronic rhinitis as well--driving behind a bus, being around fresh paint or inhaling perfumes, hair spray, etc. The nose of a person with chronic rhinitis will often over-react to temperature and humidity changes; and, as a result, some people with chronic rhinitis have a stuffy and/or drippy nose with weather changes, in air conditioning in the summer or in a dry, heated building in the winter. Some peoples' symptoms are brought on or aggravated by certain foods, alcohol, the act of eating, various medicines and emotions.

Attachment #3

M.D.
OTOLARYNGOLOGY
HEAD & NECK SURGERY

PRESCRIPTION NASAL SPRAYS

The prescription nasal sprays that have become available in the past few years represent a great step forward in the ability of doctors to treat chronic rhinitis. These drugs are both safe and effective for long-term use, unlike non-prescription sprays which are good for short-term use but cause rebound and can lead to dependency if used regularly for more than a few days. I will describe two types of these drugs--the steroids and cromolyn. Usually the use of one spray will suffice, but in severe cases the sprays can be used with tablets or with each other.

The newer steroids nasal sprays--Vancenase, Vancenase AQ, Beconase, Beconase AQ and Nasalide--contain a corticosteroid, or drug of the cortisone class. These drugs are different from the steroids used by some athletes, who are actually taking male hormones. These medicines were used first as oral inhalers for treating asthma, and there are years of experience confirming the safety of long-term use. The corticosteroids are helpful in the treatment of chronic rhinitis because of their efficiency in suppressing inflammation. They are good for allergic and non-allergic rhinitis and are good at shrinking nasal polyps, which often co-exist with chronic rhinitis.

The corticosteroids are well-known for producing side effects, especially in long-term use. The big advantage of the newer nasal steroids is that there are none of these side effects. The steroid ingredient of the nose sprays does get into your bloodstream, as will any water soluble substance you put into the nose; but once in the bloodstream this medicine is rapidly broken down by the body's enzymes, not allowing it enough time to have any effect. The absence of measurable steroid side effects has been nicely documented in studies utilizing higher doses than those normally used for the nose.

Attachment #5

Differences in clinical and immunologic reactivity of patients allergic to grass pollen and to multiple-pollen species

Bousquet J, Becker WM, Hejjaoui A, Chanal I, Lebel B. J Allergy Clin Immunol 88:43–53, 1991.

Multiple antigen immunotherapy, although it is the basis of clinical allergy as it is practiced in the United States, has not had its efficacy proved using double-blind, placebo-controlled techniques and standardized antigens. Studies of this sort are critical to the future of allergy, both for the well-being of the patients being given the immunotherapy and for the reimbursement of physicians administering it. This group of French investigators presents data on one of the fundamental unanswered questions of modern immunotherapy: does polyantigen immunotherapy work? The preliminary answer in their hands is a surprising no.

The goal of this study was to determine if there are immunologic differences between persons who are specifically allergic only to grass pollens versus multiple-pollen allergic patients in their response to immunotherapy. Patients selected had seasonal symptoms of allergic rhinitis, and half had additional asthma or conjunctivitis. There were no patients with perennial symptoms, and no patients had previously received immunotherapy. All patients' clinical symptoms correlated to specific antigen exposure and had concordant skin and radioallergosorbent tests (RASTs). Treatment and control groups were well matched.

Seventy patients were enrolled, and 66 completed the study. Thirty-three patients were only orchard-grass allergic, and 33 had orchard-grass allergy with other pollen allergies. There were four experimental groups, 17 placebo-treated patients with grass-pollen allergy, 17 placebo-treated patients with multiple-pollen allergies, 16 grass-pollen allergic patients treated with grass-pollen immunotherapy, and 16 multiple-pollen-allergic persons treated with multiple-pollen immunotherapy. Immunotherapy was given via a rush protocol that had been shown to be effective specifically for grass-pollen allergy. All immunotherapy reagents were standardized. The maintenance dose was 2000 Biologic Units for each clinically relevant allergen the person was allergic to. This relatively high dose of immunotherapy was selected based on previous investigations. Three of the grass-pollen allergic and four of the multiple-pollen allergic patients had systemic reactions. Both nasal challenges and symptom scores were followed and only significantly improved for the grass-pollen-only allergic persons given grass immunotherapy.

The conclusion of the study was that specific immunotherapy with an equipotent biological dose of standardized extract effective in patients allergic to grass pollen was ineffective in patients allergic to multiple-pollen species receiving a mixture of pollen extracts. This does not mean that polyantigen immunotherapy cannot work, but that it is more complex than just adding up all of what a person is allergic to and administering the mix. Pushing the dose up in the mixtures may be helpful, but given the number of systemic reactions, this may be a problem.

Eric Macy, M.D.

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BONE MARROW TRANSPLANTS FOR MALIGNANT DISEASES

Intensive chemotherapy, with or without total body radiation, followed by bone marrow transplantation is now widely used in the treatment of malignant diseases. The drugs and radiation needed to try to eradicate the malignancy unavoidably destroy the bone marrow; intravenous infusion of bone marrow cells restores the marrow by repopulating it. Diseases for which bone marrow transplantation has been used include the leukemias and lymphomas, *breast cancer, neuroblastoma, ovarian cancer, germ cell tumors, melanoma, multiple myeloma,* and malignant gliomas (NC Gorin, Am J Clin Oncol, 14 suppl 1:S5, 1991; Medical Letter, 33:39, 1991; G Gahrton et al, N Engl J Med, 325:1267, 1991).

PROCEDURE — Pre-transplant treatment with anticancer drugs, with or without total body radiation, usually takes four to ten days. Bone marrow or hematopoietic stem cells previously collected from the patient's own marrow or blood, or from a donor's marrow, are then infused intravenously. For two to four weeks afterward, patients require close monitoring, reverse isolation, prophylaxis and treatment of viral, bacterial, and fungal infections, and frequent infusions of blood products (JM Goodrich et al, N Engl J Med, 325:1601, 1991; JL Goodman et al, N Engl J Med, 326:845, 1992).

AUTOLOGOUS *VS* ALLOGENEIC — Autologous bone marrow transplantation is safer; it does not require a donor or immunosuppression and usually does not cause graft-versus-host disease. Advances in collecting normal hematopoietic stem cells from peripheral blood and in removing cancer cells from bone marrow with drugs or antibodies may lead to an increase in autologous transplants (LB To et al, Bone Marrow Transplant, 9:277, 1992; SC Gulati et al, Curr Opin Oncol, 4:264, 1992). Allogeneic transplants from HLA-matched siblings or unrelated donors have the advantages that the graft will not include tumor cells and that the graft-versus-host reaction may include a graft-versus-tumor effect.

HIGH-DOSE CHEMOTHERAPY — Drugs used before bone marrow transplants, depending on the indication, include cyclophosphamide *(Cytoxan,* and others), cytarabine *(Cytosar-U,* and others), busulfan *(Myleran),* melphalan *(Alkeran),* thiotepa, carmustine *(BiCNU),* etoposide *(Vepesid),* and carboplatin *(Paraplatin).* These drugs, in addition to their effect on cancer cells, also suppress the immune cells that may interfere with engraftment in allogeneic transplants. Other immunosuppressive drugs, such as prednisone, methotrexate, or cyclosporine, are almost always used prophylactically in allogeneic transplants and may also be needed to treat graft-versus-host disease (R Storb, J Pediatr, 118:S10, 1991).

HEMATOPOIETIC GROWTH FACTORS — Use of the new leukocyte colony-stimulating factors G-CSF *(Neupogen)* or GM-CSF *(Leukine, Prokine)* may shorten the time to recovery after transplantation and decrease the incidence of infection. In addition, growth factors are now used before collection of peripheral blood to increase the harvest of stem cells. There is no evidence that these growth factors themselves stimulate growth of hematological malignancies (Medical Letter, 33:61, 1991; R Advani et al, Ann Intern Med, 116:183, 1992; GJ Lieschke and AW Burgess, N Engl J Med, 327:99, July 9, 1992).

