U. S. Department of Justice

Criminal Division

Washington, D.C. 20530

MAR 2 1994

The Honorable Elliot Enoki
United States Attorney
for the District of Hawaii
Honolulu, Hawaii 96850

Re: United States v. Henry Emerick, et al.
(District of Hawaii, Cr. No. 91-00834 DAE)

Dear Mr. Enoki:

The purpose of this letter is to respond to your February 4, 1994, letter to Gerald Stern, Special Assistant to the Attorney General, and to follow up on our February 17 and 22, 1994, telephone conversations concerning this case. After our conversations, I discussed this matter with Mr. Stern and he asked that I respond to your letter on his behalf.

As I understand the facts, the outstanding charges are against Henry Emerick and his wife. The matters which you raise in your letter are serious considerations which bear not only on the cost and length of litigation, but also on the likelihood of prevailing in jury trial. Accordingly, your decision to dismiss the indictment against the defendants seems to be an appropriate one. Certainly, you have done all you can to pursue the options available to the government in this matter. If you would like to discuss this matter or related matters, please do not hesitate to call me.

Sincerely,

Gerald E. McDowell
Chief, Fraud Section

By:

Karen A. Morrissette
Deputy Chief, Fraud Section

GMcD:KAM:pw
T: 2/28/94

Records Section Chron. Garland Stern McDowell Morrissette D. Washington

MBG

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Date 2-9-94

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U.S. Department of Justice

United States Attorney
District of Hawaii

300 Ala Moana Blvd., Box 50183
Honolulu, Hawaii 96850

COML (808) 541-2850
FAX (808) 541-2958
FTS 8-551-2850

February 4, 1994

GERALD M. STERN
Special Assistant to
the Attorney General
U.S. Department of Justice
Room 4119, Main Justice Bldg.
10th & Constitution Ave., N.W.
Washington, D.C. 20530

Re: United States v. Henry Emerick, et al.
(District of Hawaii, Cr. No. 91-00834 DAE)

Dear Mr. Stern:

It was a pleasure to meet you at the United States Attorneys' Conference on January 20, 1994. As you may recall, I informed you that Deputy Attorney General Philip Heymann asked that I direct this letter to you.

A trial in the above-captioned criminal case is now pending in our District which raises questions of policy, cost-efficiency and proper court utilization. These issues have brought us to the conclusion that the best interest of justice would be served by a dismissal. That conclusion is made even more difficult by the fact that Department of Labor attorneys handling the above matter from the civil/administrative standpoint previously declined to go forward with any civil action until all criminal proceedings had been concluded. All civil remedies now appear to be barred by the statute of limitations.

On March 7, 1991, a Grand Jury for the District of Hawaii returned an 80-count Indictment against the Defendant, HENRY EMERICK, and his putative spouse and longtime nurse, CAROL HANNA. There is no question that MR. EMERICK, age 51, has been quadriplegic for many years due to a diving accident. The Indictment charged a mail fraud scheme that lasted from November

of 1983 through and including the date of the Indictment. The charges included mail fraud and various false statements relating to claims for medical reimbursement received by the Defendant, HENRY EMERICK, relating to his medical condition. The total amount alleged to have been obtained by the Defendant, through his fraudulent activities, approached $1 million.

Shortly after the Indictment was returned, this Office was made aware of a disconcerting internal dispute between the Department of Labor's Criminal Investigative Division and its attorneys handling civil and administrative matters relating to the propriety of EMERICK's claims for reimbursement for nursing services. Because of that dispute, and the civil attorneys' ultimate decision that many of the claims considered fraudulent by criminal investigators and attorneys were, in fact, compensable, the Indictment was superseded in May of 1991 with all of the questionable claims being deleted from the Superseding Indictment. The remaining fraud was set out in a 52-count Superseding Indictment.

Counts added in the Superseding Indictment addressed mail fraud, relating to a double-billing scheme which caused claims for medical reimbursement to be sent both to the Department of Labor and a private carrier, Prudential Insurance. The Superseding Indictment also charged violations of 18 U.S.C. §1001 relating to those double-billings. There were also some false claim counts for services purportedly rendered by practical nurses which the nurses say did not occur. The surviving fraud claims alleged in the Superseding Indictment approximate $300,000.

The trial has been continued on numerous occasions during the last three years because of the medical needs of the Defendant, extremely involved motion practice, and the unexpected and then possibly terminal illness of the wife of a key Government witness. In 1992, the Defendant, who had previously obtained a number of continuances because of his quadriplegia and the health problems associated with it, claimed that his health precluded any trial of this matter and asked the Court to dismiss all charges. The Court ordered the Defendant to make himself available for medical examinations. The Government retained two separate neurologists and the Defendant presented himself to two doctors of his own choosing.

The two doctors chosen by the Defendant, DeHAY and NAKANO, found that a protracted criminal case might well result in the death of the Defendant. The two doctors selected by the

Government to evaluate MR. EMERICK, however, found that though he suffers from significant medical problems, those problems should not prove to be life-threatening, simply because of the rigors of trial.

When confronted with these mutually-exclusive positions, the Court selected a fifth physician, DR. ANTHONY MAURO. DR. MAURO reviewed the finding of the earlier doctors and two other written reports by physicians that were used during the course of the preliminary examinations. DR. MAURO also conducted his own independent physical examination. DR. MAURO's report provided the basis for the District Court determining that there was no absolute medical prohibition to proceeding with this trial. (Enclosure).

A review of the Mauro Report discloses that though there is no absolute medical prohibition to proceeding with this case, there will be monumental problems in going forward due to the Defendant's deteriorated health. Obviously, the Court will have to take extreme steps to compensate for the Defendant's medical problems. Those steps will include:

1. [redacted] FOIA(b)(6) FOIA(b)(7) - (C)

2. [redacted] FOIA(b)(6) FOIA(b)(7) - (C)

3. [redacted] FOIA(b)(6) FOIA(b)(7) - (C)

4. [redacted] FOIA(b)(6) FOIA(b)(7) - (C)

5. [redacted] FOIA(b)(6) FOIA(b)(7) - (C)

In addition to the burden on the Court's time and the tremendous involvement of Government assets that will be necessary to go forward with this case, there is the obvious problem that may result from any media attention that may come to be focused on this matter. If we do not proceed, there may well be questions asked as to why the Government declined to prosecute an individual whose manipulation of the health care system has resulted in a very significant fraud. If we elect to go to trial, there may also be questions asked as to what it is that the Government intends to accomplish by a Criminal proceeding and its related costs when there is no effective punishment that a Court can fashion for a defendant in MR. EMERICK's position. He cannot be incarcerated, and it appears that he has no assets out of which a fine could be realized or restitution awarded, other than the home in which he and his wife reside. A set-off on future payments, which we are informed cannot be done, would in any event most likely result in a loss to medical providers, not merely the Defendant.

We now anticipate that the trial of this case could take from two to three months. If the Defendant should attempt to manipulate the Court by exacerbating his very real health problems, for which he already has demonstrated a propensity, there is a possibility that the matter may never be resolved, even though a trial is commenced.

We have thus concluded that it would be in the best interest of justice to dismiss all pending criminal charges against the Defendant. While such a decision would ordinarily be made without any communication to Washington, and although this case has thus far not attracted widespread media coverage, because health care fraud is a very high priority of the Attorney General and because this decision has the potential for adverse

publicity (as does continued pursuit of the charges), we felt it necessary to inform you of our decision.

If you need additional information concerning this matter, please do not hesitate to contact me or AUSA Les Osborne. The trial in this matter is set for May 10, 1994. In order not to expend the judicial and prosecutorial resources necessary to prepare for a trial in a case such as this, we intend to inform the court of our decision to dismiss by March 4, 1994. Thus, if the dismissal should not be made, it would be appreciated if you would let me know by that date. Thank you for your attention and effort.

Very truly yours,

ELLIOT ENOKI
United States Attorney
District of Hawaii

EE:imt
Enclosure

cc: Philip B. Heymann
Deputy Attorney General
U.S. Department Of Justice
Room 4111, Main Justice Bldg.
10th & Constitution Ave., N.W.
Washington, D.C. 20530

Jo Ann Harris
Assistant Attorney General
Criminal Division
U.S. Department Of Justice
Room 2107, Main Justice Bldg.
10th & Constitution Ave., N.W.
Washington, D.C. 20530

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Subject: U.S. v. Emerick

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U. S. Department of Justice

Criminal Division

Office of the Assistant Attorney General *Washington, D.C. 20530*

FEB 22 1994

MEMORANDUM

TO: Gerald Stern
Special Assistant to the
Attorney General

FROM: Jo Ann Harris
Assistant Attorney General

RE: Criminal Division Health Care Fraud Matters

Pursuant to your request, I am forwarding to you information prepared by Criminal Division components concerning health care fraud cases and matters being handled by the Division.

Attachments

U. S. Department of Justice

Criminal Division

Office of the Assistant Attorney General *Washington, D.C. 20530*

MEMORANDUM

TO: Gerald Stern
Special Assistant to the
Attorney General

FROM: Jo Ann Harris
Assistant Attorney General

SUBJECT: Criminal Division Health Care Fraud Matters

Pursuant to your request, attached is information concerning health care fraud cases and matters which are being handled by the Criminal Division.

Attachments

Records
Section Chron
McDowell
Morrissette (2)
Garland
Harris
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FRAUD SECTION HEALTH CARE FRAUD CASES/MATTERS

February 15, 1994

[redacted] FOIA(b)(7) - (C) Attorneys: Arbor, Serafini

[redacted] FOIA(b)(7) - (C) is a publicly traded company which owns hundreds of psychiatric and acute care hospitals nationwide. The investigation has focused primarily on allegations that the psychiatric hospitals paid kickbacks for referrals, engaged in billing fraud and submitted false cost reports to Medicare.

The Fraud Section has responsibility for the investigation and prosecution of the corporate entities and high level corporate officers and employees. We have established an investigative task force in the District of Columbia to investigate the national case. Several agencies are part of the task force, including the FBI, HHS Inspector General, Defense Criminal Investigative Agency, the IRS, and the Civil Division of DOJ.

The Fraud Section also coordinates the investigations of local hospitals and lower level employees which are being conducted by approximately 20 United States Attorney offices. We have established a Working Group which meets regularly to facilitate that effort. Last August, we executed search warrants at corporate and regional [redacted] FOIA(b)(7) - (C) offices and coordinated other simultaneous search warrants in six other districts.

[redacted] FOIA(b)(7) - (C) The Department has been negotiating a global settlement with [redacted] FOIA(b)(7) - (C). On the criminal side, we have reached a plea agreement in principle regarding [redacted] FOIA(b)(7) - (C) psychiatric business. Under the agreement, an [redacted] FOIA(b)(7) - (C) subsidiary will plead guilty to a seven count Information charging conspiracy to defraud the government and paying kickbacks for referrals. [redacted] FOIA(b)(7) - (C) will pay substantial criminal fines and forfeiture (at this time the government's offer is $49 million dollars), and will institute an aggressive legal compliance and corrective action program in both its psychiatric and acute care facilities. [redacted] FOIA(b)(7) - (C) will also divest itself of almost all its psychiatric facilities and will terminate all corporate employees in the psychiatric division. Under the agreement, the government will be free to prosecute any individuals, and [redacted] FOIA(b)(7) - (C) will be required to cooperate in those investigations, including waiving attorney-client privilege claims.

We are working through the National Association of Attorneys General in order to include in the settlement states or state Medicaid Fraud Control Units that wish to be included. The Civil Division and [redacted] FOIA(b)(7) - (C) are simultaneously negotiating a civil settlement for civil penalties and restitution. At this time, the parties are approximately $230 million dollars apart.

There are three possible impediments to the settlement. [redacted] FOIA(b)(7) - (C) First, [redacted] wants to resolve its criminal exposure for paying kickbacks for referrals at the acute care hospitals, but the government has not undertaken a full scale investigation as it has in the psychiatric business. We are directing further investigation of this issue and are continuing to negotiate with [redacted] FOIA(b)(7) - (C). Second, [redacted] must reach a satisfactory settlement with the

Civil Division. And finally, HHS must agree not to exclude from the Medicare program [redacted] acute care facilities, or the buyer of the psychiatric business. FOIA(b)(7) - (C)

In Re [redacted] (E.D. Va.); Attorney: DeWaal FOIA(b)(7) - (C)

This investigation is one of the local investigations of [redacted] facilities. The allegations include mail and wire fraud in billing Blue Cross/Blue Shield, the Federal Employees Benefits Program, and patients for services not rendered; for payment of referral fees to physicians and other referral sources in violation of federal law; and related violations. The Fraud Section is handling the investigation jointly with the USAO in the E.D. Va. The investigative agencies are the FBI and HHS OIG. The investigation has not been presented to a grand jury but is proceeding by review of documents seized by search warrant and interviews of witnesses. FOIA(b)(7) - (C)

In Re Investigation of [redacted] (S.D. Ohio); Attorneys: Goel, Bowne FOIA(b)(7) - (C)

This is an investigation of a national home infusion therapy provider, [redacted] for possible violations of the Medicare anti-kickback statute, 42 U.S.C. § 1320a-7b. [redacted], provides parenteral nutrition, chemotherapy, antibiotic, growth hormone, and other forms of infusion therapy in the patient's home after receipt of a physician's authorization. [redacted] created numerous business arrangements with doctors and medical service providers under which the providers received payment for patients, including Medicare and Medicaid patients, that they referred to [redacted] FOIA(b)(7) - (C)

The Fraud Section, in conjunction with the Southern District of Ohio, is coordinating a national joint criminal/civil investigation of [redacted] which targets the corporation and key, high-level employees for prosecution. The investigating agencies are the HHS OIG, the FBI, and the Railroad Retirement Board OIG. FOIA(b)(7) - (C)

Operation Labscam; (S.D. Cal.); Attorney: Morrissette

Seven clinical laboratory chains are under investigation for possible fraud associated with the bundling/unbundling of laboratory tests for purposes of billing to Medicare and other payers. This is a multi-agency task force operation presently venued in the S.D. Cal. This is a non-grand jury investigation,

and a joint civil/criminal investigation. A Fraud Section Deputy Chief functions in a supervisory/coordination role. No Fraud Section line attorney is assigned to this project.

In Re Investigation of [redacted] FOIA(b)(7) - (C)
(S.D. Fla.); Attorney: Joaquin

[redacted] FOIA(b)(7) - (C)

Based on the recusal of the local United States Attorney's Office, the Fraud Section has sole responsibility for this matter. We are presently working with the corruption and health care fraud squads of the Miami FBI, as well as the IRS. [redacted] FOIA(b)(7) - (C) is not yet aware of this investigation, pro-active investigative techniques are being considered. This is a non-grand jury matter.

In Re Investigation of [redacted] FOIA(b)(7) - (C) (non-grand jury);
Attorney: Joaquin

This is an investigation of [redacted] FOIA(b)(7) - (C) (a company FOIA(b)(7) - (C) owned by [redacted] which provides rehabilitation services to nursing home patients throughout the southern and midwestern United States. It is alleged that the various offices of [redacted] FOIA(b)(7) - (C) conspired with others to bill Medicare for services not rendered.