RESULTS — The mortality of autologous marrow transplants has ranged from 5% to 20%; with allogeneic transplants, mortality ranges from 10% to about 30%. The effectiveness of bone marrow transplants varies with the disease, its stage, previous treatment, the patient's age and condition, the pre-transplant treatment, the source of the marrow, the transplant regimen, and the experience of the transplant center. In general, bone marrow transplant has led to long-term disease-free survival most often in patients with leukemia and least often in those with solid tumors. The incidence of leukemia-free survival for at least two years has been near 60% in patients with early leukemia, 40% with intermediate leukemia, and 20% with advanced disease (MM Bortin et al, JAMA, 268:607, August 5, 1992). For any indication, few clinical trials are available comparing high-dose chemotherapy supported by bone marrow transplantation with conventional chemotherapy (DM Eddy, J Clin Oncol, 10:657, 1992), and some have found no advantage in survival with the more intensive procedure (MM Horowitz et al, Ann Intern Med, 115:13, 1991; GJ Schiller et al, J Clin Oncol, 10:41, 1992).

COST — The cost of autologous transplantation may be more than $100,000, depending on the complications. An allogeneic transplant costs, on the average, about $150,000, but the total cost has exceeded $500,000 in some cases.

CONCLUSION — High-dose anticancer treatment followed by bone marrow transplantation offers the hope of long-term disease-free survival to some patients with hematological and other malignancies. Morbidity and mortality are high, however, and in most conditions an advantage over conventional chemotherapy has not been demonstrated.

ORAL MESALAMINE FOR ULCERATIVE COLITIS

An oral formulation of mesalamine (5-aminosalicylic acid, 5-ASA, *Asacol* - Proctor & Gamble), was recently approved by the US Food and Drug Administration (FDA) for treatment of mildly to moderately active ulcerative colitis; it has not been approved for maintenance of remissions. Olsalazine *(Dipentum)*, a similar drug (Medical Letter, 32:105, 1990), is approved for maintenance of remissions but not for treatment.

PHARMACOLOGY — Sulfasalazine (*Azulfidine*, and others), which has been used for many years to treat patients with ulcerative colitis, is a combination of sulfapyridine with mesalamine; the sulfapyridine component is thought to be responsible for many of the drug's adverse effects, including allergic skin reactions (sometimes severe), anemia, thrombocytopenia, leukopenia, and possibly male infertility. Mesalamine is active against ulcerative colitis topically in the colon, but not systemically. Given orally, plain mesalamine is mostly absorbed in the upper gastrointestinal tract and does not reach the colon. Olsalazine is a dimer of mesalamine, two molecules linked by an azo bond; most of the mesalamine is released only after the bond is split by bacteria in the colon. The new mesalamine tablet is coated with a pH-sensitive film that protects the drug from absorption in the upper gut; at the higher

THE WHITE HOUSE

WASHINGTON

September 9, 1994

Margaret M. Craven, M.D.
Woman's Health Care Plus
2093 Western Avenue
Guilderland, NY 12084

Dear Dr. Craven:

Dr. Koop shared with me your very compelling letter to the President about your personal experiences with the current malpractice system.

As you well know, lawsuits take a toll on physicians and their families, both emotionally and financially. Senator Mitchell and Congressman Gephardt have introduced health care reform bills with malpractice provisions that will minimize frivolous lawsuits while compensating deserving individuals.

Both bills establish an alternative dispute resolution process to resolve malpractice claims in a fair, efficient and timely way. An individual may bring a case to court only after participating in the process. In addition, before filing a lawsuit, a lawyer must obtain a "certificate of merit" verifying that there is reasonable cause for filing an action.

Both bills also limit attorneys' contingency fees. Congressman Gephardt's plan limits contingency fees to one-third of an award and Senator Mitchell's plan limits contingency fees to one-third of the first $150,000 and 25 percent of any additional award. In addition, the plans permit damage awards to be paid by a defendant over a period of time.

The President and I look forward to continuing to work with Congress to pass meaningful health care reform. In the meantime, I truly hope that your experiences with the malpractice system will not prevent you from continuing to provide invaluable service to your community.

Sincerely yours,

Hillary Rodham Clinton

Hillary Rodham Clinton

cc: C. Everett Koop, M.D.

THE WHITE HOUSE

August 24, 1994

C. Everett Koop, M.D.
The C. Everett Koop Institute
Hanover, New Hampshire 03755

Dear Dr. Koop:

Thank you for letting me know about Dr. Kenneth Clark. Fraud and abuse rob our health care system of billions of dollars each year, and it is inexcusable that those doctors who make legitimate attempts to report fraud must fear punishment. The bill that Senator Mitchell has introduced protects "whistle-blowers" who provide information about possible violations of the Health Security Act.

It was good to visit with you last week. We are still hopeful that Congress will pass real, workable health care reform this year.

With best wishes, I remain

Sincerely yours,

Hillary

Hillary Rodham Clinton

THE WHITE HOUSE

June 23, 1994

C. Everett Koop, M.D.
5924 Maplewood Park Road
Bethesda, Maryland 20814

Dear Dr. Koop:

Thank you for sharing with me the concerns of Dr. Billy Melvin, Executive Director of the National Association of Evangelicals. The religious community provides desperately needed health care services for so many people, including the most disadvantaged in this country. The President and I are committed to preserving the essential role of religious institutions under health care reform.

Nothing in the President's proposal for health care reform will limit the ability of churches to sponsor nursing homes and lifetime care centers. Instead, the plan will support hospitals and nursing homes with religious affiliations by continuing to provide tax exemption to non-profit health care providers that serve their communities. In addition, as you know, universal coverage will relieve religious health care institutions of the burdens of uncompensated care.

The Christian community has been tireless in its advocacy for health security. I look forward to continuing to work with them to pass health care reform legislation that will make that goal a reality for all American families.

With best wishes, I am

Sincerely yours,

Hillary Rodham Clinton

Hillary Rodham Clinton

I'm looking forward to another visit soon. Thanks too for making the huge effort to appear on the NBC special. I believe it will help inform millions who watch. Hillary

MEMORANDUM

DATE: April 28, 1994

TO: Melanne Verveer

FROM: Chick Koop

RE: Letter to me from the National Association of Evangelicals

---

I wonder if you would be good enough to put this in the hands of the First Lady. I would appreciate it very much.

Jean -
Can we talk
about this.
MV

C. EVERETT KOOP, M.D.

April 28, 1994

Dear Hillary:

I am enclosing the first page of a letter to me from Dr. Billy A. Melvin, Executive Director of the National Association of Evangelicals. I have bracketed the last three paragraphs for your attention.

The zealous activity of government to separate church and state was never meant to separate man from his own faith. I do not take what Dr. Melvin says lightly because I have enough experience with similar things in days gone by to know that it doesn't take long for things to get out of hand and then become regulatory.

I hope you will use your considerable influence to assure us that this will not happen in reference to health care, especially from nursing homes and lifetime care centers under Christian auspices.

It was good to see you the other day, if only for a few minutes.

Sincerely yours,

Chick

C. Everett Koop, M.D.

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NATIONAL ASSOCIATION of EVANGELICALS

Office of the Executive Director

National Office
450 Gundersen Drive
Carol Stream, IL 60188
Phone: 708-665-0500
FAX: 708-665-8575

Dr. Billy A. Melvin
Executive Director

April 15, 1994

Dr. C. Everett Koop
5924 Maplewood Park Rd.
Bethesda, MD 20814

Dear Dr. Koop:

This past week NAE sponsored a one-day meeting of representatives from our member denominations and churches who are working in the area of retirement homes, nursing homes, homes for unwed mothers, troubled teens and homes for children. Our objective was to learn what evangelicals are doing in these areas, some of the current challenges and what we might do together to help one another.

Happily I can report to you that there is a lot of activity. It was gratifying to hear the reports of how life care agencies are thriving in the evangelical community and how lives are being blessed and changed through the work being done. Perhaps some time in the future I will be able to provide you with more specific information -- including statistics.

One thing we know for sure. The need for life care facilities and programs will continue to accelerate. There are currently 65 million people in our country age 50 and above. It is estimated that this segment of our population will double by the year 2010 -- just 16 years! And, with the growing number of dysfunctional homes in our society, it is hard to dispute the need we will have for more Christian facilities to care for children and troubled teens.

An ominous note, however, was sounded that could impact our ability to respond. There is growing pressure on church sponsored life care facilities by both state and federal governments. Deep concern was expressed as to whether or not the churches could continue to extend such care without giving up their distinctive Christian witness and emphasis.

For example, one administrator reported that even though his church sponsored retirement home has been careful to follow all Equal Employment Opportunity practices because of receiving state and federal funding through Medicaid and Medicare, he is concerned that the government will try to control what type of activities his facility can offer.

In the past, he reported, state surveyors had been critical of activities they considered religiously based, such as Bible studies and hymn sing-a-longs. Their comments suggested such activities were not meaningful. Keep in mind that each of these activities were strictly voluntary. No one was compelled to attend. Residents attended by choice.