We are presently coordinating the preliminary nation-wide investigation of this matter and are working jointly with the Civil Division. The investigative agencies involved are HHS OIG and the FBI.

In Re Investigation of [redacted] FOIA(b)(7) - (C) (N.D. Ga.); Attorney: Goel

[redacted] FOIA(b)(7) - (C) purchased smaller companies by creating sham employment agreements for the ex-owners. The purchase price was paid to the ex-owners through these sham employment agreements, which were then reported as costs to Medicare. This is an active

grand jury investigation, which is being handled jointly with the USAO. Related allegations are being investigated as civil matters. The HHS OIG is the investigative agency.

In Re [redacted]; Attorney: Goel FOIA(b)(7) - (C)

[redacted] routinely waived Medicare co-payments and deductibles after testing patients to assess their likelihood as stroke candidates. This is a non-grand jury investigation which is being investigated jointly by the HHS OIG and the FBI in several states. This investigation is in a covert mode.

In Re [redacted] Attorney: Joaquin FOIA(b)(7) - (C)

This is an investigation of [redacted] which has a procurement contract with the VA permitting [redacted] to sell specific medical supplies to that agency. It is alleged that [redacted] sales representatives misled the VA into believing erroneously that other medical supply items they offered for sale appeared on the procurement contract. The intended result was to induce the VA to purchase non-contract items in violation of the VA's regulations.

Based on the VA's investigation, it appears that the loss to the VA may not be substantial and that the Civil Division of the Justice Department is better able to pursue this matter. Thus, a memorandum recommending that the investigation be declined is being prepared.

In Re Investigation of [redacted] (D.N.J.); Attorney: Bowne FOIA(b)(7) - (C)

This is an investigation of a national pharmaceutical company, [redacted], for possible violations of the Medicare anti-kickback statute, 42 U.S.C. § 1320a-7b through [redacted] operation of the [redacted] is an antibiotic manufactured by [redacted] Physicians received payments in return for reporting the effectiveness of [redacted] as observed in their patients. This is a grand jury matter which was investigated by the HHS OIG. A declination memorandum is being prepared; the case will be referred to the Civil Division.

ORGANIZED CRIME AND RACKETEERING SECTION
HEALTH CARE FRAUD CASES/MATTERS

February 15, 1994

United States v. Arthur Alan Teale, et al. (E.D.Pa.)

[redacted] FOIA(b)(7) - (C)

[redacted] FOIA(b)(7) - (C)

On December 2, 1993, Arthur Alan Teale and, his wife, Charlotte Cox Rentz, were sentenced in Mobile, Alabama, to seventeen and thirteen years, respectively, in connection with employee group health and property insurance abuses. Both defendants had entered guilty pleas to mail fraud and money laundering charged in the Southern District of Alabama and to RICO conspiracy and wire fraud charged in an information filed by the Philadelphia Organized Crime Strike Force Unit.

United States v. Gerald M. Wiedyk, Cr. No. 93-81174 (E.D.Mich. indictment returned November 16, 1993).

Richard Convertino, an attorney with the Section's Litigation Unit (202-616-8383), assisted the grand jury investigation in this case by the Detroit Strike Force Unit of the United States Attorney's Office and is expected to participate in the trial which is currently scheduled for April 11, 1994. No civil attorney is assigned to this criminal prosecution.

The indictment charges the Executive Director of the Michigan Conference of Teamsters Welfare Fund in Detroit, Michigan with the receipt of graft payments in violation of 18 U.S.C. § 1954 and false statements relating to such payments in violation of 18 U.S.C. § 1027. Wiedyk allegedly received approximately $458,925 between 1980 through August 1988 from a medical laboratory doing business with the Fund.

B. The Section is currently performing more than a monitoring function with respect to the following Organized Crime and Racketeering Strike Force Unit matters involving health care inasmuch as the commencement of Strike Force Unit participation, initiation of prosecution, reduction of charges, and disposition of prosecution by plea agreement must be approved by the Section.

United States v. Fred Dellorfano, et al.
Cr. No. 92-27 (E.D. Pa.)

Philadelphia Strike Force Unit attorney Andrea Foulkes (215-451-5685) prosecuted this case with assistance from Lynn Panagakos of the Section's Litigation Unit. Dellorfano, a Boston attorney, and four former officers of the Cabot Day Insurance Company of Denver, Colorado, pled guilty to participation in schemes to defraud employee benefit plans in 14 states of $5.5 million in health care premiums. The scheme was conducted through the operation of Cabot Day, an unlicensed insurance company, and Equity Med-Kare Plan Trust, a multiple employer welfare arrangement (MEWA). As a result of the scheme, employees and their families were left with more than $5.6 million in unpaid medical bills.

As the escrow agent for approximately $4 million in premiums sent him by hundreds of small employers and employer associations, Dellorfano converted $3 million to his own benefit and $400,000 to the benefit of his co-conspirators. In July 1992, following his guilty plea to racketeering conspiracy, Dellorfano was sentenced to pay more than $5 million in restitution and to imprisonment for ten years and ten months -- the largest sentence of imprisonment imposed in a Federal prosecution of employee health insurance abuses to date.

Dellorfano is currently appealing his sentence. Co-defendant Neil Smith is appealing the denial of his request to withdraw his guilty plea. Co-defendant Frank O'Brien is pending sentence. No civil attorney has been assigned to the case.

United States v. Cloyd Holmes and Sal Frasca (E.D.N.Y.).

Brooklyn Strike Force Unit attorneys Pamela Davis and Patricia Notopoulos (718-330-7447) prosecuted two officers of Retail Clerks Local Union 377 in Long Island City, New York, for conspiracy, theft, and money laundering. As a result of a scheme involving fraudulent medical claims and forged applications for benefits, the defendants obtained approximately $931,000 from the self-insured employee welfare benefit plan sponsored by the union. On December 10, 1993, Holmes, who also served as administrator of the plan, and co-defendant Frasca, were sentenced to imprisonment for 97 months and 56 months, respectively, which commenced on February 14, 1994. The case is pending appeal. A civil attorney is assigned to the case in connection with the civil forfeiture of approximately $100,000 which was the subject of a restitution order dated February 10, 1994.

United States v. Barbara A. DiPerna (N.D.N.Y.)

Syracuse Strike Force Unit attorney Kevin McCormack (315-423-5445) is assigned to the pending prosecution of Barbara A. DiPerna, a former claims evaluator for the New York State Teamsters Health

and Welfare Fund. DiPerna is charged with theft from the Fund of approximately $12,755 between January 1989 and December 1990 by alteration of dental claim forms. Former Fund administrator, Josephine A Russo, was previously convicted of embezzling $138,000 from the Fund. No civil attorney has been assigned to this criminal prosecution which is scheduled to begin trial on March 14, 1994.

United States v. Santo J. Volpe, Cr. 92-0034 (BAC) (N.D.Cal. superseding indictment filed January 1994).

San Francisco Strike Force Unit attorney William Schaefer (415-556-0750) is assigned to this prosecution of a Chicago attorney. Volpe is charged with mail fraud and the making of false statements as part of a scheme to obtain health care coverage and benefits for individuals who were not eligible to participate in the Western Employers Trust, a multiple employer welfare arrangement (MEWA) in California. No civil attorney has not been assigned to this criminal prosecution which is pending trial.

U.S. Department of Justice
Office of the Deputy Attorney General

Merrick Garland -

Gerald Stern asked me to send you copies of the attached correspondence.

If you have any questions, I can be reached at 514-3052.

Debra Cohn

U. S. Department of Justice

Office of the Attorney General

Special Assistant to the Attorney General

Washington, D.C. 20530

January 31, 1994

The Honorable June Gibbs Brown
Inspector General
Office of the Inspector General
Department of Health and Human Services
Washington, D.C. 20201

Dear June:

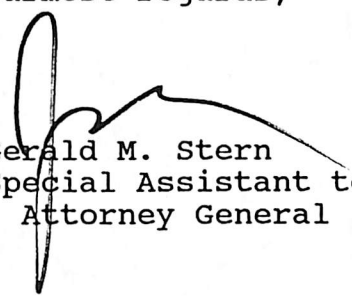
I would like to invite your assistance in addressing a problem recently reported by Patrick H. NeMoyer, United States Attorney, Western District of New York.

As you can see from the enclosed correspondence, his office has one of the Department of Justice pilot programs with U.S. Attorney's Office personnel devoted to White Collar Fraud Civil Enforcement and, in this case, to health care fraud. As you know, many United States Attorneys have had significant success with health care fraud civil enforcement. United States Attorney NeMoyer unfortunately reports that his program has been frustrated by the inability of his investigator to access records maintained by Medicare carriers without the intervention of the Office of Inspector General of the Department of Health and Human Services (HHS-OIG). United States Attorney NeMoyer has suggested that the investigator be cross-designated with some of the investigative authority of an HHS-OIG agent. This appears to be a creative solution to the problem of limited HHS investigative resources. I would like your thoughts on this proposal and other possible solutions.

I also would like to work with you to address the larger issue of access to records maintained by Medicare carriers and intermediaries. As the number of health care fraud cases increases and investigative resources stay constant, the burden

of handling all document requests will unduly burden the HHS Office of Inspector General. Together we need to devise some creative solutions for addressing this issue.

Warmest regards,



Gerald M. Stern
Special Assistant to the
Attorney General

Enclosure

rec'd 1/31/94

U.S. Department of Justice

United States Attorney
Western District of New York

United States Courthouse
Buffalo, New York 14202

January 25, 1994

Gerald M. Stern, Esq.
Special Counsel to
the Attorney General
Department of Justice
10th and Pennsylvania Ave., N.W.
Room 4119
Washington, D.C. 20530

Re: Health Care Fraud
Special Project

Dear Mr. Stern:

This is to request your assistance with a special project that we believe will streamline our health care fraud investigations. If successful, the project could serve as a model for similar efforts to improve the return on the limited investigative resources that we have for fighting health care fraud.

The Western District of New York has one of three pilot programs in the country with U.S. Attorney's Office personnel devoted exclusively to White Collar Fraud Civil Enforcement. Consequently, we have a civil investigator on our staff. He devotes a substantial majority of his time to health care fraud.

We are trying to obtain authority for this investigator to have direct access to the records maintained by the private insurance companies that administer the Medicare and Medicaid programs, and to medical records of program beneficiaries. Presently, the Office of Inspector General of the Department of Health and Human Services ("HHS-OIG") is the only investigative agency with ready access to these records, and its monopoly over direct access to these records slows our health care fraud investigations. We understand that even the FBI is routinely denied access to the records underlying health care fraud unless and until HHS-OIG agents become involved and lend their assistance.

In our own case, the Office's civil investigator has to enlist an HHS-OIG agent to request health care provider billing records, patient records, and even basic information about program coverage that has already been given to health care providers by the private

insurance companies that administer these programs for the government. It is a cumbersome procedure that diverts the HHS-OIG agents in our District and our civil investigator from matters under investigation and frustrates our attempts to fight health care fraud.

If our civil investigator is cross-designated with some of the investigative authority of an HHS-OIG agent, the arrangement will increase the investigative resources devoted to health care fraud in our District without added personnel expense to the government. If the experiment succeeds, it could be a model for similar cross-designations between HHS-OIG and others, including the FBI, and could streamline health care fraud investigations in many other parts of the country where investigative resources are severely limited.

Enclosed are copies of two letters that we sent to the Regional Inspector General of HHS-OIG last summer asking for her assistance with this potential special project. She was generally cooperative, and indicated to us that she was in favor of our suggestion because it would free her agents to concentrate on their criminal caseloads. She has since indicated that she passed our suggestion up the chain-of-command, but we have heard nothing further.

We raised the suggestion with the Attorney General during her visit to our District on September 23, 1993. She made a note of it and indicated that she considered the idea a promising one.

If we can obtain the requisite authority for our investigator, we are committed to making this special project succeed. Any assistance that you can lend will be greatly appreciated. Please let us know if there is anything we can do to help you evaluate the suggestion.

Very truly yours,

Patrick NeMoyer

PATRICK H. NeMOYER
United States Attorney
Western District of New York

U.S. Department of Justice

United States Attorney
Western District of New York

United States Courthouse
Buffalo, New York 14202

June 30, 1993

Linda Little
Regional Inspector General
for Investigations
Dept. of Health and Human Services
Office of Inspector General
Office of Investigations-Region II
26 Federal Plaza
New York, New York 10278

Re: Potential Special Project

Dear Ms. Little:

This is to confirm my request that you explore whether, and under what circumstances, an Investigator employed by this Office can be deputized or in some manner granted authority like that of your Special Agents to examine and obtain Medicare billing and patient records. Thank you for your assistance.

It was a pleasure to meet you and your agents this morning. I look forward to working with you.

Very truly yours,

/s/

PATRICK H. NeMOYER
United States Attorney

July 12, 1993

Linda Little
Regional Inspector General
for Investigations
Dept. of Health and Human Services
Office of Inspector General
Office of Investigations-Region II
26 Federal Plaza
New York, New York 10278

RE: Potential Special Project

Dear Ms. Little:

Since our June 30, 1993 meeting, I have had an opportunity to review some of our pending criminal investigations in the health care fraud area. I share your concern that these matters be given the time, attention and priority they deserve.

I look forward to working with you and your office. If for any reason you have questions or concerns regarding either our civil or criminal efforts, please do not hesitate to call me directly.

I would again ask you to explore the possibility of authorizing or deputizing a civil investigator in the U.S. Attorney's Office in the Western District of New York so that he would have the authority to examine and obtain Medicare billing and patient records. As you stated at our meeting, this will resolve the problem of differentiating or building a wall between a civil and criminal agent on matters in this district.

If I can provide any further information that will help advance this process of cross certification or credentialing please advise.

Very truly your,

Patrick H. NeMoyer

PATRICK H. NeMOYER
United States Attorney
Western District of New York

PHN/njs

cc: Debra

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

FEB 11 1994

Mr. Gerald M. Stern
Special Assistant to the Attorney General
Department of Justice
Washington, D.C. 20530

Dear Mr. Stern:

This is in response to your letter dated January 31, 1994, concerning Department of Justice (DOJ) direct access to Medicare records maintained by Medicare carriers and intermediaries. You have specifically requested assistance in addressing an issue of access to Medicare records raised by Patrick H. Nemoyer, United States Attorney, Western District of New York.

As you know, in the last several years, the Office of Inspector General (OIG) has coordinated requests by DOJ and other outside law enforcement agencies for carrier and intermediary records needed in the conduct of Medicare or Medicaid investigations. Previously, this exact role was performed by the Health Care Financing Administration (HCFA). Legal and policy decisions on disclosures of Medicare records have always been the responsibility of this Department, and have never been delegated to the carriers and intermediaries because they are private entities.