THE WHITE HOUSE

WASHINGTON

May 24, 1994

Mr. Bill Sanders
President
Dynacor Division
Medline Industries, Inc.
One Medline Place
Mundelein, Illinois 60060

Dear Mr. Sanders:

The First Lady asked me to respond to your letter about the Food and Drug Administration's recent actions on laparotomy sponges. I have spoken with Jerold Mande, Executive Assistant to the Commissioner of the FDA, about the questions you raised in your letter. I could not locate Dr. Patty at the Centers for Disease Control.

Enclosed please find the memorandum distributed to the industry about the contamination by mold found by the FDA on cotton being imported into the United States. According to Mr. Mande, the FDA discovered the mold when it began using a more sensitive and, they believe, more reliable test. While both the FDA and the CDC have concluded that the mold is nonpathogenic, the FDA has recommended that manufacturers of gauze products conduct appropriate validation studies of each sterilization cycle.

The FDA is continuing to review this issue and will revise its recommendations as additional information becomes avail-able. I have asked Mr. Mande to notify me if the FDA changes its policy in any way. Please feel free to contact me with any additional questions or concerns at (202) 456-2599.

Sincerely yours,

Jennifer Klein

Jennifer Klein
Special Assistant
to the President
for Domestic Policy

MEDLINE

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Mundelein, Illinois 60060.4486

1.708.949.2056
Fax 708.949.2691

Bill Sanders
President
Dynacor Division

April 5, 1994

Mrs. Hillary Rodham Clinton
The White House
Washington, D.C. 20500-2000

Dear Hillary,

First of all, I want you to know how great it was to see you again yesterday at Wrigley. As I'm sure Betsy has or will tell you, the group went to Helen Alanso's house after the game, and then later to Rick Rickett's restaurant. I guess the price of fame makes it next to impossible for the First Lady to spend an evening like we did. You've done so much to be proud of, and to make us all proud to know you. Whether you really remembered me or Betsy remembered for you was unimportant, as your positive reaction was very rewarding, and I thank you for that. How many people can say that they've been kissed on the cheek by the First Lady of the U.S.A.?

I have mixed emotions about writing this letter. It seems hypocritical to not have been in contact with you for 30 years and now ask for your help, but my excuse is simple. You're the only First Lady I've ever known, and the problem I'm involved with is directly related to health care and health care costs. The short version of my problem is as follows:

The FDA has involved itself in gauze related products that are imported and either sterile or to be packaged and sterilized. (Examples of products affected are laparotomy sponges, gauze sponges and pads, and cotton bandages.) The FDA efforts have caused three companies to have voluntary recalls, and forced the industry to begin double sterilizing these products. The recalls of course cost millions of dollars, and the double sterilization will raise costs by a minimum of 10%. My problem with all of this is two-fold:

1) The CDC has indicated that there has been no increase in infection in these related products -- in fact, on the laparotomy sponges, the infection rate had dropped prior to any FDA action. Our contacts at the CDC feel the recalls on lap sponges are totally uncalled for based on what they are experiencing in the medical field.

2) The FDA's new findings have been based on a new test procedure never

done before, and from what we understand, never validated.

Another way to state the above is that the FDA has caused the American health care patient a measurable increase in costs while not improving health care one iota, on the basis of a non-validated test.

Obviously, Hillary, I'm biased, and am not expecting you or anyone else to act on my opinions. What I would like is to have my information verified. If possible, I would like someone to:

- call Dr. Patty of the Center for Disease Control and ask his opinion on the lap sponge recall;
- ask the head of the FDA why instructions coming from Washington have put imported sterile gauze products on alert status, and;
- ask the FDA the following questions regarding the new testing method for these types of products:
    - why is the current test method different from previous years?
    - why wasn't the industry notified?
    - why hasn't this new method been validated?

Hillary, at the same time that I strongly support your husband's health care program and would like to see costs contained for everyone in the country, I have a selfish interest in this matter as well. The division I am president of is responsible for lap sponges, and the FDA's actions have cost my division dearly. At the present time, health care costs are continuing to increase, and since we're talking about a significant amount that is in both of our best interests to eliminate, I've come to you for help.

Once again, it was a real pleasure seeing you again, and once again I apologize for capitalizing on the situation, but my company and I are at a loss as to how to get the FDA to respond to our requests, and to encourage the FDA and the CDC to work together for the common good. Thank you so much for taking the time to consider this letter.

Yours truly,

Bill Sanders
President
Dynacor Division

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville MD 20850

APR 22 1994

To: All Device Manufacturers/Repackers Using Cotton

Since August 1993, the Center for Devices and Radiological Health (CDRH) has become aware of several instances where devices made of Chinese cotton have been found to be contaminated with mold, even though the devices were labeled as sterile. Devices containing cotton include, but are not limited to laparotomy sponges, surgical sponges, surgical drapes, operating room towels and wound dressings. To date, we have not noted problems regarding cotton grown in other countries, including the United States. As a precaution, the following information should be considered regardless of the cotton's origin.

The prevalent mold which has been identified thus far is Pyronemia domesticum, which belongs to the class Ascomycetes and is believed to be nonpathogenic.

Several companies who have experienced problems with mold have changed their sterilization practices. One manufacturer has determined that P. domesticum is resistant to standard ethylene oxide (EO) sterilization cycles and to standard gamma radiation doses. The manufacturer is using a standard steam sterilization cycle followed by a standard EO sterilization cycle. Other companies have instituted a standard EO sterilization cycle followed by a standard gamma radiation cycle, or vice versa.

CDRH is not advocating any of the above methods, but is recommending that you conduct appropriate, adequate and thorough validation studies of each sterilization cycle in use. The sterilization validation studies should not only focus on bacterial contamination, but should also include molds and yeasts. The following points should be included as part of your sterilization validation:

1. Bioburden of the incoming cotton device. The bioburden assessment must include bacteria, molds and yeasts using established test methods. The entire device must be submerged in the culture media. Bioburden should be assessed as part of sterilization cycle development, and then periodic bioburden assessment should be performed once the cycle has been validated.

2. Sterilization cycle development studies should include inoculated product using P. domesticum and any other microorganisms found during initial bioburden assessment. The inoculated product should be placed in the hardest to sterilize locations within the chamber. Standard methods

should be utilized for inoculation, recovery and culture techniques. Again, the entire device must be submerged in the culture media. If gamma radiation is used to sterilize the device, our experience has shown that incubation up to 30 days may reveal slow growing microorganisms which were not found at the traditional 14 day incubation period.

Use of inoculated product should not preclude the use of biological indicators and/or dosimeters during validation and during routine processing.

3. During validation, sterility testing of the sterilized cotton should be performed using established test methods. The testing regimen should include identification of bacteria, molds and yeasts. Again, the entire device must be submerged in the culture media. Traditionally, FDA does not require that routine sterility testing be conducted on each sterilization load, provided that the sterilization process has been properly validated. However, for cotton devices, it is recommended that at least periodic sterility testing be performed to assess that the cycle is adequate.

If you have any questions regarding this letter, you may contact John Samalik of the General Surgery Branch at the above address or at (301) 594-4595.

Sincerely yours,

Ronald M. Johnson
Director
Office of Compliance
Center for Devices and
Radiological Health

11 May 1994

MEMORANDUM FOR JENNIFER KLEIN/DOMESTIC POLICY

FROM: Jerold Mande/FDA 301-443-3255

SUBJECT: DeRoyal Industries and Laparotomy Sponges

As I mentioned when we spoke last week, Dr. Kessler and I met with Pete DeBusk and Susan Hevey of DeRoyal Industries on April 1 in a "get acquainted" meeting. One of the matters we discussed generally was DeRoyal's experience with mold and lap sponges made from Chinese cotton. The issue was not any specific event involving DeRoyal, lap sponges, or FDA, but rather DeBusk's generic concern about Chinese cotton, mold, and lap sponges.

Further investigation after the meeting revealed that FDA was already pursuing the generic problem. The matter was first brought to our attention by the Canadian government. FDA has taken a number of actions dating back to last August.

On 22 April 1994, FDA issued a letter to companies using Chinese cotton (attached). A copy was sent to DeBusk. FDA is engaged in a number of other activities, including a visit to the Chinese manufacturers.

You also mentioned an interest in CDC on this matter. FDA and CDC have consulted about the human health risk of the mold -- Pyronemia domesticum. The conclusions of the two agencies to date are that P. domesticum is nonpathogenic.