The Medicare records maintained by these fiscal agents of the Department are Federal records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and the confidentiality provisions in 42 U.S.C. 1306. The latter statute prohibits the release of Social Security and Medicare records except as specifically authorized to be released by regulations of the Department or otherwise provided by Federal law. Both HCFA confidentiality and disclosure regulations, 42 CFR Part 401, and all relevant Privacy Act systems of records notices make clear that disclosure decisions are the responsibility of Department officials, not its fiscal agents. This necessarily limits the discretion which can be delegated to the fiscal agents with regard to direct access to records by anyone, including other Government agencies.

Additionally, we believe that it is in the best interests of both of our agencies if the OIG continues to be the point of contact within the Department. Our agents have extensive health care investigative experience and are in the best position to assure that the records necessary to conduct a particular health care investigation are gathered and made available to the requestor. We are also then available to the requestor to explain the Medicare data and answer other program questions. Because

Medicare records are often coded and difficult to interpret, assistance is frequently requested. Please note that we do not condition release of records or our assistance on our participation in an investigation.

Even if there were no legal issues involved, many of the carriers and intermediaries have been concerned about the time and resources necessary to respond to some of the more wide-ranging requests for information, such as the request from the Houston United States Attorney, a copy of which is enclosed. The Office of Inspector General expertise in formulating responses to those requests has been sought to avoid an unnecessary strain on the limited budget in the carrier and intermediary contracts for anti-fraud activities.

In keeping with the National Performance Review, this office is committed to exploring all avenues for making our relationship with other law enforcement agencies as efficient and responsive as possible. With the considerations outlined above in mind, we believe that we can work together to find ways to expedite responses to law enforcement requests for carrier and intermediary data. For example, with the concurrence of HCFA, it may be possible to make blanket disclosure decisions for certain types of requests to expedite the process. We will also work to assure that adequate resources are available to absorb the administrative burden of coordinating these requests in a timely manner.

With regard to Mr. Nemoyer's request, we believe that we can work with Mr. Nemoyer to provide necessary records without detailing U.S. Attorney staff to the OIG. No additional records would be available to outside law enforcement agencies under this proposal since the person detailed would be under the same disclosure restrictions as OIG staff. Furthermore, it does not appear that the U.S. Attorney's Office has been denied information. The question is simply whether the process should be streamlined by going directly to the carriers and intermediaries. As we have already explained, it has always been Department policy that disclosure requests be handled by Department officials rather than carrier and intermediary employees. However, we will contact Mr. Nemoyer to discuss his concerns and determine if we need to be more responsive to requests from his office.

We believe it would be productive to explore another issue, the resolution of which could assist in meeting the administrative burden discussed above. We have over 80 percent of our special agents deputized as Deputy United States Marshals. Almost all of these deputations have required DOJ approval on an individual case or project basis. This continues to place a significant administrative burden on this office. While DOJ has worked with us to expedite the deputation process there are still delays which adversely affect our investigations. Furthermore, some of

these delays appear to be unavoidable so long as we must depend on the deputation process for necessary law enforcement authority and the protection of our personnel. We believe that the time and resources we devote to this process could be better utilized in the conduct and coordination of investigative activities, and we ask DOJ support for legislation granting us full law enforcement authority.

We agree with you that these issues of cooperation are extremely important to both our agencies and hope we can work together to resolve them to our mutual satisfaction.

Sincerely yours,

June Gibbs Brown
Inspector General

Enclosure

LEAH ANN EMBRY

SEP 2 3 1992

U.S. Department of Justice

United States Attorney

Southern District of Texas

3300 Federal Building and U.S. Courthouse
515 Rusk Avenue
Houston, Texas 77002

Post Office Box 61129
Houston, Texas 77208

September 23, 1992

Ms. Leah Ann Embry
Blue Cross and Blue Shield of Texas
Room 108, P.O. Box 660156
Dallas, TX 75266-0156

Re: Health Care Fraud

Dear Ms. Embry:

The United States Attorney's Office in the Southern District of Texas in conjunction with various investigative agencies has begun a Health Care Fraud Task Force. The goal of the task force is to identify and prosecute significant federal program health care fraud in the District. As an initial step, we are requesting each of the major health care insurance carriers in the District to help us by identifying the types of federal program fraud that they have observed in the health care industry and by referring to us suspected cases of criminal activity where a pattern of fraud has been observed by one or a group of health care providers, where the loss equals or exceeds $50,000 or where other factors may make the matter worthy of federal investigation. Each referral will be assessed on a case-by-case basis to determine whether federal investigation and prosecution is warranted.

We request that you provide us with the following information to help in the fraud identification process:

1. A list of all medical providers concerning whom your office has received complaints, who have not yet been made subjects of investigation. (Please supply nature of complaint.)

2. A list of all medical providers investigated by your office and referred to any other organization for further action in which prosecutions have not been initiated (including nature of complaint and agency to whom case was referred.)

3. A list of all medical providers felt by your office to be "problem providers" and the basis for such a designation.

4. A layout of your office's complaint programs (regarding providers, to include utilization review, etc.)

5. A description of the utilization review parameters being used to isolate potential problem providers.

6. A list of the top twenty-five providers in each major category of service in terms of dollars.

7. Any information you have available regarding "chains," set forth by type of procedure (i.e., nursing home chains, ambulance chains or individuals engaged in providing more than one type of service.)

8. Please provide a suggested time when members of the task force might visit and examine files in your office (i.e., audit files and complaint files). Advise us if work space for our investigators may be made available to complete such a review.

9. Please provide a list of any other cases that you have forwarded to state prosecutors concerning matters in your own line of business. In this regard, please tell us what procedures have been set up for referrals.

10. Please provide a copy of your utilization review book.

11. Please provide a list of all providers whose names were submitted to the state licensure boards for possible actions.

12. Please provide a list of the type of on-site audits conducted by your company and state whether the results of those audits can be made available for review by task force investigators.

While we realize that the information requested above is voluminous, the task force believes that receipt of this information will enable it to have a real impact regarding fraudulent activities by medical providers which, in turn, will reap substantial benefits for both the private and public sectors.

If you have any questions regarding the items listed above, please contact Special Agents Flo Logan or Ray Hooper, Federal Bureau of Investigation. Please supply the requested items to Special Agent Flo Logan, at the following address:

Federal Bureau of Investigation
P.O. Box 3046
Texas City, Texas 77592-3046

If you have questions about the operation of the task force or other general inquiries about prosecutive matters, please contact Assistant United States Attorney Anthony Brown at telephone number 229-2617.

cc:
MBG

U. S. Department of Justice

Office of the Attorney General

Special Assistant to the Attorney General *Washington, D.C. 20530*

per Stern, 2/94, Nothing has been done with this

January 13, 1994

MEMORANDUM

TO: Jo Ann Harris
Assistant Attorney General
Criminal Division

FROM: Gerald M. Stern
Special Assistant to the
Attorney General

SUBJECT: Guidelines for Assignment of Health Care Fraud Cases - Draft

Attached is a redraft of some proposed guidelines to help me obtain the necessary authority to coordinate health care fraud enforcement efforts between Main Justice and the U.S. Attorneys offices. This draft contains the Civil Division's suggestions. I would appreciate any suggestions or changes you might have. I note, for example, in paragraph 4 the language states that the U.S. Attorneys offices must seek authority from the Criminal Division before they may file a suit. I assume that that may have been the case for the Civil Division, but is not the case for the Criminal Division. Please feel free to make any changes you like.

Attachment

cc: Karen Morrissette
Deputy Chief, Fraud Section
Criminal Division

DEPARTMENT OF JUSTICE GUIDELINES FOR ASSIGNMENT OF HEALTH CARE FRAUD CASES

BACKGROUND

The Department of Justice pursues several goals in health care fraud enforcement: (1) increase the number of cases brought and successfully resolved; (2) increase high profile, multi-district cases; (3) maintain a presence in more judicial districts; and target frauds with programmatic or social significance.

The Department can promote these goals by assigning health care fraud cases among the United States Attorneys' Offices, the Criminal Division and the Civil Division to reflect the critical but different strengths of each office in investigating and prosecuting health care fraud. In addition, health care fraud cases should be assigned to promote the parallel (criminal/civil/administrative) investigation and prosecution of these cases. The coordination of the Department's handling of these cases is the responsibility of the Special Assistant to the Attorney General for Health Care Fraud.

INITIAL ASSIGNMENT OF HEALTH CARE FRAUD CASES

1. In connection with the assignment of health care fraud cases, there should be consultation between the Civil Division, the Criminal Division and the relevant United States Attorneys' Office.

2. In deciding assignment of health care fraud cases, the following factors should be considered:

a) whether the case is multi-district;

b) if the case requires Department of Justice or investigatory resources beyond that available to the United States Attorneys' Office;

c) if the case is part of a national program initiative which requires centralized coordination including whether a case is a qui tam matter;

d) if the case requires expertise and/or experience beyond that available in the United States Attorneys' Office;

e) the United States Attorneys' Office declines to take the lead in handling the case.

f) the potential size of the recovery for the U.S. Treasury.

3. An effective response to health care fraud requires the closest possible cooperation between the litigating divisions in Washington and the Offices of United States Attorneys. In this

regard, joint assignments of cases to personnel from the Criminal or Civil Division and their colleagues in the United States Attorneys' Offices have often proved successful and should be utilized wherever feasible and appropriate.

4. Case assignment does not eviscerate any existing requirements setting forth circumstances under which the United States Attorneys' Offices must seek authorization from the Civil or Criminal Divisions before they may file suit; accept a settlement; or take a particular action in a criminal case.

REVIEW OF ASSIGNMENT OF HEALTH CARE FRAUD CASES

The Special Assistant for Health Care Fraud has been designated by the Deputy Attorney General and the Associate Attorney General to handle disagreements over assignment of health care fraud cases consistent with the guidelines set fourth herein. It is assumed that, prior to seeking the intervention of the Special Assistant, parties will make attempts at resolution at appropriate levels within the Criminal and Civil Divisions and the Offices of the United States Attorneys.

U.S. Department of Justice
United States Attorney
Eastern District of Pennsylvania

DLWC: 451-5335

615 Chestnut Street
Suite 1250
Philadelphia, Pennsylvania 19106-4476
(215) 451-5200

By Facsimile

December 3, 1993

Gerald Stern
Special Counsel for Financial
Institution Fraud
Department of Justice
10th and Constitution Ave., NW
Washington, D.C. 20530

Dear Mr. Stern:

Thank you for your call inviting me to contribute to the ongoing discussions concerning the Department of Justice's national health care fraud program. I have enclosed a memorandum containing some preliminary thoughts. Recognizing its brevity and informality, if you would like me to expound further on any particular issue, please let me know.

I remain interested in exploring opportunities to work with you on health care fraud issues. I look forward to hearing from you.

Sincerely,

MICHAEL R. STILES
United States Attorney

DEBRA L.W. COHN
Assistant United States Attorney

Enclosure

THOUGHTS ON DEVELOPING A NATIONAL HEALTH CARE FRAUD PROGRAM[1]

I. INTRODUCTION

A national health care fraud program, coordinated by the Department of Justice, is the natural product of the growing concern with high health care expenditures. It coincides with the public's greater willingness to treat professionals' misconduct as fraud rather than mere negligence or a permissible exercise of discretion.

II. THEMES FOR NATIONAL HEALTH CARE FRAUD PROGRAM.

The nature of health care fraud dictates that the Department of Justice take the following steps:

1. Institute All Payor Health Care Fraud Enforcement.

Current investigation and prosecution of health care fraud is hampered severly by the multipayor system. Agency inspector generals frequently investigate fraud their programs but ignore related fraud in other agencies or in private insurance programs. As a result, an investigation of one health care provider may require investigators from several different agencies and even then private health care fraud may be ignored.

2. Promote Parallel Proceedings.

Health care fraud defies many traditional law enforcement techniques. Typically, health care fraud is perpetrated by individuals and relatively small organizations; it must be proved as a scheme over time; a number of people have varying degrees of knowledge; many raise professional medical judgement as a

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[1]By Debra L. W. Cohn, Assistant United States Attorney for the Eastern District of Pennsylvania.

defense. Moreover, many of witnesses to health care fraud are elderly, ill, disabled or dead.

Given these characteristics, health care fraud requires parallel (criminal/civil/administrative) investigation and prosecution to ensure that all those responsible are held accountable. This approach permits prompt action to recover financial losses; and prosecution of all participants including smaller players; medical professionals and those profiting from the fraud.

3. Work Closely With Numerous Federal Agencies.

Health care prosecutors must work closely with investigators from a variety of federal agencies to develop and prosecute these cases. This means drawing on the experience of seasoned white collar law enforcement investigators at the FBI, Postal Inspector, Office of Inspector General of the Department of Health and Human Services, as well as working with agencies not traditionally considered members of the law enforcement community: Office of Personnel Management; Railroad Retirement; Veterans Administration. In addition, health care prosecutors must collaborate with private insurance companies and medicare carrier and intermediaries.

4. Decentralize Health Care Fraud Prosecutions.

Several factors suggest decentralizing health care prosecutions. First, the present as well as the proposed health care plan results in federal funds administered at the state and local level by state agencies and intermediaries. Second, parallel proceedings are most successful when the civil and

criminal attorneys work jointly each day with the investigators. Third, developing cases over time requires close working relationships with local advocacy and provider communities. Fourth, deterrence is maximized by having a presence in as many judicial districts as possible. Fifth, training and interaction is facilitated if Department activity is centered in cities hosting the Federal Bureau of Investigations ("FBI") Health Care Fraud squads and Regional Inspector Generals of Department of Health and Human Services ("HHS").

The decentralization of prosecutions should not deprive the main office of the Department of Justice of bringing certain large-scale health care fraud cases with national scope and which require a significant commitment of resources. In addition, the Main Office serves the critical role in setting policy; coordinating agency relationships; advocating legislative and regulatory reform; and collecting and transmitting information. See infra.

III. GOALS

In formulating a national program against health care fraud, the Department of Justice could address several goals: (1) increase number of cases brought and successfully resolved; (2) increase high profile, multidistrict cases; (3) target specific health care frauds with programmatic or social significance; and (4) maintain a presence in more judicial districts.

While each of these goals must be pursued, priorities will guide resource allocation and the organizational structure of the program.

A. Increase Number of Cases

In measuring the success of anti-crime efforts, the public, Congress and other concerned individuals and groups typically first look at total numbers of cases filed and their rate of successful resolution. Thus, the Department needs to maximize indictments; rates of conviction; civil complaints; civil judgments; and monetary recoveries.

The numbers of cases filed can be increased by building on past successes. Several United States Attorney's Offices have perfected civil and/or criminal prosecutions of certain health care frauds: telemarketing of durable medical equipment; ambulance frauds; misbilling; pharmacy drug diversion; and hospital credit balances. Their efforts are serving as models for prosecutions elsewhere, often successfully promoted by the Affirmative Civil Enforcement Working Group ("ACE").