We continue to be in touch with DeBusk on this subject. Please call me if I can provide any additional information.

THE WHITE HOUSE

WASHINGTON

February 9, 1994

Mark C. Shields, M.D.
637 Clarendon Lane
Aurora, Illinois 60504

Dear Mark:

Thank you for your thoughtful letter. I appreciate the time you took to share your ideas and concerns about the Health Security Act.

You expressed reservations about the structure and power of alliances. As you noted, insurance coverage is best purchased in the private market, and employers should be included in purchasing decisions. That is why the Health Security Act builds on the private, employer-based system that exists today. Under the Act, employers contribute to health insurance premiums for their workers. Alliances simply increase purchasing power and lower administrative costs for businesses and individuals who today buy small group and individual insurance. Alliances offer to these consumers a choice of health plans that compete by providing high quality health care at a reasonable cost rather than by selecting only healthier applicants or varying premiums based on health status or other characteristics, as so many do today.

Alliances do not have the power to select which health plans may bid and do not have authority to regulate plan premiums. An alliance may refuse to contract with a health plan only if the premium substantially exceeds the alliance's premium target. Further, alliances do not cap premium rates. Instead, allowable increases in premiums are based on a formula set in legislation that adjusts for inflation and other factors, with no enforcement power or discretion on the part of the State or the alliance.

You also expressed concern about price controls. The President considered, and specifically rejected, a plan imposing price controls on health care. Price controls mean government micromanagement of every health care service and product. The President's primary strategy for cost containment is private sector competition -- creating the right economic incentives to encourage health plans to compete on price and quality.

Under the Health Security Act, caps on premiums, rather than price controls, act as a reinforcement mechanism or backstop. If employers and individuals have a responsibility to contribute to coverage and the federal government provides discounts to small

businesses and individuals, we need to guarantee that premiums will not rise unchecked and the government will not spend without accountability. The Congressional Budget Office (CBO) released a report in September outlining how to best structure premium caps to control health care costs effectively without creating adverse effects. The Health Security Act includes all of CBO's suggested methods.

You also mentioned malpractice reforms. The proposed Health Security Act includes limitations on contingency fees, mandatory use of alternative dispute resolution, reductions in damages based on recovery from collateral sources, and periodic payment of awards at a plaintiff's request. The Act also authorizes demonstration projects to test whether enterprise liability reduces defensive medicine and to determine the effects of allowing practice guidelines to be used as a defense in malpractice actions. We hope that these reforms will begin to relieve physicians of the threat of litigation that may lead to the practice of defensive medicine and increased health care costs.

Finally, you noted that the benefit package may be too broad. We believe that only if all Americans have coverage for a comprehensive package of benefits, including preventive services, will health outcomes improve and overall costs decrease. We have been conservative in all of our calculations and believe that the benefit package can be delivered for the premiums that we have estimated.

Thank you again for sharing your support and ideas. I am sorry that I will not be able be with you in May in the Fox Valley.

With warm personal regards, I remain

Sincerely yours,

Hillary

Hillary Rodham Clinton

March 15, 1994

Cynthia V. Carpenter
45 Crescent Road
Willingboro, New Jersey 08046

Dear Mrs. Carpenter:

Thank you for writing to support our proposal for health care reform. Your words of encouragement mean a great deal to me.

Under the President's plan, all Americans will have the security of knowing that if they lose their jobs or change jobs, if they move or get sick, they will be guaranteed a comprehensive package of benefits that can never be taken away. As you point out, the plan asks both employers and individuals to contribute to make that guarantee a reality.

We are committed to assuring all Americans the security that they deserve. Thank you again for your support.

Sincerely yours,

Hillary Rodham Clinton

THE WHITE HOUSE

November 2, 1994

Ray Bourhis, Esq.
Ray Bourhis & Associates
1050 Battery Street
San Francisco, CA 94111

Dear Ray:

I am sorry that it has taken so long for your letters to reach my desk. I very much appreciate your taking the time -- several times -- to respond to my questions about insurance reform. Ironically, though, as we continue our work on health care reform, your comments are timely again.

I have shared your letter with Jennifer Klein on my staff and have asked her to work with the Justice Department on this issue. As part of their Civil Justice Reform Project, they are considering studying unfair insurance trade practices. I have also asked Jennifer to contact you as this project continues.

With best wishes, I am

Sincerely yours,

Hillary Rodham Clinton

TO: Hillary Rodham Clinton
FROM: Jennifer Klein J.K.
DATE: 10/28/94
RE: Ray Bourhis

You had asked me to look into the series of letters from Ray Bourhis to various people in the Administration. He has been writing since last year, but has not yet received an appropriate response. I would recommend sending the attached response. The issues he raises -- federal regulation of insurance and the creation of a Presidential Commission to study unfair insurance practices -- are, according to the Justice and Labor Departments, quite controversial, so I did not think you should take a position in writing. I will follow up with Mr. Bourhis.

cc Jennifer Klein

Al Sprabery

PHOTOCOPY
HRC HANDWRITING

THE WHITE HOUSE

July 20, 1994

Ms. Patricia Domzalski Solans
5800 Arlingdale Drive
Palatine, Illinois 60067

Dear Pat:

Thank you for your letter. It was good to hear from you. Since the election, I've heard from a number of our high school classmates. It has been great for me to have the opportunity to catch up on all their activities and where they are living now.

I understand the reunion committee members have discussed the possibility of holding our class reunion in Washington this year. When plans are finalized for the reunion, I'm sure the committee will notify you and all the members of our class.

With warm, best wishes, I am

Sincerely yours,

Hillary

Hillary Rodham Clinton

If you think the Convention you're attending would like a speaker, please call my office (202-456-2369) and talk to Jennifer Klein.

June 24, 1994

Ms. Hillary Rodham Clinton
The White House
Washington, D.C.

Dear Hillary,

The last time I wrote to you it was a hand written letter of congratulations from one of your many old high school classmates. I have tried on numerous occasions to write to you as a small business owner with concerns about the different things that affect the business climate in this country, and my business directly. Unfortunately, none of those letters ever got mailed. I always found myself trying to say too much. I seemed to ramble on about issues like tax credits and health care costs, etc. I began to feel like the Congress, always talking in circles and never getting to the point.

Lately two things have happened that have prompted me to write another note with the intention of actually mailing it.

The first thing is a convention that we are attending in Washington D.C. this year over the Labor Day weekend. I was disappointed to get information regarding the speakers at our convention. I thought that someone at the corporate offices (My husband and I own a franchise operation. We are Kwik Kopy Printers.) in Houston would have the common sense to find someone in Washington to speak to our convention about how our small business will be affected by health care proposals. Unfortunately, they did not. Instead they are parading a group of motivational speakers before us. Not that we don't need extra motivation, but it seemed an ideal situation to get something explained first hand. I was sure that someone would still be in Washington, eventhough it is a holiday, who would be willing to talk to us. Kwik Kopy has over a thousand franchises around the world, but the majority of them are in this country. That adds up to a lot of people who should be interested in how future government regulations could impact our businesses. On the other hand, I've been wrong before.

The next issue that compelled me to write is the news reports that next year's 30th reunion will be at the White House. I just want to say thank you for making such a thing possible.

Several years ago I had the privilege of sitting in a hotel lobby in New Orleans with Alan Shepard (he's on the board of directors with Kwik Kopy). We were having a casual conversation while my husband went to our room to get some things for the Admiral to autograph for our two boys. Other than my wedding and the birth of my sons, I thought that was going to be the high point of my life. Well, you just topped it! Thank you! I should have learned by now that life is full of surprises. This is one of the good ones that I will always treasure.

Sincerely,

Pat

Patricia Domzalski Solans
5800 Arlingdale Drive
Palatine, IL 60067

THE WHITE HOUSE

May 31, 1994

Mrs. Moreland G. Smith
3750 Peachtree Road, N.E. #855
Atlanta, Georgia 30319

Dear Mrs. Smith:

It is always wonderful to hear from a fellow Wellesley graduate. I truly admire your persistence in uncovering the over-charges paid by the Medicare program for your husband's care.

It is illegal today and will continue to be illegal under the President's health reform proposal for physicians to charge Medicare for services that they have not performed. I have forwarded your letter to the Office of Inspector General at the Department of Health and Human Services for further review.

The General Accounting Office has estimated that fraud and abuse account for as much as ten percent of all health care expenditures. I agree with you whole-heartedly that we must take serious steps to eliminate the fraud and abuse in our health care system.

With best wishes, I am

Sincerely yours,

Hillary Rodham Clinton

Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

April 18, 1994

Mrs. and Mr. David Markson
223 Garnet Lane
Bala Cynwyd, Pennsylvania 19004

Dear Mrs. and Mr. Markson:

Thank you for taking the time to write your very thoughtful letter and for sharing your personal and professional experiences. I was saddened to learn of your son's relapse and hope that his second transplant is successful.

My visits over the past year to places like the Children's Hospital of Philadelphia (CHOP) have confirmed that we have the highest quality of care, the most talented and dedicated health professionals, and the most advanced research institutions in the world. We must preserve what is good about our health care system. The problem, as you point out, is that too many Americans do not have access to these benefits. Too many Americans are denied insurance because of pre-existing conditions or pay more because they are sick or old. Others risk losing their coverage when they reach lifetime limits -- just as they need it the most.

The President's proposal for health care reform will guarantee private health insurance to all Americans. It will also ensure that all Americans can choose their doctor and health plan. You raised specific concerns about the ability of alliances and managed care plans to restrict choices and compromise health care quality. Alliances will not have the power to exclude health plans. Instead, they will simply give bargaining power to small businesses and individuals who today pay 35 percent more than big businesses for the same insurance. Consumers will choose among health plans based on understandable information about quality, consumer satisfaction and the range of health care providers offered by the plan. As I mentioned when I spoke at CHOP, all Americans will be offered at least one fee-for-service plan that allows patients to see any doctor they choose, and all managed care plans will be required to offer a point-of-service option.

Once again, thank you for writing. My thoughts and prayers are with you and Zachary.

Sincerely yours,

Hillary Rodham Clinton

THE WHITE HOUSE

May 23, 1994

Peter Barg, M.D.
P.O. Box 855
Mendocino, CA 95460

Dear Peter:

Thank you for writing to share your support and advice. Your words of encouragement mean a great deal to me.

You noted that you support the single payer approach. As I am sure you know, the Administration's proposal for health care reform gives each state the flexibility to form a single payer system in all or part of the state. Within a national framework guaranteeing coverage and real access to comprehensive, high quality and affordable health care services, we chose to allow states to develop and implement a system best able to meet the needs of their citizens. In some areas of the country, a single payer system certainly will be most effective.

I was so sorry to hear about your friend Chris Carnes. I truly hope that he has received the care he so obviously needs and deserves.

With best wishes, I am

Sincerely yours,

Hillary Rodham Clinton

THE WHITE HOUSE

May 13, 1994

Sunil Chacko, M.D., M.P.H.
549 Riverside Drive
Apartment 1G
New York, New York 10027

Dear Dr. Chacko:

I am so sorry if you thought that my comments at the Columbia Institute suggested a lack of appreciation for the tremendous struggles and contributions of undocumented aliens to our national economy.

As you noted in your letter, the President's proposal for health care reform does not extend coverage to undocumented aliens. It does, however, cover those categories of legal aliens that are traditionally eligible for federal programs such as AFDC and SSI. The Clinton plan also prohibits discrimination against health care providers and patients on the basis of race, national origin and language.

In addition, the President's plan recognizes that while uncompensated care will be largely eliminated as all Americans and legal residents are guaranteed coverage, hospitals will continue to provide emergency care to undocumented aliens. The plan therefore dedicates $800 million each year to a "vulnerable populations fund" to support hospitals providing unreimbursed care. The President's

proposal also increases funding for community and migrant health centers -- health care providers that today so often serve undocumented aliens -- by providing $100 million each year for the next five years.

The richness of our nation's economy and spirit have developed in large part because of the hard work and dedication of immigrants. Thank you for writing.

Sincerely yours,

Hillary Rodham Clinton

Hillary Rodham Clinton

Sunil Chacko, MD, MPH (Harvard)
549 Riverside Dr., 1g
New York, NY 10027, USA
Tel. and Fax: (212) 932 - 2397

March 19, 1994

Mrs. Hillary Rodham Clinton
Chairperson
Presidential Task Force on Health Care
The White House
Washington D.C.

Dear Mrs. Clinton:

I was deeply pained and saddened by your harsh tone and abrupt manner when you replied to a question a few days ago at the Columbia Institute, Colorado, on the question of covering "undocumented workers" under the new health plan. This is indeed astonishing as it comes from the First Lady we respect and admire. There are many health problems that can be tackled through collaboration with institutions in neighboring countries such as Mexico, to provide health care at moderate/low cost. In today's global economy, the First Lady's views couched in nationalistic language: "It is time to take care of our people," may send out a wrong message to the country.

I think you would be well advised to read Robert Reich's book: "The Work of Nations" -- especially the chapters "Who is Us" and "Who is They." Recent immigrants whether documented or not, toil in the bitter cold to deliver pizzas to others, and do similarly unpleasant tasks merely in the hope of a better future for themselves and their families. There is no need to behave harshly towards their needs.

We all know that there is a suspicion in this country that somehow some of the economic problems in the country are due to immigrants, even though everyone here is a descendant of immigrants! We also know that there just is not enough money to pay for services for all the people who live in the US, and that some categories of illnesses such as mental illnesses have been left out for budgetary reasons. However, surely there is a better way to answer that question -- the President has perfected a good way to explain the reasons why some categories of people have had to be left out. He comes across as caring and humane.

I am not recommending covering undocumented workers under the tightly budgeted health plan. I only hope the First Lady cares a little more about those who are working hard for the US economy.

With best wishes.

Yours sincerely,

Sunil

Sunil Chacko

Sunil Chacko, MD, MPH (Harvard)
549 Riverside Dr., 1g
New York, NY 10027, USA
Tel. and Fax: (212) 932 - 2397

March 19, 1994

Mrs. Hillary Rodham Clinton
Chairperson
Presidential Task Force on Health Care
The White House
Washington D.C.

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I am not recommending covering undocumented workers under the tightly budgeted health plan. I only hope the First Lady cares a little more about those who are working hard for the US economy.

With best wishes.

Yours sincerely,

Sunil

Sunil Chacko

DEPARTMENT OF THE TREASURY
WASHINGTON

ASSISTANT SECRETARY

MAR 11 1994

Mr. Roger H. Stephenson
Executive Director
Connecticut Health and
Educational Facilities Authority
10 Columbus Boulevard, Second Floor
Hartford, Connecticut 06106

Dear Mr. Stephenson:

Thank you for your letter to Ira Magaziner, relating to the interaction of the Administration's health care reform proposal and the Internal Revenue Code limitations on the issuance of tax-exempt bonds for health care providers. In particular, you raised questions regarding the current law limitations on the issuance of tax-exempt advance refunding bonds, the $5 million small issuer exception to the bank deductibility prohibition, and the $150 million limitation applicable to bonds for section 501(c)(3) organizations. Your letter was referred to this office because it concerns matters of tax policy.

Advance refunding bonds are bonds issued more than 90 days before the retirement of the issue being refinanced, typically to take advantage of lower interest rates or to defease outstanding bonds in order for the issuer to be relieved of restrictive covenants. Current law generally provides that a tax-exempt bond may only be advance refunded once (twice if the refunded bond was issued before 1986). You suggest that the health care reform proposal may encourage mergers of health care providers and that bond covenants may limit these mergers such that it will be necessary to defease outstanding bonds. For this reason, you suggest that waivers of the limitations on advance refundings may be justified. We are carefully reviewing this issue. In this regard, it would facilitate our review if you could provide us with examples of the bond covenant language that might realistically limit merger activity. It is important to note, however, that liberalizing the advance refunding limitations would have a substantial revenue cost and raises a number of tax policy concerns.

You also propose that the bank deductibility provisions be modified to benefit nonprofit health care providers. Under current law, banks may not deduct interest expense attributable to investment in tax-exempt bonds except in the case of bonds of certain small issuers. Qualification for this exception depends on the issuer of the bonds being "small" (i.e., the issuer must expect to issue less than $10 million of tax-exempt bonds during the calendar year). Under your proposal, up to $5 million of

Fwd
Sec 501(c)(3)
Sec 141-150
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tax-exempt bonds for each section 501(c)(3) organization would qualify for bank deductibility regardless of the amount of bonds issued by the governmental issuer of the bonds. The proposal is intended to benefit small, non-profit health care institutions located both in rural areas and in large, urban areas.