RECOMMENDATION:

1. Increase Funding for Health Care Prosecutors, including dedicated health care fraud slots.

2. Develop Health Care Fraud Handbook. (modeled on ACE manual)

   a. Statutory Background
   b. Investigative Steps
   c. Model Pleadings.
   d. Names of Experienced Prosecutors

3. Sponsor Regional (rather than National) Health Care Training Programs.

4. Expand Civil Monetary Recoveries By Enhancing Statutory Remedies. (See infra)

B. Increase High Profile Cases

Simply increasing numbers of cases is not sufficient; we must address the types of cases, the size of the cases and the geographic focus of the cases. The Department recently garnered significant public attention and press coverage with a few high profile multidistrict cases involving significant amount of money -- National Health Labs and Operation GOLDPILL. These cases are important not only for their individual merits but also for the public attention drawn to health care fraud generally. Such cases require a commitment of significant resources and sophisticated and experienced agents and prosecutors. They are best pursued by Main Justice with its greater resources and by United States Attorney's Offices with a successful track record of white collar crime, health care prosecutions and parallel proceedings who have access to investigatory agencies with similar experiences. One of the challenges of such prosecutions is coordinating multidistrict litigation to prevent duplication.

Recommendations:

1. Allocate A Portion of Additional Resources to United States Attorney's Offices with health care fraud experience and in cities hosting FBI health care squads and Regional Inspector Generals.

2. Enhance reporting of ongoing health care fraud cases to Washington to facilitate coordination.

D. Maintain Presence in Greater Number of Districts.

While high profile cases are significant for the attention they garner, they cannot nor should not be pursued by every

United States Attorney's Office. Nor do they deter wrongdoing by the perpetrator of the frequent but small scale frauds so characteristic of health care fraud.

The need to send a message to these perpetrators coincides with the desire to deter fraud throughout the United States. All United States Attorney's Offices should be encouraged to pursue health care fraud cases, consistent with local investigatory and prosecutorial resources.

Recommendation:

1. Appoint Health Care Fraud Coordinator in Each District.

2. Establish Health Care Fraud Task Forces in every district
(sponsored by the United States Attorney's Offices, composed of federal, state and local prosecutors, investigatory agencies)

3. Develop Health Care Fraud Workbook.

4. Regional Training Of Prosecutors and Agents.

C. Subject Matter Driven Cases.

In addition to focusing on the numbers of prosecutions, the Department needs to reexamine the manner by which it brings cases as well as the types of cases it brings.

First, even where the Department has been prosecuting health care fraud, it is not always garnering maximum attention. For example, the deterrence yielded from prosecutions would be greatly enhanced if prosecutions were packaged as litigation initiatives. The Department should coordinate the filing of criminal and/or civil prosecutions around certain frauds, which are being prosecuted around the country: e.g., physician

misbilling; ambulance fraud; insurance fraud; and workers compensation. For example, a public affairs specialist at Main Justice should be assigned to promote the filing and successful resolution of health care fraud cases to the general and health care media.

Second, while the Department has brought successful prosecutions against a variety of health care providers, other health care problems of great public concern have been relatively ignored. For example, most federal prosecutors have not addressed nursing home abuse; home health care fraud; substance abuse clinics; boarding homes; and mental health programs. As public funding for these health services increases, so will the opportunities for fraud.

The reasons for the lack of prosecutorial attention to these issues are myriad: lack of resources; absence of applicable statutory remedies; and vague or nonexistent regulations. While Inspector General agents prepare program implication reports, they do not always result in corrected regulations. The Department of Justice needs to underscore the need to address deficiencies in regulations which undermine prosecutions.

In addition, health care fraud prosecutors typically do not communicate with advocates for quality care in health care, depriving each group of the knowledge and resources of the other. For example, AARP, National Coalition for Nursing Home Reform, and Elderly Legal Services address nursing home access, quality of care, and abuse but do not see these issues as fraud. The

Department of Justice should facilitate discussion with these advocacy groups who have considerable expertiese and resources for preventing, detecting and prosecuting health care fraud.

Finally, existing cost controls typically have not been enforced. The need for such cost control enforcement only will grow under proposed health care reforms. A few United States Attorney's Offices have initiated balance billing programs. These efforts take time as professional providers and the public are not accustomed to viewing such "misbillings" as criminal or civil fraud. A several prong campaign has been initiated in at least two districts whereby prosecutors develop relationships with the beneficiary communities; then bring actions under the civil injunction statutes and then criminal mail fraud statutes. This should serve as a model elsewhere.

Recommendations:

1. Launch litigation initiatives in certain subject areas.

2. Expand program against cost controls violations.

3. Collaborate with agencies to correct loopholes and eliminate vague language in regulations undermining prosecutions.

4. Coordinate communication between law enforcement and advocacy communities; initiate joint education programs on health care fraud.

IV. HEALTH CARE FRAUD STATUTES.

A. EXISTING STATUTORY SCHEMES.

Numerous existing statutory and common law remedies, both general and health care specific, are used in the fight against health care fraud. Criminal statutes include general laws such

as mail fraud; wire fraud; forfeiture; RICO; money laundering; and health care specific statutes such as the Antikickback Statute and the employee benefit statutory provisions. The Department of Justice also uses civil statutes to freeze assets;[2] shut down fraud schemes;[3] obtain immediate access to records and other materials;[4] compel disclosure of corporation information;[5] condition civil settlements on complete and truthful cooperation against other subjects;[6] encourage and assist whistleblowers in fighting fraud[7]; provide restitution to victims of fraud[8]; impose damages and/or civil penalties;[9] and hold owners liable for debts of corporate shams.[10]

B. LEGISLATIVE AGENDA

Notwithstanding these statutory remedies, certain areas require congressional action. The Department of Justice must ensure that health care fraud is an integral part of any health

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[2]Mail Fraud Injunction Statute; Debt Collection Act.

[3]Mail Fraud Injunction Statute.

[4]Inspector General Act (inspector general subpoenas).

[5]Mail Fraud Injunction Statute; Debt Collection Act; Inspector General Act (inspector general subpoenas).

[6]Civil cooperation agreements and proffer agreements.

[7]Qui tam provisions of False Claims Act.

[8]Mail Fraud Injunction Statute.

[9]Civil False Claims Act.

[10]Civil common law claims such as piercing corporate veil; fraudulent conveyance; unjust enrichment; and breach of duty as liquidating trustees.

care legislative initiative. Several health care fraud legislative proposals are pending, which include:

1. Provide All Payor Health Care Fraud Enforcement.

2. Enact Health Care Fraud Injunction
(modeled on mail fraud injunction)

3. Give Civil Prosecutors Access To Grand Jury Material
(modeled on FIRREA)

4. Ban Kickbacks in Health Care Referrals

a. define kickbacks to include anything of value
b. expand kickback statute to cover all payers.
c. amend Civil False Claims Act to include kickbacks within the meaning of a false claim.

5. Ensure That Enhanced Administrative Penalties Do Not Interfere With Civil Penalty Actions Brought By Department of Justice.

V. LOGISTICS OF NATIONAL HEALTH CARE FRAUD PROGRAM.

The structure of the Department of Justice's National Health Care Fraud Program should reflect these themes and goals.

A. Department of Justice -- Main Office.

The Main Office of the Department of Justice should serve as a central clearinghouse on policy, information, legal expertise as well as the liaison to agencies and providers. In addition, it should bring cases of national scope or requiring significant resources. However, with the typical health care fraud case, it should not serve as an additional layer of approval. Specifically, the Department of Justice -- Main Office should:

1. Continue National Health Care Fraud Task Force (with agencies)

2. Advocate Health Care Fraud Legislation.

3. Serve as Liaison with Agencies.

a. Promote regulatory reform by working with regulators to correct defects in regulation which undermine prosecutions.

b. Resolve interagency conflicts.

4. Collect Statistical Information On Health Care Fraud Prosecutions.

a. House Electronic Data Bases

(1) Subjects of Health Care Fraud Prosecutions (indexing by provider and patient)
(2) Develop software to perform "network analysis" of providers.
(3) Model Pleadings.

5. Offer Training And Education.

a. Issue Bimonthly Newsletter on health care fraud (achievements; legislation; regulations)

b. Sponsor regional training sessions, with law enforcement agencies.

c. Publish looseleaf on health care fraud decisions and statutory changes

(1) modeled on updated False Claims Act manual prepared by Commercial Litigation

6. Develop Health Care Fraud Workbook

(1) modeled on ACE manual.

7. Bring cases of national scope and those requiring significant resources.

B. Executive Office of United States Attorneys

The Executive Office of United States Attorneys should continue its role in facilitating communication between the field and Main Justice. It can draw on its experiences promoting Affirmative Civil Enforcement but it should not have a

substantive role in health care fraud. Specifically, it should co-sponsor regional training programs.

C. United States Attorney's Offices.

The loci of health care fraud prosecutions will be the United States Attorney's office. Specifically, each office should:

1. Sponsor Health Care Fraud Task Forces.

   a. composed of federal and state law enforcement prosecutors and investigators;

   b. where appropriate, invite regulatory and advocacy community.

2. Appoint A Health Care Fraud Coordinator.

   a. modeled on bank fraud coordinators.

   b. Report statistics on criminal and civil health care cases and send model pleadings to Washington.

   c. Organize health care fraud task force meetings.

   d. Attend Medicaid Fraud Control Unit meetings

3. File Health Care Fraud Cases Appropriate To Office's Experience.

4. Contact Intermediaries and carriers.

5. Develop Rapport with State Licensing Boards.

6. Develop Local Education Program.

7. In cities which host FBI Health Care Fraud Squads and/or Regional Inspector Generals for HHS, offer regional training for prosecutors and investigators.

D. Agencies.

The Department of Justice should work with the numerous investigatory and regulatory agencies concerned with health care.

Specifically, the Department should:

1. Encourage agencies to address prosecutors' experiences with vague or nonexistent regulations

2. Support Exclusions and Suspensions.

a. Enact Legislation to expand basis for exclusion and suspension to include;

(1) criminal convictions for abuse or neglect of patients;

(2) offenses involving controlled substances;

(3) failure to provide documentation

(4) civil false claims judgments.

b. Encourage agencies to exercise exclusion.

c. Establish electronic data banks to enable effective exclusion.

d. Give Department of Justice access to disclosures by providers of identity of owners; officers; managers; and ownership/control of other providers.

3. Eliminate Difficulties in Proving Providers Knowingly Conducted Health Care Fraud.

a. require providers to certify services comport with regulations

b. require providers to certify absence of ownership interest in other providers.

c. require providers to certify they bill only one payment source. (addresses billing to multiple payors for same service)

d. require providers to certify that they have not given or received kickbacks in connection with billed services.

4. Ensure that federal law enforcement agencies work equally with Civil and Criminal Prosecutors and Receive equal credit for such work.

DATE: January 6, 1994

ROUTING AND TRANSMITTAL SLIP		
TO: (Name, Office, Room, Building)	INITIALS	DATE
1. Gerald E. McDowell Chief, Fraud Section Rm. 4100 - Bond		
2. Gerald Stern Special Counsel to the Attorney General, Rm. 4119, MN		
3. Merrick Garland Deputy Assistant Attorney General Rm. 2113 - Main		
4.		

	Action Approval As Requested Circulate Comment Coordination		File For Clearance For Correction For Your Info Investigate Justify		Note and Return Per Conversation Prepare Reply See Me See Remarks Signature

Here is some data related to health care cases/matters. It indicates that a significant increase in activity occurred from 1992-1993, and that half of the activity is taking place in 15 districts.

FROM: Karen A. Morrissette Deputy Chief Fraud Section	ROOM NO. 4100 BOND BLDG. TELEPHONE NO. 514-7023

TOP 15 DISTRICTS WITH HEALTH CARE FRAUD CASES/MATTERS

(based on PROMIS printout ending October 31, 1993)

DISTRICT	# of CASES	# of MATTERS	TOTAL
1. MIE	7	56	63
2. ILN	6	55	61
3. PAE	7	42	49
4. FLS	17	29	46
5. FLM	3	38	41
6. CAN	1	37	38
7. NJ	8	24	32
8. PAM	5	25	30
9. CAC	6	22	28
10. OHS	10	17	27
11. ARE	4	23	27
12. WVS	0	27	27
13. GAN	2	22	24
14. TXS	3	18	21
15. LAE	4	16	20
TOTALS	83	451	534

Cases pending at end of FY 92	89
Cases pending at end of FY 93	161
Matters pending at end of FY 92	445
Matters pending at end of FY 93	868

WASHINGTON G-2 REPORTS

NATIONAL INTELLIGENCE REPORT®

The Biweekly on Medicare Policy for Laboratories, Blood Banks & Physician Services

Established since 1979
Dennis W. Weissman, Publisher

Vol. XV, No. 3/November 11, 1993

Highlights In This Issue

Medicare To Deny Payment For Overused Tests Added To Panels/Profiles

Hundreds of independent medical laboratories nationwide routinely bill Medicare for separate payment of certain tests commonly added to automated chemistry panels and profiles, the Health Care Financing Administration has found in a recent analysis of national claims data.

> With billing patterns for such "add-on" tests running 80% and higher, HCFA officials confirm to the *National Intelligence Report (NIR)* that the agency is developing revised guidelines to instruct local Part B contractors to deny Medicare payment for these claims.

At stake, say government sources, is close to $1 billion in annual Medicare billings for some dozen or so tests (*see box*) which will be targeted under guidelines requiring specific medical necessity documentation.

NHL Tip-Off: This news follows word last month that National Health Laboratories, Inc. has decided to eliminate its standard profiles that include serum ferritin and HDL cholesterol with automated panels (for example, NHL's Health Survey Profile) and to drop custom profiles with ferritin by next month. *NIR* also reported that HCFA was working on revised utilization rules covering specified tests ordered in combination with panels/profiles (*see NIR, XV, No. 2/Oct. 28, 1993, p. 2*).

HCFA's "Dirty Dozen" Targeted Tests

- ✘ Serum ferritin
- ✘ HDL cholesterol
- ✘ LDL cholesterol
- ✘ Magnesium
- ✘ Amylase
- ✘ Serum iron
- ✘ Total iron-building capacity
- ✘ Protein-bound glucose
- ✘ Phosphatase (RIA)
- ✘ Thyroxine, total
- ✘ Triiodothyronine (T3); resin uptake
- ✘ Thyroid-stimulating hormone (TSH)

The agency's policy stance was thrust into the national spotlight this month in a November 1 *Wall Street Journal* report quoting senior HCFA officials as confirming that Medicare intends to stop paying for specified "add-on" procedures not demonstrated to be medically necessary but included in test packages (panels/profiles). The article noted that the government crackdown "could lead to a reduction of tens of millions of dollars in billings for the Nation's laboratories over the next few years."

Clark Mclar Tants

HCFA is working with local Medicare contractors and physician advisors to eventually install new computer programs that will automatically flag inappropriate test combos billed to Uncle Sam, said Carol Walton, director of the agency's Bureau of Program Operations.

HCFA Memo: Significantly, HCFA's latest thinking about panel/profile billing practices is revealed in a September 1 memo targeting NHL. The memo was transmitted to regional offices by the Office of Medicare Benefits Administration.

Noting that NHL was continuing to bill SMAC tests in combination with three other tests—"ferritin (82728), HDL (83718), and phosphatase, acid; prostatic fraction, RIA procedure (84066)"—HCFA advised that several carriers have identified these being billed with one another 80% or more of the time. Further, the agency instructed that "when these combined tests are claimed at a high frequency level (greater than 50% of the time), carriers are to deny the additional tests on the universe of claims as medically unnecessary and only pay for the SMAC tests."

Multi-Agency Probe Of Labs

- Justice Department continues to investigate billing practices of national lab chains
- OIG examines wide array of lab payment & billing policies, including a look at medical necessity issues relating to physician ordering & lab billing of panels/profiles
- HCFA concentrates on test ordering patterns of labs and related utilization review activities to assure stricter claims processing oversight of medically unnecessary procedures

By ruling that the burden is on NHL to document the medical necessity of the additional tests, HCFA's move resulted in the company being denied some $3.5 million in payments in September alone. NHL says it plans to contest this move and is discussing the status of these claims with HCFA.

More Guidance: Responding to questions about what contractors should do with claims where the ordering physicians specifically state they did not order the additional tests, HCFA says these cases are to be referred to the appropriate field investigation office for review. In the event that this office declines the case, the carrier is to deny payment for the tests done in addition to the SMAC and recover any overpayment.

Meantime, government sources confirm that separate task forces are at work at the Justice Department, the HHS Office of Inspector General, and HCFA examining different aspects of panel/profile policies.

These same sources stress that NHL's decision to drop ferritin and HDL from custom profiles and panels was strictly voluntary and credit the company for its willingness to play a leading role in changing long-standing industry practices which, though not necessarily fraudulent, have clearly gotten out of hand in the government's view.

While refusing direct attribution by name, HCFA staff directly involved with the issue acknowledge that they are not fully comfortable with the evolving policy process and recognize that it may not always treat the industry fairly, particularly in regard to documenting medical necessity for tests where the lab neither sees the patient directly nor has immediate access to diagnosis information.

Voluntary Guidelines: These HCFA officials suggest that since it is essential that doctors have full information when they order tests, the lab industry could help itself greatly by developing industry guidelines for test requisition forms with the cooperation of physician groups. While HCFA would never endorse any specific form, key officials tell *NIR* they believe the agency would be willing to play a "middleman" role in the development of guidelines.

Lab Co-Pay, Competitive Bidding Back On The Congressional Table

The prospect that Congress could restore co-pay requirements for laboratory services under Medicare Part B is being taken seriously in Washington as political pressure mounts to find ways to finance health care reform in the long term, plus make a more immediate cut in federal spending.

> The 20% lab co-payment, abolished by Congress in 1984 as part of the switch to a fee schedule payment methodology, is revived in the President's health care reform bill unveiled last month and also is endorsed in the leading legislative alternatives, making it difficult to defeat, say opponents throughout the lab community.

Also up for legislative deliberation is the issue of competitive bidding for Part B lab and other services. This provision is tucked into the Clinton bill as a vehicle to help pay for health care reform, and if it fails to hit the mark, the Department of Health & Human Services would be given standby authority to cut lab spending by at least 10%. During the 1980s, Congress repeatedly prevented the Health Care Financing Administration from launching a limited competitive lab service bidding demonstration.

First Go-Round On Lab Co-Pay Imminent: Rather than reinstate Part B lab co-insurance for health reform purposes, a bipartisan measure sponsored by Reps. Timothy Penny (D-MN) and John Kasich (R-OH) seeks to restore it as a deficit-cutting device. Backers of the Penny-Kasich initiative, which the House leadership has indicated could come up for a vote in the next week or so as an amendment to the President's more modest supplemental budget-cutting proposal, contend that reimposing the lab co-pay could save $700 million in 1994 or $7.1 billion over the next five years.

Overall, the Penny-Kasich plan proposes to reduce federal spending by some $103 billion over the next five years. In other Medicare changes, the plan would require a 20% co-pay on home

Lab Service Provisions In Clinton's Health Security Act

Co-Payments

The President's standard benefits package includes outpatient laboratory services. For the lower cost-sharing schedule, there is no co-payment for lab services; for the higher cost-sharing schedule, the co-pay would be "20% of the applicable payment rate," that is, the fee schedule negotiated between providers and health alliances for individuals enrolled in fee-for-service plans.

Under Medicare, the President's bill reinstates co-insurance for clinical lab services, dropping the program's payment rate from 100% to 80% of the negotiated payment.

Competitive Acquisition

The HHS Secretary would establish competitive acquisition areas and award a contract or contracts for furnishing Part B clinical laboratory services on or after January 1, 1995.

Competitive Acquisition Areas: Initially these would be, or be within, metropolitan statistical areas and would be chosen based on availability and accessibility of suppliers and probable savings to be realized by competitive bidding.

Conditions For Contract Awards: Must meet HHS-determined quality standards; must offer a total quantity of service sufficient to meet expected need within the competitive area.

Payment Cuts: If competitive bidding doesn't result in at least a 10% reduction in fee schedules and negotiated rates from the previous year, the Secretary is directed to reduce each payment amount by at least 10%.

Direct Billing

Under this heading, the Act proposes: "A provider may not charge or collect from an enrollee amounts that are payable by the health plan (including any cost-sharing reduction assistance payable by the plan) and shall submit charges to such plan in accordance with any applicable requirements...."

[**Note:** *This will require clarification since the wording appears to be more a protection of enrollees from balance billing than what is traditionally meant by "direct billing" in the lab industry. Though sources say there is an inclination at the White House to look at direct billing as a component of reform, the underlying politics reportedly seek to avoid alienating physician support.*]

health services for beneficiaries with incomes above 150% of the federal poverty level, would make upper-income individuals pay more in premiums, and would establish a means test for the hospital insurance deductible.

New Counter-Coalition: The lab payment and policy changes envisioned in the health reform debate and in the Penny-Kasich measure have galvanized significant opposition among virtually all major lab professional and industry groups and have led to the formation of a laboratory budget issues group to coordinate lobbying efforts. Acting on behalf of the American Association of Bioanalysts, its Washington counsel Robert Waters convened the first meeting of the group on November 1. Though the current focus is on the Penny-Kasich plan, the group's aim is to promote greater cooperation to counter what Waters called a view by many in the Administration and on Capitol Hill that labs are still "the place to make cuts."

Participating in the coalition are the American Association of Bioanalysts/International Society for Clinical Laboratory Technology, American Medical Technologists, Hoffman-LaRoche, Nichols Institute, MetPath, American Society of Clinical Pathologists, American Society for Clinical Laboratory Science, American Association of Blood Banks, American Clinical Laboratory Association, American Association for Clinical Chemistry, Clinical Laboratory Management Association, College of American Pathologists, National Association for Support of Long-Term Care, and the Jefferson Group (representing labs in Puerto Rico).

Competitive Bidding: The Administration's plan in this regard has yet to be fleshed out beyond the basics spelled out in its health reform bill, but the authors appear to see it as a "winner-take-all" approach in sharp contrast to the "multiple winners" under HCFA's stalled program model.

> The betting among informed observers is that it should be easier for lab lobbying efforts "to knock out" this latest competitive bidding proposal than to thwart resurrection of lab co-insurance. The prevailing view is that Congress would find it difficult to "buy into" the proposed HHS standby reduction authority over lab fees.

CLIA Watch: Administration Steers Away From Statutory Changes

Signaling its intent to avoid wholesale statutory changes in order to modify the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), the Clinton White House is proposing only one change in the CLIA law covering exempt laboratories as part of its massive health care reform proposal unveiled late last month on Capitol Hill.

Exempting Waived Tests: Under its proposal, the Administration would eliminate all current registration and related fee requirements for certificate of waiver facilities performing only so-called simple lab procedures. If enacted, the change would take effect during the first month following congressional approval of the President's Health Security Act.

The White House stance on CLIA modifications largely validates the position of Department of Health & Human Services officials who have strongly opposed opening up the law and instead favor accomplishing the Administration's policy objectives through changes in CLIA regulations.

Dingell Cancels CLIA Hearings

A hearing on CLIA '88 implementation scheduled this month by the House Energy & Commerce oversight and investigations subcommittee has been officially scrubbed by chairman John Dingell (D-MI). First set for November 10 and then pushed off to the next week, the hearing is now off for good, confirm congressional staffers who report that the influential legislator will instead pen a letter to senior HHS officials raising questions about how the lab law has been handled.

This late development comes as no surprise to many legislative observers who speculate that Dingell remains reluctant to publicly attack the Clinton White House on CLIA, particularly as the health care reform debate heats up. No similar aversion tugs at another key backer, Sen. William Cohen (R-ME), who is said to be considering a CLIA oversight hearing to grill the Administration on its policy stance on the statute, particularly as it relates to physician office labs.

For example, though only a handful of lab tests are currently exempt, HHS is moving ahead to revamp criteria for exempt tests which could result in additional procedures qualifying for exemption. Likewise, other changes sought by the Administration to ease the regulatory burden on physician office labs are being pursued by the Centers for Disease Control & Prevention, including a new test category with fewer personnel and inspection requirements (*see NIR, XV, 20/Aug. 20, 1993, p. 6*).

Cytology PT Change: Meantime, HHS officials acknowledge that another statutory change in CLIA will be necessary once the Department decides how to deal with cytology proficiency testing. Set to be implemented January 1, 1994, the current legal requirement for cytology PT is regarded as unworkable and will be modified once an alternative approach is adopted. Toward this end, CDC is hosting a national conference this month in Atlanta (*see NIR, XV, 1/Oct. 12, 1993, p. 2*).

Clinton's Health Reform Bill Expands Fraud and Abuse Powers

The President's Health Security Act proposes a greatly expanded anti-fraud and abuse initiative not just in Medicare and Medicaid, but throughout the health care field. Providers would face more restrictions on health care-related investments and referrals, new and tougher sanctions for prohibited conduct, plus a more coordinated—and partially self-funded—enforcement effort by the Justice Department, the HHS Office of Inspector General, and state agencies.

The Act would broaden the reach of the Stark prohibitions against physician self-referral, confer a legislative stamp of approval on several of the OIG's broad readings of kickback prohibitions by incorporating safe harbor criteria in the law, and grant the OIG new enforcement authority and increased resources.

Major Stretch For Stark: The Clinton bill would extend the ban on physician self-referral beyond anything proposed during the legislative debate over this year's Omnibus Budget Reconciliation Act (OBRA '93). It would expand Stark to all payors and to all health care services. At the same time, the bill would delete or narrow certain Stark exceptions:

- Eliminated would be the exception allowing a physician to refer a patient for physician services to another physician in his/her group practice.

- The exception for in-office ancillary services would be restricted to "clinical laboratory, x-ray, and ultrasound services that are provided at low cost" by or under the supervision of physicians in their offices.

- The exception for ownership of publicly traded securities would be narrowed and the exception for rural providers would specify that 85% of services must be furnished to residents of rural areas.

The types of holding company and loan arrangements which may give rise to a self-referral problem are clarified by replacing OBRA '93 language defining a financial relationship as including "an entity that holds an ownership or investment interest in any entity providing the designated health service" with the following: "a loan from the entity, and an interest held indirectly through means such as (but not limited to) having a family member hold such investment interest or holding a legal or beneficial interest in another entity (such as a trust or holding company) that holds such investment interest."

Conforming To Safe Harbors: The current statutory exemption of discounts under anti-kickback law would be written to conform to the OIG safe harbor specifying that certain discounts are not considered remuneration as long as they are properly disclosed and reflected in a claim form, are not given in exchange for an agreement to buy another item or service, are not offered only to selected entities, and are not given in cash.

Bona fide employer-employee relationships would be protected as they now are under the safe harbors as long as the payment is in line with fair market value and does not account for the volume or value of referrals. Also protected would be services rendered by a physician or physician group under an at-risk, prepaid capitated arrangement.

New, Stiffer Sanctions: Under the Health Security Act, the OIG would have, for the first time, authority to impose stiff civil money penalties in an administrative proceeding under anti-kickback law. The maximum sanction would be an assessment three times the total remuneration involved (not merely the portion constituting a kickback), plus a penalty of up to $50,000 per violation.

> Moreover, in certain cases in which the OIG now has discretion both about the decision to exclude a provider under permissive sanctions provisions and about the length of the exclusion, the Clinton bill would require that once the OIG decides to exclude a provider, the minimum duration would be three years.

Enhanced Enforcement Authority: Tucked into Title V of the Health Security Act, Quality and Consumer Protection, is a subtitle devoted to beefing up federal and state anti-fraud and abuse efforts through stronger enforcement authority supported not just by appropriated funds, but by the proceeds of the fraud and abuse program. The bill calls for the creation by January 1, 1996 of an "All-Payor Health Care Fraud and Abuse Control Program."

Its aim is to coordinate activities of the Department of Health and Human Services, the OIG, and the Justice Department in identifying, investigating, and prosecuting health care fraud and abuse. These agencies would have on-line access to information from health alliances and health plans relating to investigations and sanction activities.

To supplement funds appropriated for enforcement, an "All-Payor Health Care Fraud And Abuse Control Account" would be established. The account would be credited with all criminal fines imposed in federal health care offenses, all penalties and damages assessed under the False Claims Act, and all administrative penalties and assessments in health care fraud and abuse proceedings. The account would be authorized to accept private gifts and bequests.

Clinton's Anti-Fraud and Abuse Program
Major Provisions

Title IV

Medicare and Medicaid Provisions

- IG authorized to impose civil money penalties (CMP) in anti-kickback cases
- Civil anti-kickback sanction set at CMP of up to $50,000 plus assessment of three times the total amount of remuneration in the transaction (not just the amount of the kickback)
- Maximum criminal penalties increased from $25,000 to $50,000 plus an assessment equal to three times the total remuneration involved
- Stark ban extended to all payors and all services
- Stark exception for referrals to another physician in group practice repealed
- Compensation arrangement exception created for physician payment for clinical laboratory services if payment equals fair market value
- Civil money penalty for improper claims increased from $2,000 per item or service to $10,000 per item or service
- Three year minimum exclusion imposed for certain permissive sanctions

Title V

Quality and Consumer Protection

- All-Payor Health Care Fraud and Abuse Control Program created to coordinate IG, Justice and state fraud and abuse efforts
- All-Payor Health Care Fraud and Abuse Control Account established, to be funded from penalties, assessments, and fines in fraud and abuse proceedings—supplements rather than replaces appropriations for enforcement programs
- IG's exclusionary authority extended beyond Medicare and Medicaid program to all payors deemed to violate Health Security Act

Forfeiture: If a federal health care offense is determined by a court to pose a serious threat to an individual's health or to have a severe impact on the health care system, the court could order forfeiture by a person convicted of the offense of property used in the offense, derived from goods that can be traced to the offense, or having proportionate value to the serious nature of the crime.