The policy justification for the small issuer exception is that, given the size of their borrowings, banks are often the most cost-effective market for selling bonds of small issuers. In testing whether an issuer is small for this purpose, it seems appropriate to take into account the tax-exempt qualified 501(c)(3) bonds that it issues. In addition, the proposal would significantly increase the number of organizations, and the volume of bonds, qualifying for this exception.

We recognize the benefit to small, non-profit health care providers that the increased availability of bank deductibility would provide. The proposal would, however, at least in part, reverse an important reform made as part of the Tax Reform Act of 1986 in a manner that would result in private activity bonds for non-profit health care providers receiving more favorable treatment than true, governmental debt. In 1986, while it recognized the increased cost to issuers of tax-exempt bonds, Congress provided only a very limited exception for bonds issued by relatively small governmental units. We believe it necessary to continue to carefully balance the tax policy concerns raised by bank deductibility against the benefits of the subsidy that it provides. For these reasons, we oppose this proposal.

An alternative solution would be to permit a small issuer to allocate a portion of its $10 million exemption to a state issuer so that it could issue bank qualified bonds for small, non-profit health care providers. This addresses the problem that in many states it is a state entity that issues the bonds for non-profit health care providers. This alternative, however, would not provide relief in large urban areas. As a general matter, in evaluating this type of proposal we believe that tax-exempt bonds are less efficient and more costly to the federal government than more direct forms of subsidy, like those provided under the President's health care reform bill.

Current law provides that an organization described in section 501(c)(3) of the Internal Revenue Code may not be the beneficiary of more than $150 million of outstanding tax-exempt bonds. This $150 million limitation does not apply to bonds to finance hospitals. You suggest that the hospital exception to the $150 million limit should be expanded to cover "health care providers" and we are studying this issue. In the past, the Treasury Department has not opposed a more general proposal to repeal the $150 million limitation.

If you have any other questions on this issue, I would be happy to discuss them.

Sincerely,

Leslie Samuels

Leslie B. Samuels
Assistant Secretary
(Tax Policy)

cc: Ira Magaziner

THE WHITE HOUSE

April 18, 1994

Ms. Kathleen A. Mulvey
Alverno College
3401 South 39th Street
P.O. Box 343922
Milwaukee, Wisconsin 53234-3922

Dear Ms. Mulvey:

Thank you for sending a copy of Alverno Today and for a wonderful visit to Alverno College. As I looked at the magazine, I was reminded again of the enormous and essential contribution of our nation's nurses to the delivery of high quality health care.

Thank you also for your support for our work to guarantee private health insurance to all Americans.

Sincerely yours,

Hillary Rodham Clinton

Hillary Rodham Clinton

November 4, 1993

The Honorable William Jefferson Clinton
President of the United States
The White House
Washington, D.C. 20500

Dear Mr. President:

We salute you for your leadership in developing a comprehensive health care reform proposal. Although we may not agree on every aspect of your plan, we look forward to working with you and all of your colleagues in the Congress to fashion a health care reform bill that adheres to the six principles you outlined in your address to Congress and the nation: security, simplicity, savings, responsibility, quality and choice.

We are very concerned, however, about your call for five year Medicare and Medicaid reductions of $189 billion to help finance your proposal. Just last August, Congress approved and you signed into law P.L. 103-66, the Omnibus Budget Reconciliation Act (OBRA) of 1993. The 1993 budget law achieves $55.8 billion and $7.2 billion in savings from the Medicare and Medicaid programs, respectively, over the next five years. These savings come on top of the $43 billion in Medicare savings enacted as part of the 1990 budget agreement, OBRA 90.

Medicare and Medicaid savings of the magnitude that are contemplated in your proposal, coupled with those already enacted as part of the OBRA 93 and OBRA 90, will continue to push many health care providers toward the brink of financial disaster and risk eroding access to care for millions of poor, elderly and disabled Americans. It is unclear whether the rigid, formula-driven budget caps that your proposal would impose on the Medicare and Medicaid programs bear any relation to the actual health needs of a community, or if they will be flexible enough to respond to changing and unforeseen circumstances.

It is clear that savings can be achieved in the Medicare and Medicaid programs as part of a comprehensive health care reform package. We believe, however, that the level of reductions you have suggested in your proposal may place these important programs for the poor, elderly and disabled in severe financial jeopardy.

Don't know if this has been sent

We stand ready to work with you to reform our nation's health care system so that all Americans have access to high quality health care services.

Sincerely,

ED TOWNS, M.C.

PATSY MINK, M.C.

SUSAN MOLINARI, M.C.

HAMILTON FISH, M.C.

NITA LOWEY, M.C.

KAREN THURMAN, M.C.

GENE GREEN, M.C.

JIM MCDERMOTT, M.C.

JACK REED, M.C.

LYNN WOOLSEY, M.C.

JAN MEYERS, M.C.

NICK RAHALL, M.C.

TILLY FOWLER, M.C.

LUCIEN BLACKWELL, M.C.

NANCY JOHNSON, M.C.

ALBERT WYNN, M.C.

TIM JOHNSON, M.C.

JIM NUSSLE, M.C.

JIM SAXTON, M.C.

STEVE GUNDERSON, M.C.

WILLIAM HUGHES, M.C.

ROBERT WISE, M.C.

ELIOT ENGEL, M.C.

RONALD DELLUMS, M.C.

ILEANA ROS-LEHTINEN, M.C.

DALE KILDEE, M.C.

NORMAN MINETA, M.C.

DAVID LEVY, M.C.

DAN MILLER, M.C.

JOHN LEWIS, M.C.

KAREN SHEPARD, M.C.

L. F. PAYNE, M.C.

BILL EMERSON, M.C.

DAVE CAMP, M.C.

HAROLD ROGERS, M.C.

MEL WATT, M.C.

DONALD PAYNE, M.C.

RON MACHTLEY, M.C.

SONNY CALLAHAN, M.C.

MICHAEL BILIRAKIS, M.C.

December 7, 1993

The Honorable
Congress of the United States
Washington, DC 20515

Dear

I am writing in response to your letter regarding the level of reductions in Medicare and Medicaid expenditures called for in the Health Security Act. We clearly share the belief that savings can be achieved in the Medicare and Medicaid programs as part of a comprehensive health care reform package. I want to assure you that the Medicare and Medicaid savings called for in the Health Security Act will not erode access to care for the poor, elderly and disabled.

First, a significant proportion of the Medicare savings from OBRA 1993 and the Health Security Act come from extensions of existing provisions and from slowing down the rate of growth of some outlays, rather than from direct payment cuts. Other Medicare savings come from the elimination of provisions that will no longer be necessary once universal coverage is achieved.

Second, Medicaid savings from OBRA 1993 come largely from the repeal of a mandate that had not yet taken effect. In addition, under the Health Security Act, Medicaid beneficiaries will be integrated into the alliances, and payments for services to Medicaid beneficiaries will be made at the same level as non-Medicaid eligibles in the alliance.

While the Medicare and Medicaid savings called for in the Health Security Act are ambitious, they can be achieved in the context of systemic reform that provides universal coverage. The Health Security Act will ensure access to care for all Americans, and will provide much-needed financial relief to health care institutions and providers by virtually eliminating uncompensated care.

September 9, 1994

Ms. Rita Hurst
Superior Senior Care
Post Office Box 505
Hot Springs, Arkansas 71902

Dear Rita:

Thank you for your recent letter about health care reform.

As always, your input is important to me, and I'm glad you shared your particular concerns with me about how the Mitchell bill may affect home care referral agencies. I certainly recognize the importance of home health care in providing quality, cost-efficient treatment. As you know, a number of proposals are currently under consideration, and I assure you that we will be looking carefully at these options as we seek passage of House and Senate bills that achieve our fundamental goal of cost containment.

I have shared your letter with my health policy staff so that they have the benefit of your insight on this issue. I appreciate your continuing involvement.

Sincerely, BILL CLINTON

BC/MHM/KM/MM/efr (Corres. #1793143)
(9.hurst.r)

cc: Deb Coyle
cc: Monica Mullens, Rm. 93
cc: Jen Klein w/copy of inc.

Xeroxed copy of personally signed original to NH through John Podesta

CLEAR THRU JOHN PODESTA

PRESIDENT TO SIGN

Thru Podesta

Superior
SENIOR CARE

ABT TOWERS • SUITE 200 • P. O. BOX 505 • HOT SPRINGS, ARKANSAS 71902
(501) 623-7767 • 1-800-951-9792

August 19, 1994

President Bill Clinton
The White House
Washington, D. C. 20500-2000

Dear President Clinton:

Thank you for your letter of July 27, 1994, in response to the concerns I expressed to you about the ability of home care referral agencies to compete in the Medicare market for home care. A much more urgent issue has developed since my last letter to you.