Assessing U.S. Risk From German Blood Scandal

The issue of HIV contamination of the blood supply in Germany has made headlines in this country, but officials here say the areas of potential exposure affecting U.S. citizens are quite limited. Two German companies, UB Plasma and Haemoplas, have been shut down, at least temporarily, after it was discovered that they were not screening every unit of blood as required by law. According to a *New York Times* report on November 11, at least six cases of HIV transmission in Germany can be traced to tainted blood released by the companies.

A spokesperson for the Food & Drug Administration advises that tainted blood from the German companies should not present a risk to the U.S. blood supply because all blood imported must come from suppliers that have been inspected and licensed under FDA standards. Similarly, because U.S. military hospitals in Germany maintain their own blood collection and processing services, members of the military and their families who received transfusions in these hospitals should not be at risk.

> However, in some cases, military personnel or family members were transferred to German hospitals for treatment. U.S. military officials are encouraging any such individuals who received blood transfusions in German hospitals during the last 15 years to be tested for HIV.

In addition, though both blood suppliers are German, they exported potentially contaminated products to hospitals in a number of European countries, including Italy, France, Switzerland, Austria, and the Czech Republic. Neither the FDA nor the Centers for Disease Control & Prevention has issued a statement regarding the extent of risk to U.S. citizens who may have received blood or blood products while travelling or temporarily residing in these countries.

Congress Urges Funding Priority For Medical Tech, Cytotech Training

Expressing concern over the growing shortage of allied health personnel, especially medical technologists and cytotechnologists, appropriations committees in both the House and the Senate have urged the government to give greater consideration to funding projects at schools providing training in these professions. This congressional intent is spelled out in report language accompanying the HHS-Labor funding bill for fiscal 1994 which was signed into law (P.L. 103-112) in mid-October.

> The measure appropriates $3,647,000 to the HHS Health Resources & Services Administration for allied health special projects, an amount identical to that allowed for FY 1993 but $1,162,000 more than the Clinton Administration's request for FY 1994. The authorization level for these special projects is $5 million.

For the entire HRSA health professions budget category (which includes allied health among some 30 line items), Congress appropriated nearly $282.7 million for FY 1994 (roughly $16 million more than for FY 1993). The bulk of the increase is targeted to family medicine, area health education centers, and nurse training.

Dollars Still Don't Go Far: According to an analysis in the September issue of *Laboratory Medicine*, published by the American Society of Clinical Pathologists, HSRA funds 28 allied health projects and 21 will be continued under 1993 appropriations. Many of these projects have a clinical lab training component.

> For 1994, however, out of 83 applications received, 49 were approved but only eight will be funded. The authors note that only one funded project in this grant cycle had a lab component. To fund all the 49 approved would require an appropriations level roughly equal to the authorization level, the authors conclude.

Criteria Proposed For Levying Stark Sanctions

Rules governing imposition of new civil money penalties (CMPs) for violating Stark prohibitions against self-referral for Medicare Part B laboratory services have been proposed by the HHS Office of Inspector General. The proposal, which affects both physicians and clinical labs to which the doctors have made prohibited referrals, covers sanctions for improper claims, circumvention schemes, and failure to make a timely refund.

Improper Claims: Under the Stark statute enacted in 1989 and effective January 1, 1992, the CMP for presenting (or causing to be presented) a claim for a prohibited referral may be no more than $15,000 for each service. The offender also may be subject to Medicare exclusion and an assessment of not more than double the amount claimed for each service. The OIG is proposing to follow five criteria in setting the amount of the penalty or assessment for each violation:

1) Nature of the claim and circumstances under which it was presented.
2) Degree of culpability of the person submitting the claim.
3) History of prior offenses by the person submitting the claim.
4) Financial condition of the person presenting the claim.
5) Other matters "as justice may require."

For failing to make a refund, a sixth criterion—timeliness and completeness—would be applied.

Circumvention Schemes: CMPs and exclusion may be imposed in cases where providers devise arrangements for referrals which, if made directly, would breach the Stark ban (example: a cross-referral accord under which physician owners of "Y" refer to "X"). The maximum CMP is $100,000 per scheme; an assessment double the amount billed for the service may be imposed also. In determining the penalty or assessment per violation, the government would use the five criteria listed above, plus a new criterion based on the amount of ownership interests involved.

Comments on the proposed rules are due by December 20 to OIG, HHS, Attn: LRR-30-P, Rm. 5246, 330 Independence Ave., SW, Washington DC 20201. Contact Stuart Wright, legislation and regulations staff, 202/619-3270.

People In The News

June Gibbs Brown, previously the Inspector General for the Navy's Pacific Fleet, was confirmed by the Senate on November 5 as HHS Inspector General.....**Judith Yost** has been named medical technologist advisor to the director of HCFA's Health Standards & Quality Bureau and is serving as acting chief of the Bureau's lab and home health services branch. Her main duties continue to be CLIA survey and technical assistance as well as investigating (with FDA) fatal transfusions.....New at the Health Industry Manufacturers Association: **Kristen D.W. Morris** is director or government affairs and **Carolyn D. Jones** is director of in vitro diagnostics and biomedical technology. Before joining HIMA, Morris directed government relations for the American College of Nuclear Physicians and the Society of Nuclear Medicine; Jones, a registered medical technologist, was a consumer safety officer in FDA's Center for Biologics Evaluation & Research.

Correction re story on Washington state's CLIA-exempt status (*NIR, XV, 1/Oct. 12, 1993*): The $700,000 exemption fee cited on page 4 is a government-estimated average for all states; for the first year of Washington's program, the fee negotiated with the Health Care Financing Administration is $114,250, according to Martha Simon, director of the state's Office of Laboratory Quality Assurance. The fee will be renegotiated later, she said, after all labs in the state are relicensed and agreement is reached on certain CLIA overhead amounts put forth by HCFA.

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U. S. Department of Justice

Criminal Division

Deputy Assistant Attorney General *Washington, D.C. 20530*

December 23, 1993

Mr. Bryan B. Mitchell
Principal Deputy Inspector General
Office of the Inspector General
Department of Health & Human Services
Washington, D.C. 20201

Dear Mr. Mitchell,

On December 21, 1993, the Department received a letter from you to Gerald Stern, Special Assistant to the Attorney General, seeking his concurrence in the transmission of certain documents to the House Government Operations Subcommittee on Human Resources and Intergovernmental Relations pertaining to the investigation and prosecution of National Health Laboratories (NHL). Your letter noted that a federal grand jury had been involved in the investigation of NHL, and that Rule 6(e) of the Federal Rules of Criminal Procedure, which bars disclosure of grand jury information, was therefore implicated. Your letter requested written comments from Mr. Stern by December 23, 1993.

Unfortunately, your letter arrived after Mr. Stern left for the holidays, and I am replying in his absence. As your staff has been advised by telephone, given the possible application of Rule 6(e) and other investigative concerns to the materials at issue, the Department is obligated to review the documents and then to confer with you before they can be released or transmitted. We have already begun the review process, and do not expect it to take very long. Even given the holiday season, we expect to be able to be in a position to confer with you within two weeks.

We appreciate your consulting with us, as well as your cooperation in awaiting the outcome of the Department's review of the documents before transmitting them. If you have any questions, in Mr. Stern's absence please feel free to contact me at 514-2636, or Karen Morrissette of the Fraud Section, at 514-0640.

Sincerely,

Merrick Garland
Deputy Assistant Attorney General

FACSIMILE TRANSMITTAL

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Special Instructions

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General
Washington, D.C. 20201

DEC 17 1993

Mr. Gerald Stern
Special Assistant to the Attorney General
Office of the Deputy Attorney General
U. S. Department of Justice
Washington, D.C. 20530

Dear Mr. Stern:

This is to apprise the Department of Justice of a request we received from the Subcommittee on Human Resources and Intergovernmental Relations, House Committee on Government Operations. Chairman Edolphus Towns requested certain specified information and documentation pertaining to the Government's investigation and prosecution of National Health Laboratories (NHL). See Enclosure 1. Consistent with our statutory responsibilities, we desire to fully cooperate with the Subcommittee.

We are reviewing our investigative files pertaining to our past investigation of NHL and are proposing to transmit to the Subcommittee certain information compiled by our Office of Investigations (OI) and Office of Audit Services (OAS). See Enclosure 2. However, in view of the involvement of a Federal grand jury in the investigation of NHL, and the concomitant proscriptions of Rule 6(e), Federal Rules of Criminal Procedure, as well as the new ongoing review of recent NHL practices, we seek your concurrence in the proposed transmittal. Please note that, at the request of the United States Attorney's Office for the Southern District of California, we are not including documentation secured through grand jury subpoena or OAS analyses based on this information.

The Subcommittee requested the specified information by December 17, 1993. Due to the voluminous investigative file and the fact that the majority of the documentation compiled in the NHL investigation is located in the OAS field office in San Diego, California, we are not able to meet this deadline. However, we desire to be timely in our response and request your written comments by December 23, 1993. If we do not hear from your office by December 23, 1993, we will assume that our response to the Subcommittee is appropriate.

FAX 619-0160

Page 2 - Mr. Gerald Stern

If you have any questions, please contact either Judith Kidwell of our Civil and Administrative Remedies Division, OI, at 619-0070 or Thomas E. Herrmann of our Office of the General Counsel at 619-1306. Thank you for your assistance.

Sincerely yours,

Bryan B. Mitchell
Principal Deputy Inspector General

Enclosures

cc: Karen Morrisette
Michael Hertz
Carol Lam

Attachment 1

ONE HUNDRED THIRD CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT OPERATIONS
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6143

December 8, 1991

Eileen T. Boyd
Assistant Inspector General
U.S. Department of Health and
Human Services
330 Independence Ave., S.W.
Room 5600
Washington, D.C. 20201

Dear Ms. Boyd:

Pursuant to Rules X and XI of the House of Representatives, the Human Resources and Intergovernmental Relations Subcommittee, of the Committee on Government Operations, is investigating, Medicaid and Medicare fraud. As part of that investigation, we are examining the marketing and billing fraud case regarding National Health Laboratories (NHL). In furtherance of the subcommittee's investigation I would like you to respond to the following questions by close of business Friday, December 17, 1993:

1. How did the Office of Inspector General first become aware of the marketing and billing fraud being committed by NHL?

   a. On what date was this information brought to the attention of the Office of Inspector General?

   b. What member of the Office of Inspector General was initially contacted?

2. On what date did the Office of Inspector General begin a formal investigation of National Health Laboratories?

   a. What is the name, address and telephone number of the investigator within the Office of Inspector General who conducted the investigation of National Health Laboratories?

b. Please provide copies of all written correspondence to and from the IG's office which conducted the investigation of National Health Laboratories and the Headquarters Office of Inspector General.

3. Please provide the name, address and telephone number of the principal Department of Justice attorney who was responsible for the National Health Laboratories case?

a. Please provide copies of all written correspondence to and from the Department of Justice and the Office of Inspector General regarding the National Health Laboratories case.

4. Please provide the name, address and telephone number of all personnel within the Department of Health and Human Services (HHS) who were involved in efforts to calculate the financial loss to the Department as a result of the fraud committed by National Health Laboratories.

a. Please provide copies of any written estimates or any other document written by HHS personnel, regarding the financial loss to the Department as a result of fraud committed by National Health Laboratories.

5. Please provide the final settlement agreement in the National Health Laboratories case, as well as any drafts of that agreement within the possession of the Office of Inspector General.

If you have any questions regarding this request, please contact Ron Stroman of my subcommittee staff at 225-2548.

Sincerely,

Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations

KAM draft 12/6/93

PROPOSED MODEL FOR STRUCTURE OF FEDERAL HEALTH CARE FRAUD ENFORCEMENT EFFORT

PREAMBLE

The Department of Justice, the Department of Health and Human Services Office of the Inspector General (OIG), and the Federal Bureau of Investigation (FBI) recognize that health care fraud is a very significant white collar crime problem which warrants an increased focus. Billions of dollars are lost each year to health care fraud and abuse. This loss affects all Americans and all health care programs, government and private. The President has introduced the Health Security Act. An indispensable component of the success of health care reform is the integrity of the data which is generated by the health care system. A second key component is cost savings which can be obtained by effective fraud enforcement techniques.

STATEMENT OF PURPOSE

An effective federal health care fraud enforcement effort must have a mechanism for setting enforcement priorities, ensuring that those priorities are implemented, and utilizing resources and remedies in the most efficient way possible. This proposal includes all of those components.

FORMULATION OF HEALTH CARE FRAUD ENFORCEMENT POLICY

Special Counsel for Health Care Fraud

The Attorney General has appointed a Special Counsel for Health Care Fraud (the Special Counsel). The Special Counsel's responsibilities include the following:

--setting health care fraud enforcement policy for all Department of Justice components and ensuring that that policy is implemented.

--representing the Department at the policy level with other federal departments/agencies.

--ensuring that the Department's health care enforcement resources are allocated in the appropriate fashion.

--ensuring that the Department's headquarters and field components perform enforcement functions which complement each other in an effective fashion.

Executive Level Health Care Fraud Policy Group

The Special Counsel chairs an Executive Level Health Care Fraud Policy Group. The Group's membership consists of the Department of Justice, the FBI, and the OIG. The missions of the Group are:

--to marshal information concerning the health care fraud crime problem

--set enforcement priorities based on that information

--develop methodologies for addressing the crime problem

--ensure that resources are assigned in a manner which is consistent with the crime problem

--ensure that the key elements of the federal health care enforcement strategy are implemented

The Group will meet on a monthly basis and will delegate to sub-groups or to the National Level Health Care Fraud Working Group the responsibility for assessing specific proposals for enforcement initiatives and for allocation of significant resources.

KEY ELEMENTS OF THE FEDERAL HEALTH CARE FRAUD ENFORCEMENT STRATEGY

A. Maximize Access to Information Regarding Health Care Spending and Health Care Crimes Among Enforcement and Program Agencies.

The government currently pays for health care via a myriad of government programs and payors. Each of those programs has its own watchdog, the Inspectors General. The primary program agency for federal health care spending is the Health Care Financing Administration (HCFA), which administers the Medicare and Medicaid programs.

HCFA, through its contractors, has access to information which is extremely useful as a tool for the formulation of health care enforcement priorities. The enforcement agencies will form a partnership with HCFA for the purpose of obtaining and analyzing Medicare claims information in an effort to detect fraudulent billing patterns and predicate criminal, civil, and administrative investigations of providers. As that effort bears fruit, the enforcement agencies will establish similar relationships with the other government health care program agencies, and with private health care insurers, for the purpose of using their health care spending data in the same fashion.

The enforcement agencies will communicate with HCFA (and other

health care program agencies) at the headquarters level for the purpose of identifying significant trends in health care spending and for the purpose of identifying providers which are executing fraud schemes on a large, multi-district scale. In addition to this line of communication, enforcement agencies at the local (district and regional) level will communicate directly with HCFA contractors for the purpose of identifying single providers who are perpetrating fraudulent billing schemes. With respect to access to HCFA information through both the headquarters and local level, computerized analysis of health care spending information will be used to the maximum extent possible.