Last Friday I met with Senator Pryor and Congressman Dickey concerning the fate of home care referral agencies, such as mine, under the Senate Leadership bill offered by Senator George Mitchell, S 2357.

Section 1203(4) of the Senate Leadership bill would put me out of business.

That provision defines home health care, for purposes of the "standard benefits package," by incorporating the definition of home health services under the Medicare statute. As I mentioned to you previously, home care referral agencies are barred from the Medicare market. Consequently, by defining home health care, for the purposes of the "standard benefits package," by incorporating the Medicare definition of home health services, home care referral agencies would be barred from the private sector market as well.

As I have advised you previously, the cost of home care services purchased from a home care referral agency -- like mine -- is substantially less than when purchased from a home health agency. Thus, by denying my type of business access to the private sector markets for home care, the Mitchell bill would effectively "mandate" that the private sector incur significantly higher costs for home care. To me, this appears entirely anathema to your objective of cost containment.

If the Mitchell bill were enacted -- with Section 1203(4) unchanged -- my business would be finished and the cost of home care nationwide would undoubtedly increase. I have enclosed additional background information concerning this issue for your review. Any assistance you could provide would be most appreciated.

Sincerely,

Rita

Rita Hurst

LITTLE ROCK OFFICE
10 CORPORATE HILL DR., SUITE 140
LITTLE ROCK, ARKANSAS 72205
(501) 224-7117

EL DORADO OFFICE
210 N. JACKSON
EL DORADO, ARKANSAS 71730
(501) 863-0012

ROGERS OFFICE
114 SOUTH FIRST STREET
ROGERS, ARKANSAS 72756
(501) 621-8394

September 1, 1994

Jennifer-

I received this letter today September 1. I have forwarded the original to the Office of Agency Liaison. I have attached a copy of the letter for your review. Do you think anything else should be done?

-Stacey Roth
x. 65956

United States Senate

COMMITTEE ON ARMED SERVICES
WASHINGTON, DC 20510-6050

August 25, 1994

Mrs. Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Mrs. Clinton:

Dr. M. Miles Goldsmith, of the Georgia Ear Institute, has asked me to forward to you the attached letter. Because of your keen interest in the United States health care industry and your desire to see that all of its aspects are improved, Dr. Goldsmith believes that you may be interested in his experiences with the Food and Drug Administration. While I am not an expert in this area, I believe Dr. Goldsmith has raised some reasonable concerns regarding the Food and Drug Administration's review and approval procedures for medical safety devices. In view of the concerns expressed by Dr. Goldsmith, I would appreciate your review of this matter, consistent with your established policies and procedures.

Thank you for your attention to this issue.

Sincerely,

Sam Nunn

Enclosure

GEORGIA EAR INSTITUTE

Hearing Disorders
Dizziness and Balance
Facial Nerve Disorders
Accoustic Tumor
Neurotologic Skull Base Surgery
Pediatric Otology
Cochlear Implant Surgery
General Otolaryngology
Endoscopic Sinus Surgery
Head & Neck Surgery

M. MILES GOLDSMITH, MD
MALCOLM D. GRAHAM, MD
PHILLIP B. FLEXON, MD

Affiliated Physicians
FRANK HOFFMAN, MD
J. ROBERT LOGAN, MD

Audiology
Clinical Electrophysiology
Vestibular Laboratory

SUSAN W. KARPF, EDD
CYNTHIA NELSON, M. AUD.
JOHN P. RENO, MA, CCC-A

Mrs. Hilary Rodham Clinton
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

August 10, 1994

Dear Mrs. Clinton,

This week, as the spotlight once again falls upon the tragic scourge of the worldwide AIDS epidemic and our lack of significant scientific breakthroughs in this area, I am compelled to inform you of the stifling frustration that I have experienced with the development of a medical product which would definitely and positively impact upon one frightening aspect of this disease — the risk of transmission to health care providers by hollow bore needle sticks.

As you may be aware, approximately 40 – 50% of accidental hollow bore needle sticks to health care providers occur when a needle is recapped after medical use. In fact, OSHA has therefore mandated that needles not be recapped after medical use, and if an audited sharps disposal container reveals a capped needle, a health care provider is subject to a $2,000 fine. The problem here is that as sharps containers become full of uncapped needles, they eventually protrude from the container and accidental sticks occur as a result.

I have been involved with a unique product which crimps, electrolyzes, and sterilizes with ultraviolet radiation used needles. This product, the SDS5000, was developed in concert with engineering efforts at the University of Georgia and the Georgia Institute of Technology and currently is bogged down in the ever-narrowing bottleneck for the medical product industry, the Food and Drug Administration. For no clear reason other than bureaucratic inertia, our efforts to improve upon this worrisome aspect of AIDS transmission to health care providers has been stifled with little or no guidelines or direction for us to push this product through to the marketplace. The FDA, in fact, admitted as much yet continues to deny us criteria for resolution of the PMA process for this device.

PROVIDENT PROFESSIONAL BUILDING • 4750 WATERS AVENUE • SUITE 103 • SAVANNAH, GEORGIA 31404
TEL. (912) 355-7226 **FAX** (912) 350-5109
MEMORIAL MEDICAL CENTER

The number of people with AIDS is nearing 17,000,000 world-wide, increasing at an alarming rate, while the gap between the growing epidemic and meritorious scientific advancements related to cure and/or vaccination is ever-widening. It therefore appears that preventive measures are our only hope for curtailing this epidemic. At this critical time of health care reform, when health care providers are being asked to trust the government to "do it better," I would hope that the FDA's floundering passivity is not indicative of your vision for our universal health care system.

Mrs. Clinton, I challenge you personally to get involved on this one small yet scientifically significant preventive device and show the health care providers and the nation at large that you care not only about universal coverage of the sick and the needy afflicted with AIDS, but for the health provider who must daily assume some personal risk in the care for these unfortunate people.

I look forward to your response.

Sincerely,

M. Miles Goldsmith, MD
President, Georgia Ear Institute

MMG:mgp

cc: Sen. Sam Nunn
Sen. Paul Coverdale
Rep. Jack Kingston
Rep. Don Johnson

THE WHITE HOUSE

WASHINGTON

August 18, 1994

Peter J. Kuzmick, D.O.
406 Boston Boulevard
Sea Girt, NJ 08750

Dear Dr. Kuzmick:

Thank you for your letter about health care reform and for your thoughtful suggestions and comments.

The President has an unwavering commitment to guaranteeing private health insurance to all American families. Without universal coverage, the poor will continue to receive health care through government programs and the wealthy will continue to be able to afford to purchase coverage, while the middle class remains at risk. Twenty-four million Americans, most of whom work hard to earn a living, will have no insurance coverage at all, and one million will lose coverage each month. And without universal coverage, cost shifting and the need of individuals without insurance to rely on costly emergency care will persist, causing health care costs to continue to skyrocket.

To reach his goal of health security, the President shares your support for shared responsibility of health care costs between employers and employees. Because nine out of ten Americans with private health insurance get it through their employers, the President believes that reform should build on that tradition by asking employers to help pay for their workers' health insurance premiums.

I appreciated learning that you support the President's fundamental goal of guaranteeing private health insurance coverage for all Americans. I was also pleased that you are interested in a range of issues that are also important to the President -- including ensuring access to preventive care, prescription drug coverage, elimination of insurance company discrimination and malpractice reform.

As you mentioned in your letter, the need for health care reform is clear. The President and I will continue to work with Congress to pass legislation that guarantees every American the health security they deserve.

Sincerely yours,

Hillary Rodham Clinton

Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

August 11, 1994

Sister Helen Huewe, OSF
President
Mercy Health Center
250 Mercy Drive
Dubuque, Iowa 52001

Dear Sister Huewe:

Thank you for your letter about the proposed partnership between Mercy Health Center and The Finley Hospital. I am advised that this matter is currently the subject of litigation, and I am therefore unable to comment on it.