The analysis of health care claims information will enable federal enforcement to operate in an increasingly proactive, rather than purely reactive, mode. In addition, this partnership between the program agencies and the enforcement agencies will result in a streamlined referral process of fraud allegations from HCFA contractors. HCFA contractors' fraud and abuse coordinators will also be participants in local level health care fraud working groups.

B. Headquarters and Field Components Will Each Play Key Roles in Health Care Fraud Enforcement

The headquarters and field components of the enforcement agencies each have distinct, and key roles to play in the enforcement framework. Headquarters components ~~are uniquely able to~~ examine the national picture, and make assessments about whether crime problems are localized, regional, or nationwide in scope. As a result of increased accountability and tracking of referrals and investigations (see point E, infra), as well as the communication which will exist with the program agencies, headquarters components ~~will be able to~~ formulate enforcement initiatives to address specific crime problems, ~~and initiate~~ and coordinate investigations and prosecutions which cut across district/region lines. The Criminal and Civil Divisions of the Department of Justice as well as the headquarters of the OIG and the FBI, will perform this function.

~~A plan has been developed for the interaction of all of the enforcement agencies at the local level.~~ Local (district/regional) health care working groups have been very successful in a number of districts. ~~A model for such success has been~~ formulated and investigators and prosecutors will be trained concerning this model and resource materials provided so that the model can be implemented on a nationwide basis.

C. Providers/Individuals in Possession of Information Concerning Health Care Fraud Will Be Encouraged to Provide that Information to Enforcement Agencies

The headquarters components of the enforcement agencies will

develop and operate a program to encourage health care providers to voluntarily provide to the government information about health care fraud offenses. Incentives will be offered to providers who participate in the program.

The government obtains valuable information through civil complaints filed by qui tam relators concerning health care fraud offenses. Those complaints will be expeditiously analyzed and, if of sufficient merit, will be investigated by the FBI and the OIG so that an informed judgment can be made as to whether the government should take over the lawsuit. If the government joins the litigation, sufficient investigative resources will be devoted to ensure that the full scope of the alleged fraud is uncovered and the full scope of available civil remedies is brought to bear on the defendants.

Memoranda of Understanding will be signed by the Department of Justice, the FBI and the OIG concerning the allocation of resources to investigate disclosures made under the incentive program and to investigate qui tam complaints.

D. The Government Will Consider the Application of Criminal, Civil, and Administrative Remedies in Each Investigation/Case

The government has a number of remedies at its disposal to prevent health care fraud, punish the offenders, and seek reimbursement for losses. All of those available remedies will be considered as an enforcement strategy is formulated for each investigation/case.

Criminal remedies serve a number of purposes, including punishment of the offender. Forfeiture remedies result in the disgorgement of ill-gotten gains from the offender. Administrative remedies serve the purpose of preventing the offender from victimizing the government program in the future. Civil remedies seek reimbursement to the government program for losses resulting from the fraud offenses. In many cases, these remedies can be used in tandem and in harmony with each other. Indeed, particularly in the health care provider arena, the offenders may have assets which should be specifically targeted for seizure, forfeiture, or other affirmative civil enforcement action, so that they are not dissipated by the offender during the course of the investigation or litigation. Agents and prosecutors will be trained to consider all of the available remedies and to formulate investigative strategies to target the assets of offenders.

E. Enforcement Agencies will Catalogue their Efforts and Constantly Reassess the Results of their Efforts

The enforcement agencies will devise and implement an accountability system to track every health care fraud

investigation and case (civil, criminal, and administrative). Each case will be catalogued and tracked from the date it is received as a referral, or is otherwise generated, through the course of investigation/litigation, to closing.

The system will be capable of producing information about the types of providers which are under investigation, the source of the case, the investigative agencies, the status of the case, the dollars involved/recovered, and the remedies used. Reports will be generated and cross referenced on a monthly basis. This information will be used to reassess the allocation of resources, and to evaluate the relative success of various means of generating health care fraud cases.

F. The Allocation of Investigative and Prosecutive Resources will be Reassessed on an Ongoing Basis.

The enforcement agencies will analyze the type and quantity of resources which are presently devoted to health care fraud enforcement. Through the auspices of the Executive Level Health Care Fraud Policy Group, the agencies will formulate a proposal for the augmentation of resources, and/or reallocation of existing resources to health care fraud enforcement from other areas. This process will be done on an ongoing basis.

G. The Enforcement Agencies Will Assist the Program Agencies in Their Efforts to Detect and Prevent Health Care Fraud.

During the course of investigations, agents and prosecutors sometimes identify aspects of government programs and reimbursement systems which render the program vulnerable to fraud and abuse. Investigators and prosecutors are sometimes able to communicate these findings to the program agency, but there is no specific vehicle by means of which to do so.

A form will be developed which can conveniently be used for this purpose. It will be disseminated to all agents and prosecutors working on health care fraud matters and its use will be mandatory. The forms will be reviewed in the headquarters of the enforcement agencies and forwarded to the appropriate program agency. The agents/prosecutors who identified the vulnerability will be available to discuss their observations with the program agency representatives.

H. Federal Enforcement Agencies, at the Headquarters and Field Levels, will Develop a Strong Liaison with State Law Enforcement Offices With Responsibility for Health Care Fraud Enforcement.

State Medicaid Fraud Control Units exist in 40 states. In addition, state Attorneys General also have responsibility for health care fraud related investigations. Other local law enforcement offices also work on health care matters. It is

essential that federal enforcement work closely with those state and local agencies so that information is shared to the maximum extent possible and so that precious resources are not wasted.

The model for local level health care fraud working groups will include a component for liaison with state agencies. The headquarters components of the federal enforcement agencies will also meet on a regular basis with the associations which represent the state enforcement offices.

I. The Enforcement Agencies Will Conduct Outreach to the Public and To Private Entities which could Aid the Health Care Enforcement Effort.

Regardless of the nature of the crime problem, investigative agencies need intelligence information about criminal activity in order to launch a successful enforcement program. Much information about health care fraud is provided by citizens and program beneficiaries who notice discrepancies between the services which they received, and the billings which are delineated on the Explanation of Medicare/Medical Benefits Forms.

Private health insurance entities are also victims of health care fraud offenses. Many private insurers have sophisticated fraud detection systems in place and have anti-fraud units which specialize in fraud prevention and detection. Federal enforcement agencies should utilize the fruits of those investments to the maximum extent possible.

Accordingly, the enforcement agencies will continue to do "outreach" to the public and to program beneficiaries about health care fraud. The agencies will also ~~continue to maintain a good working relationship with private insurers, to~~ encourage private insurers to share information about fraud with each other and with the enforcement agencies.

J. A Legislative Agenda Will Be Formulated and Implemented.

Many legislative proposals have been drafted concerning improvements to the health care fraud statutes/remedies. In addition, the Health Security Act, which was introduced to the Congress on November 20, 1993 has a fraud and abuse component.

The enforcement agencies will analyze these proposals and formulate a legislative proposal containing the statutory improvements which are essential to the success of the health care enforcement effort.

K. The National Level Health Care Fraud Working Group Will Continue to Operate.

The National Level Health Care Fraud Working Group was formed

include USAOs, CRM DIV, etc

in 1991 for the purpose of coordinating the health care fraud enforcement effort among the executive branches. The Group is chaired by the Department of Justice and its membership includes every federal agency which has a role in health care fraud enforcement. The Group has played a vital role in fostering positive working relationships among agencies, providing a forum for the exchange of information about health care fraud, and identifying obstacles to effective enforcement. For these reasons the Group will continue to function and will assist the Executive Level Health Care Fraud Policy Group by providing valuable information to the Executive Level Group.

L. Health Care Fraud Training will be Provided.

Although health care fraud is similar to other forms of white collar crime in many respects, health care fraud enforcement also requires some specialized knowledge and the application of special techniques. The enforcement agencies will devise a health care fraud training program which takes into account these special factors, and which will train agents and prosecutors concerning the key elements of the federal health care fraud enforcement strategy, and concerning the model for local health care fraud working groups.

M. Preparation for Health Care Reform.

The reformed health care system will present new challenges in terms of health care fraud detection, prevention, and enforcement. As the federal health care fraud enforcement strategy is implemented, the enforcement agencies will simultaneously be preparing to meet those challenges.

The Executive Level Health Care Fraud Policy Group will develop a plan for the formation and staffing of the All Payer Health Care Fraud Enforcement Program, as proposed in the Health Security Act.

DATE: November 26, 1993

ROUTING AND TRANSMITTAL SLIP		
TO: (Name, Office, Room, Building)	INITIALS	DATE
1. Gerald Stern, Acting Special Counsel Rm. 4119 - Main		
2.		
3.		
4.		

	Action Approval As Requested Circulate Comment Coordination		File For Clearance For Correction For Your Info Investigate Justify		Note and Return Per Conversation Prepare Reply See Me See Remarks Signature

Here is draft memo per your request. E-mail is down today.

cc: Merrick Garland
Gerald McDowell

FROM:	
Karen A. Morrissette Deputy Chief Fraud Section	ROOM NO. 4100 BOND BLDG. TELEPHONE NO. 514-7023

draft 11/26/93

MEMORANDUM

TO: ALL UNITED STATES ATTORNEYS

FROM: Philip B. Heymann
Deputy Attorney General

Webster L. Hubbell
Associate Attorney General

SUBJECT: Health Care Fraud Enforcement

The purpose of this memorandum is to reaffirm the status of health care fraud enforcement as one of the Department's top white collar crime priorities and to encourage you to develop innovative strategies for identifying health care crime problems in your districts and for investigating them in the most efficient manner.

A number of districts already have local health care fraud task forces which meet on a regular basis to exchange information about health care fraud offenses and to pool resources on particular investigations/cases. One of the hallmarks of success of these task forces is their ability bring together agents and other personnel from all of the federal enforcement agencies, the criminal and civil sides of the United States Attorney's office, and representatives from the federal health care program agencies (and the Medicare carriers/intermediaries), and to establish a liaison with the private insurance industry, and state/local law enforcement. When all of these entities join forces with a common goal, and work together to apply the various remedies at our disposal in the most cost effective manner, the overall interests of justice and of the United States are well-served.

Accordingly, we urge you to discuss with other federal enforcement officials in your district the best way to obtain and analyze information about health care fraud in your district and to devise a methodology for attacking it. As a result of these efforts, the Department will be well prepared to meet the enforcement challenges which will be presented by health care reform.

Office of the Attorney General
Washington, D. C. 20530

September 29, 1993

MEMORANDUM TO THE DEPUTY ATTORNEY GENERAL

From: Gerald Stern
Special Assistant to the Attorney General

Subject: Meeting with HHS IG Designate June Brown, Thursday, September 30, at 2:00PM in Room 4111

Attendees from HHS:

1. June Brown, IG Designate
2. Brian Mitchell, Principal Deputy IG
3. Larry Morey, Deputy IG for Investigations
4. Lewis Morris, Deputy Associate General Counsel, IG Division

Attendees from DOJ:

1. Philip Heymann
2. Jerry Stern
3. Nancy McFadden
4. Larry Urgenson
5. Merrick Garland
6. Karen Morrissette

I would also like to invite, with your permission, Stuart Schiffer, Deputy Assistant Attorney General for the Civil Division and Mike Hertz, Director of the Commercial Litigation Branch of the Civil Division.

Goals for the meeting:

1. To confirm that the Department of Justice is the lead on health care fraud law enforcement matters, working with HHS and others pursuant to the model created by the National Health Laboratories case and the LABSCAM investigation;

2. To coordinate DOJ and HHS efforts on the drafting of the Health Care Fraud provisions of the Health Care bill so there is no inconsistency with, and maybe even a reiteration of, the fact that the Department of

Justice is the lead on health care fraud law enforcement;

3. To get IG HHS investigative support in ongoing qui tam civil cases which may end up in combined criminal-civil proceedings.

4. To begin a dialogue with HHS on new ways to force immediate compliance with health care laws - for example, can HHS require the labs under investigation in LABSCAM to file a written certification, co-signed by their outside accountants, that they have not engaged, and are not engaging, in the practices found to be unlawful in the National Health Laboratories case, with debarment if they do not file such certifications within 10 days?

Talking points:

1. I think we should congratulate the IG HHS for their investigative work in the civil qui tam proceeding which began the National Health Laboratories case and which ended in a combination of criminal pleas by the Corporation and its president, a criminal fine of $1 million paid by the corporation, a $500,000 criminal forfeiture by the president, a $100 million federal civil settlement for unnecessary tests billed to Medicare and Champus, a $10 million reimbursement of state Medicaid agencies, and administrative sanctions.

2. I think we should agree with the HHS Report Prepared by Multi-agency Task Force (dated September 24, 1993) that refers to "the recent prosecution of National Health Laboratories as a model for similar investigations." The lessons HHS says it learned from that case were: federal and state agencies must work together, we need proactive and parallel civil and criminal investigations, and these are document-intensive investigations.

3. We should also agree with the HHS Report's proposal "that a recently created multi-agency effort, the LABSCAM task force, receive the necessary OIG support to pursue clinical laboratory fraud" and ask what OIG HHS has decided to do.

4. I think we should then emphasize the need for continuing IG HHS investigative support in health lab civil qui tam cases, as well as LABSCAM and other direct criminal cases (HHS' Larry Morey wrote a letter to the Civil Division on September 8, 1993, saying that IG HHS "will be putting the qui tam cases on national laboratories on hold until criminal investigations are resolved.")

5. We should ask HHS if there is any way to use their threat of debarment to more quickly obtain a civil resolution of the investigations of the national laboratories.