I do share your concern that spiraling health care costs have made it difficult for small health care institutions to deliver affordable health care. The Antitrust Division of the Department of Justice has been working to ensure that the antitrust laws do not have the perverse effect of raising, rather than lowering, the cost of health care. In September 1993, the Department of Justice and the Federal Trade Commission issued joint Statements of Antitrust Enforcement Policy in the Health Care Area to provide guidance to institutions on mergers, acquisitions and joint ventures. Just last month, the Department reached an innovative agreement with hospitals in Florida that allows cost savings to be realized while preserving competition and consumer choice.

I regret that I am unable to discuss the specifics of your case. I appreciate your efforts to provide affordable, high quality health care in Dubuque. This nation now has an historic opportunity to change our health care system to make it work for all of us. The President and I look forward to continuing to work with Congress to make health security a reality for all American families.

Sincerely yours,

Hillary Rodham Clinton

Hillary Rodham Clinton

MERCY
HEALTH CENTER

250 Mercy Drive • Dubuque, Iowa 52001 • 319/589-8000

Original mailed to Mike Lux

COPY

April 20, 1994

Stephen Gleason, M.D.
Chief Medical Officer
Mercy Clinic System
Des Moines, Iowa 50309

Dear Steve:

Thank you for agreeing to take a letter to Hillary Clinton on our behalf. I have enclosed a copy of the letter for you to see so that you can be knowledgeable of the Dubuque Regional Health System partnership and can speak personally to Ms. Clinton about it.

Once again, thank you. Your efforts are greatly appreciated.

Sincerely,

Sister Helen

Sister Helen Huewe, OSF
President

SHH/ims

enc

Melanne- This person, who is a close friend of Gleason's, never got a response on her letter. Can you check with your correspondence

MERCY HEALTH CENTER

250 Mercy Drive • Dubuque, Iowa 52001 • 319/589-8000

Please

Thanks,

Mike

COPY

April 20, 1994

Hillary Rodham Clinton, Esq.
Conversations on Health
The Robert Wood Johnson Foundation
George Washington University
2121 I Street, N.W., Suite 502
Washington, DC 20052

Hi - can you please respond

Dear Ms. Clinton:

In March of 1993, I had the privilege of being on a panel with you in Ankeny, Iowa, regarding cost containment in health care. It is interesting that the one issue I pointed out to you as needing to be addressed was antitrust enforcement. That is why I am writing to you today.

Our community, Dubuque, Iowa, needs your help. Dubuque is located in rural Iowa on the Mississippi River. We have two hospitals in Dubuque, Mercy Health Center and The Finley Hospital, serving the tri-state area of Wisconsin, Illinois, and Iowa. Both are not for profit, charitable institutions.

To become more cost effective and to position our community for health care reform, the two hospitals have developed a partnership, Dubuque Regional Health System ("DRHS"). The purpose of DRHS is to reduce the cost of health care to the community by eliminating unnecessary duplication. The parties estimate that the partnership will result in savings of $24 million over four years. The parties are forming a partnership (as opposed to merging) so that they can preserve the identity and culture of Mercy and Finley while still achieving these savings.

We expect a broad range of savings from DRHS. Our initial studies indicate that cost savings will be realized in six specific areas of administrative operations, including billing; purchasing; biomedical engineering; planning and marketing; administration; and human resources. Cost savings will also be realized in eight patient care areas, including ER, surgery, cardiovascular, oncology, occupational medicine, orthopedics and neurosurgery, physical therapy and obstetrics. The study estimates that the transaction will also produce opportunities to realize savings (through future cost avoidance) with respect to ten major areas of substantial capital expenditures, ranging from CT scanners, to magnetic resonance imagers ("MRIs"), to invasive cardiac equipment, to ER expansion.

These savings reflect the fact that Mercy and Finley today operate with small censuses and therefore high excess capacity in many of their patient care units. Substantial costs can be eliminated by combining units and reducing this excess capacity. The same efforts will result in the elimination of a need for substantial expensive duplicative equipment at both hospitals. These two small hospitals, only six blocks

apart, certainly do not need two MRIs, two sets of complex invasive cardiology diagnostic equipment, two fully equipped 24-hour emergency rooms/trauma centers, two OB units, and two 24-hour surgery suites, all of which they have today despite very substantial excess capacity. Competition has driven them to duplicate all these services and increase costs.

This plan to enter into a partnership to save costs has been created at the direction of the business community, the purchasers of health care. At least 71 different business and community leaders, representing virtually all of the significant ultimate purchasers of health care from the hospitals, have strongly endorsed DRHS in specific written statements received by the hospitals. This group includes business and labor, community leaders and political leaders, ranging from the city and county of Dubuque to local state representatives to the Governor of Iowa and both Iowa United States Senators.

This reflects a long tradition of involvement by the Dubuque community in controlling health care costs. Many of the Dubuque business leaders have demonstrated their willingness as Mercy and Finley board members to keep prices down. For example, in 1993 Finley management requested a 4.5% rate increase, but the Finance Committee of its board approved only a 3.5% rate increase. The Finley Board also instituted a 1% price roll-back, effective for the period October, 1993 through July, 1994.

DRHS has been structured to maximize community input. A majority of the board members of DRHS are representatives of purchasers of health care. The first action of DRHS will be to form a community-based planning process which will obtain input from all segments of the community in deciding on the configuration and cost of future hospital care in Dubuque. DRHS also intends to regularly inform the public of its progress in achieving cost savings and controlling prices, so that employers, unions and other purchasers of health care will be in a position to judge our performance and take steps if we do not perform.

In fact, the administration of Mercy and Finley have visited a large number of community leaders, and indicated that we expect to achieve the efficiencies mentioned in this letter. We realize that by making these statements, we are setting a public standard by which we will be held accountable. We recognize this, and intend this, because we know that DRHS must succeed and must help the community.

Mercy and Finley also know that DRHS will need to keep prices down in order to survive in this increasingly competitive environment. Though Mercy and Finley are the only hospitals in Dubuque, they are unusually susceptible to competitive pressures from the broad tri-state region from which they draw patients. Mercy and Finley must deal with substantial actual and potential competition from more than fifteen hospitals in their region. In particular, because of their small size (Finley has an inpatient acute care census of only 55 and Mercy 108), the hospitals badly need incremental business to cover their fixed costs. They can therefore ill afford to lose any business to the competition. In fact, if the large number of hospitals providing actual or significant potential competition for Mercy and Finley each took less than <u>one patient per day</u> from DRHS, that would be sufficient to make a price increase unprofitable.

The importance of this competition is confirmed by statements from at least 35 Dubuque employers and labor leaders. These statements all indicate that if, contrary to their expectations, DRHS attempted to raise prices above competitive levels, that would provide incentives for their employees to seek hospitalization at one of the many other hospitals in the area.

Despite all these facts, we have become embroiled in a very serious antitrust investigation by the Department of Justice. We have already spent several hundred thousand dollars in responding to this investigation, and believe that we have shown how this transaction will benefit the community and create more effective competition. Nevertheless, the staff of the Department of Justice has apparently concluded that this transaction will create a "monopoly" that could result in higher prices. We are now attempting to convince the senior officials in the Antitrust Division that this conclusion is wrong. If we do not succeed, we will need to fight out this matter in court, at even greater expense. These costs will only add to the burden of health care costs faced by businesses and consumers.

When I originally met you, and raised the concern that antitrust could interfere with hospital cost savings, I was pleased to see that you agreed, and indicated that this was an issue that you were investigating. Later, the Justice Department and Federal Trade Commission issued their new guidelines, creating "safe harbors" for some transactions. Unfortunately, despite the small size of Mercy and Finley, they cannot benefit from these safe harbors. Under the safe harbors, a merger involving a hospital with an acute care census of 40 or less would ordinarily not be subject to antitrust review. Finley's acute care census is only 55, just over the safe harbor figures. But this has not prevented our transaction from being subject to this extensive review and the risk of a challenge, even though our two non-profit hospitals have never acted to abuse the system or overcharge purchasers.

I am writing to you because I hope that you can help us with this serious problem. I know that you are concerned with health care reform as part of a process of seeking new ways of solving our problems to reduce costs and increase health care coverage. Finley and Mercy have been attempting to do just that. We would appreciate your help in assuring that the federal government does not frustrate our efforts. If you would speak to Assistant Attorney General Bingamin about our transaction, that could tremendously help the delivery of health care in Dubuque.

Thank you very much for any assistance you can provide us regarding Dubuque Regional Health System. If you need further information, please contact either me at 319-589-8061 or our attorney, David Ettinger, at 313-256-7751.

Sincerely,

Sister Helen Huewe, OSF

Sister Helen Huewe, OSF
President

SHH/ims
cc: David Ettinger