6. Finally, we should emphasize that the Attorney General should have the lead in law enforcement, working through interagency health care task forces like LABSCAM until the Health Care bill is passed - and that the bill should not deviate from the successful model set by the National Health Laboratories case and the now ongoing LABSCAM matter.

cc: Larry Urgenson
Merrick Garland
Karen Morrissette

Date: Tuesday, October 5, 1993 4:10 pm
From: CRM02(MORRISSE)
Subject: health care policy/press

1. I had a conference call with Public affairs (Julie), CIvil, and HHS re. the planned October 13 event. We discussed location, participants, and content. I suggested that the Director of the FBI be invited to attend, and also IG of DOD. New IG at HHS has been voted on and may be confirmed by then. If so, she will attend. All agreed that someone from NAAG should be invited because state enforcement has a big role as well. Speakers will be AG, Secretary of HHS, and President. I pushed for event to be held here or at White House on the ground that there have been and will be many opportunities for Secretary to be in spotlight on reform, but this is the one aspect that is truly within the realm of the AG. HHS also suggested that the Natl Health Care Anti Fraud Association be invited to attend. I strongly disagreed; the insurers/plans will be the targets of investigations. Also, we have had the issue with AUSA's resigning from the Association's Board due to possible ethical issue. We don't need to invite discussion of that issue with press. Final decisions on location, participants etc. will be made in consultation with White House COmmunications. (more)
2. Re. substance of the Oct 13 announcement: Content of statements will be finally determined after policy issues are resolved. On that score, I communicated to the Counsel to the HHS IG the DOJ view on key issues in draft legislation (per Jerry's guidance). The main issue is lead role of AG in coordinating civil and criminal health care enforcement. A related issue is control of spending of the trust fund. Counsel immediately recognized this as a very large issue and will talk to IG and get back to me. I see this heading in the direction of a meeting with Greg Lawler and Sara Rosenbaum at the White House (Health Care REform Task Force). When it gets to that point, I will advise you. KAM

Date: Wednesday, September 29, 1993 4:27 pm
From: CRM02(MORRISSE)
Subject: misc re. press/health

1. Per OMB/Nat'l performance review, EOUSA has been tasked to draft legislation for civil fraud enforcement units in USA's offices. Some proceeds from enforcement would be used for enforcement expenses, not salaries. Legislation will be widely circulated for comments, but I told OLA to add Gerald Stern's name for approval.
2. AG is going to San Francisco and San Diego next week. She is scheduled to attend Yamagucci press conference announcing 4 staged accident cases and first meeting of his health care task force. AG's office (Roxie) and Julie Anbender understand that staged accidents are not exactly health care. AG will not be doing a "reform" announcement out there. She will just reiterate our commitment to health care enforcement. I received large package from LA USA re. their health care efforts and forwarded it to Julie Anbender. I told Roxie and Julie that San Francisco legal press (copy of article being sent to me) has a copy of the Clinton plan and circulated the enforcement related section to the private bar and an AUSA for comment. Press then reported that new enforcement effort will make no difference because DOJ will not put resources behind it (?)
3. AG, President, and Secty Shalala will announce health care enforcemen/reform here in DC on Oct 13. Bob Borsten at White House says that some "policy changes" have been made in the legislation draft (?). Julie Anbender told me this. I don't really understand it, unless Borsten has gotten signal from DOJ that we have some fundamental problems with the draft legislation. KAM

The New York Times

DATE: 10/16/9
PAGE: A1

Manufacturer Admits Selling Untested Devices for Heart

By PHILIP J. HILTS
Special to The New York Times

WASHINGTON, Oct. 15 — One of the world's largest medical device manufacturers has agreed to plead guilty to more than 390 counts of fraud and human experimentation for selling untested heart catheters, Food and Drug Administration officials said today. The sales resulted in at least one death and 22 emergency heart surgeries.

The settlement, under which the company, C. R. Bard Inc., is to pay $61 million, is the largest health fraud case ever handled by the F.D.A. and the Justice Department.

Six executives were indicted separately and have not yet entered a plea. The United States Attorney in Boston, A. John Pappalardo, said today that a grand jury in Federal District Court had returned a 395-count indictment against the chairman and chief executive, George T. Maloney, and five former officials of Bard, which is based in Murray Hill, N.J., and its U.S.C.I. division in two Boston suburbs, Billerica and Haverhill.

The maximum penalty on the charges is 5 to 20 years in prison and a $250,000 fine on each count. Each defendant faces 200 to 300 counts.

The F.D.A. Commissioner, David A. Kessler, said in Washington that the company's board of directors agreed Thursday night to plead guilty on behalf of the corporation to illegal experimentation on humans, lying to the Government about the experimentation, selling devices without F.D.A. approval and lying to the Government about the failure of the devices.

The $61 million settlement will be divided in half, with one portion covering criminal fines and the other covering civil damages to the Government for violations of the Food Drug and Cosmetic Act and other laws.

'Patients as Guinea Pigs'

The amount was estimated to be about equal to the gross sales of all the eight models of defective devices manufactured by the company.

Bard has also agreed to an array of remedial measures. It will be monitored for four years by an outside consultant who will report its progress to the Food and Drug Administration.

Dr. Kessler said in a statement today, "For a company to engage in a pattern of using unsuspecting patients as guinea pigs and operating rooms as laboratories for unapproved products shows a blatant disregard for the health and safety of the patients who literally entrusted their lives to the company's products."

Beginning in 1980, the company manufactured about 20,000 experimental devices, almost all of which were eventually used in people. Catheters have become an increasingly popular tool for treating heart disease in which the arteries leading to the heart are blocked, a condition that can lead to a heart attack.

The catheter is essentially a four-foot-long tube that is inserted in a vein in the arm or groin and pushed up into the arteries of the heart. The advantage of heart catheters is that the chest does not need to be opened up, but when the tip of a catheter breaks off, it may be necessary to perform an emergency operation in which the chest is opened so that the tip can be removed or so that doctors can attach other arteries to one another to open a detour around the blockage.

One heart catheter in question was a wire with a balloon at the tip, which was designed to be inserted temporarily. The tip is then inflated, to press down the accumulation of plaque that blocks the arteries nourishing the heart muscle. Another catheter had rotary blades at the end, which cut out the plaque instead of compressing it.

F.D.A. officials said that in at least 50 cases, 22 of which required emergency surgery, the tip of the balloon catheter broke off inside the heart, and emergency surgery was required to retrieve it and bypass the injured artery. In other cases, the balloon failed to deflate. The one death reported so far occurred after a balloon failed to deflate. The agency says some broken catheter tips may remain in some patients.

Animals studies of the rotary blade catheter found that the blade cut into artery walls of animals in tests 50 percent of the time. The company concealed this information from the F.D.A., the agency alleged.

According to the grand jury indictment, the Bard company was the only company selling heart catheters in the United States between 1980, when they were first made, and 1985. That year, other companies began to offer catheters with new features, and by 1988 Bard's share of the market had been cut to less than 50 percent.

Bard responded by redesigning its catheters and offering several new designs under different names. The indictment charged that the company concealed the changes in design when sending documents to the F.D.A. Instead, it charged, Bard made changes, waited to see the effect in humans, then made additional changes without telling the Government when the devices began to fail.

The company concealed design changes from the agency and from doctors, concealed that they were testing the devices in humans and concealed the poor results they had got with some of them in animal tests, according to the indictments.

When the catheter tips began breaking off during surgery, the company also concealed that from regulators, the indictments said. When the tips broke off, they often blocked the arteries they were trying to clear, necessitating the emergency surgery.

Bard began selling the experimental devices in 1987, and they almost immediately began failing. The F.D.A. began an investigation and began to recall the different models of catheters in July 1989, finishing the recall of all defective models by 1990. The agency then pursued the criminal investigation that resulted in the indictments this week.

Company Expresses Regrets

Bard said today that the chief executive, Mr. Maloney, would leave the company to help prepare his defense. The Board of Directors delegated his duties to William H. Longfield, who is president and chief operating officer.

William G. Reilly Jr., a spokesman for Bard, released a statement saying: "The management of C. R. Bard Inc. sincerely regrets the activities that led to this plea agreement."

He added, "All Bard products on the market today can be used with confidence."

Trading in the company's stock was temporarily halted this morning. When the market closed there was little change, with the price of Bard stock dropping 12.5 cents, from $25¼ to $25.

The company still sells heart catheters that the F.D.A. says are safe, but Bard's market share in the devices has

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dropped to less than 20 percent, analysts estimate. With sales of other medical devices like urinary catheters, Bard is one of the world's larger medical device companies, with about $1 billion dollars in revenues.

Bard Already Damaged

Kenneth S. Abramowitz of Sanford C. Bernstein analysts in New York said today that most of the damage to the company from the problem had already occurred. "The company has paid for this problem through loss of market, and that loss is much larger than the fines from the government," he said.

He said that the story of the failed catheter had become well-known among customers, so that not much more erosion of trust in the company is expected. "The company can look ahead now," he said.

Those indicted besides Mr. Maloney are David Prigmore, a group executive vice president at Bard until 1990; John Cvinar, president of U.S.C.I. Division of Bard until late 1989; Lee Leichter, director of quality control for U.S.C.I.; Kenneth Thurston, director of regulatory affairs for U.S.C.I., and Janice Piasecki, a supervisor of the regulatory affairs division.

Mr. Prigmore, who left Bard in 1990 and became president and chief executive of Vision Sciences Inc., resigned from that company today. "The individuals are surrendering as we speak and they will be arraigned on criminal charges," said Mr. Pappalardo, the United States Attorney.

The Washington Post

DATE: 10/16/93
PAGE: A1

Firm Fined for Selling Faulty Surgical Devices

By John Schwartz
Washington Post Staff Writer

One of the world's largest health care products companies has pleaded guilty to violating federal statutes governing the safety of medical devices and agreed to pay a record $61 million fine, federal officials said yesterday.

C.R. Bard Inc. of Murray Hill, N.J., deliberately sold faulty surgical devices and used unsuspecting heart patients as "guinea pigs" to test new products, federal health and justice officials said. According to federal grand jury indictments handed up late Thursday and announced yesterday in Boston, the products failed in about 50 operations, causing one heart attack and one death.

In one of the biggest health care fraud investigations in the history of the Food and Drug Administration and the Department of Justice, Bard agreed to plead guilty to 391 counts of conspiracy, mail fraud, lying to regulators and shipping "adulterated products" that were not approved by the FDA. The $61 million in criminal fines and federal civil claims is several times larger than any in the history of FDA enforcement cases.

The charges concern angioplasty catheters manufactured by Bard's Massachusetts-based USCI division. The devices use tiny balloons that are inflated to push open clogged arteries and then deflated before removal.

In the plea bargain, the company admitted that from 1987 to early 1990, it violated the Federal Food, Drug and Cosmetics Act and other statutes by distributing catheters that had not been properly tested or approved, and by routinely making changes in the materials and design without notifying the FDA, as required by law. The company admitted it did not tell doctors, their patients or the FDA about problems they encountered with the products.

The company covered up problems, including arterial damage and a tendency of the tips of some devices to fall off. The defects created a risk of heart attack and in 22 cases required emergency bypass surgery—the very procedure angioplasty is usually intended to avoid.

William G. Reilly Jr., a spokesman for Bard, said "The management of C.R. Bard Inc. sincerely regrets the activities that led to this plea agreement. . . . Bard and USCI products, including all angioplasty products, have received all necessary FDA approvals. All Bard products on the market today can be used with confidence." The company earned $75 million in 1992 on sales of $990 million.

As part of the plea bargain, the company has agreed to a series of stringent remedial measures, including scrutiny by an outside consultant who will report to the FDA. The company said it "reorganized and restructured its management team" in 1990, and withdrew all products deemed out of compliance.

U.S. Attorney A. John Pappalardo, who investigated the case with the FDA, said yesterday in Boston that "this extraordinary settlement with Bard is a reflection of both of the severity of the criminal conduct of [USCI] . . . and Bard's desire to assure that this unfortunate episode in its past is never repeated."

The Boston grand jury also handed up a 393-count indictment charging George T. Maloney, chief executive officer of Bard, and five other former officers of the company with violating federal laws. If convicted, the defendants face sentences totaling more than 1,000 years in prison and millions of dollars in fines. Maloney has left Bard "to help prepare his defense," the company said yesterday.

Balloon angioplasty is one of the medical success stories of the 1980s, allowing obstructed arteries to be treated without opening the chest. Making only a small incision in the groin area, a doctor snakes a catheter through a large blood vessel in the leg to the blocked artery. The balloon is then inflated, flattening the obstructing material on the artery walls and opening the passageway.

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Between 1980 and 1990, the number of angioplasties increased ninefold, according to a report in the Journal of the American Medical Association. In 1991, doctors performed nearly 300,000 of the procedures, according to the National Heart Lung and Blood Institute.

Bard rode the angioplasty wave. From 1980 until 1985, it was the only U.S. company with FDA permission to market heart catheters. By the mid-1980s, however, other companies had jumped in; by 1988, Bard's share of the burgeoning market dropped to 50 percent.

The federal indictment alleges that from roughly 1987 to 1990, Bard began to "improve" its product—but without following the FDA's complicated procedures that are intended to ensure safety and effectiveness. The indictment alleges that by around 1988, the company had received at least 62 complaints that its balloons weren't deflating or were wrapping themselves around the catheter. The company changed the design, creating the "B Probe," and distributed about 30 of the new devices to hospitals and clinics around the country for evaluation, again without notifying the FDA. Meanwhile, the company had applied for FDA approval for the B Probe.

By December of 1988, complaints began to come in about the B Probe's tips breaking off, but the company again did not tell federal officials, the indictments said. In January 1989, the FDA approved the B Probe for human use. By May 1989, tips had broken off in about 50 procedures. By September of 1989, Bard had sold approximately 18,000 of the B probe and newer devices.

The indictments also state that company officials hid the existence of an entire plant from the FDA, packaging and distributing catheters from a Haverhill, Mass., plant that had not been inspected or approved by the agency. The company told federal officials the devices were coming from an approved plant in Billerica, Mass., and labeled

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them accordingly, according to the indictment.

FDA Commissioner David A. Kessler said yesterday "for a company to engage in a pattern of using unsuspecting patients as guinea pigs and operating rooms as laboratories for unapproved products shows a blatant disregard for the health and safety of the patients who literally entrusted their lives to the company's products."

THE WHITE HOUSE

WASHINGTON

October 19, 1993

'93 OCT 19 P2:11

CONFIDENTIAL

DETERMINED TO BE AN ADMINISTRATIVE MARKING E.O. 12356, Section 1.1 BY RJP DOJ/Exec. Sec. DATE 10-19-93

MEMORANDUM TO NANCY MCFADDEN

FROM: Dana Hyde, Jennifer O'Connor

SUBJECT: Health Care Survey of your Department

We may be introducing the health care legislation early next week and beginning a second phase of our public awareness campaign on health care.

Over the course of the next two weeks we hope to meet with you and develop a health care strategy tailored to your Department. In advance of these meetings, we are conducting a survey of agency/department resources devoted to health care. By Friday, we need the following information:

Staff Resources

A list of staff working full-time or part-time on health care issues and their roles within your agency.

Internal Education

A list of the methods you have already undertaken or could potentially use to educate your own employees about health care reform.

Consumers

A list of the groups of consumers your Department communicates with regularly – e.g., business groups, seniors, etc.

The mechanisms through which you communicate with these consumers -- e.g. answer hotlines, information in field offices, newsletters, individual correspondence, etc.

Issues

A list of the issues most often raised to your Department -- through correspondence and phone calls -- related to health care.

Ongoing Efforts on Health Care Reform

A list of the current efforts your Department is making on health care reform -- e.g. developing special materials, creating special events, etc.

Materials

A list of materials your Department has already put out on health care reform. Please send copies of all significant materials.

Schedule

Please provide an updated schedule of all health care events your Secretary plans to participate in between now and the end of the year.

Testimony

Please provide us with an advance, pre-OMB approved copy of any Capitol Hill testimony relating to health care presented by anyone in your agency.

This information is vital to developing a comprehensive long-term strategy for the President's health care initiative. We appreciate all the effort you have expended thus far on behalf of health care. The Cabinet's active involvement has been and will continue to be the key to our success.

cc: Maggie Williams
Jeff Eller
Bob Boorstin
Charlotte Hayes