Click on this Link, Buy Two Aspirins, and Call Me in the Morning: A Critique of Online Medicine Financial Arrangements

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“[S]cience and snake oil may not always look all that different on the Net.”

When C. Everett Koop announced in 1989 that he would resign as U.S. Surgeon General, Louis W. Sullivan, then the secretary of Health and Human Services, described him as “a voice of honesty, integrity, compassion and plain good sense.” His colleagues reported that Dr. Koop intended to engage in scholarly pursuits, which would include giving talks and writing books. Instead, Dr. Koop appears to have focused his efforts on conquering the new medical frontier in cyberspace. In 1998, Dr. Koop became chairman and a shareholder in drkoop.com. The company’s prospectus announced a goal to “establish the DrKoop.com brand so that consumers associate the trustworthiness and credibility of Dr. C. Everett Koop with our

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1 Sheryl Gay Stolberg, Need a Doctor in a Hurry? How About MD.com?, N.Y. TIMES, July 4, 1999, as reproduced at www.cyberdocs.com (Quoting Dr. George D. Lundberg when he was the editor of the Journal of the American Medical Association).


3 Id.
company.” The site became Internet’s most successful medical site.⁴

Drkoop.com offers 80,000 electronic pages⁵ which reproduce recent health care news headlines and offer information on a variety of medical conditions including asthma, HIV/AIDS, cancer, depression, heart disease, and mental health. The site also offers weekly “word from Dr. Koop,” in which he proffers advice on conditions from flatulence to migraines.⁶

And conquer cyberspace Dr. Koop has. In February 1999, less than a year after it went online, the site witnessed over 400,000 visitors. In May 1999, the site received over two million hits. And in August 1999 the site witnessed nearly three and a half million hits. By contrast, aolhealth.com, the second most visited site, received a 1.5 million hits in May 1999, less than half of drkoop.com’s traffic. Other cyberspace health leaders also operate in drkoop.com’s shadow: onhealth.com received 1.4 million hits in May and webmd.com received 1.2 million.⁷

Koop has emphasized that he did not enter cyberspace for financial gain:

I didn't go into DrKoop.com to make money. I did it to change the way that medicine is practiced, to bring important information to patients faster and get them more involved in decisions about their health.⁸ But, cyberspace has proved profitable for Dr. Koop. As chairman of the site, Dr. Koop receives an annual salary of $135,000. And his stock holding in the site was worth more than

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⁴ AMA News, Oct. 4, 1999 (indicating that drkoop.com attracts over twice the Internet traffic as its nearest competitor).


⁸ E-MEDICINE, supra note 5.
$47 million in September of 1999.⁹

A number of ingredients in drkoop.com’s financial stew, and thus, Dr. Koop’s compensations, have drawn criticism. For example, like most websites, drkoop.com features advertising. Drkoop.com runs ads for cyberpharmacies, insurance companies, weight loss products, Internet servers, vitamins, and a “lifestyle” website devoted to improving one’s “mental health.”¹⁰ Drkoop.com’s prospectus for its initial public offering disclosed that in return for the advertising, Koop would receive 2 % of revenues “derived from sales of our current products and up to 4 % of our revenues derived from sales of new products.”¹¹ The site did not disclose the commission arrangement to consumers.

Drkoop.com also features a “Community Partners Program” which consists of a list of hospitals and health centers which the site describes as “the most innovative and advanced health care institutions across the country.” And what criteria does drkoop.com employ in selecting these health care leaders? Any provider which pays a $40,000 fee is listed. The site originally did not inform visiting consumers of the fee.¹²

The site also seeks to match visiting consumers to clinical trials which address the consumer’s ailments. The site originally referred consumers to Quintiles Transnational Corporation, a newly-formed company which manages clinical trials for pharmaceutical

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⁹ Id. The value of Dr. Koop’s holdings, like the value of many dot-coms, has since dropped dramatically. See infra text & notes - .


¹¹ E-MEDICINE, supra note 5.

¹² Id.
companies. Quintiles declared itself on drkoop.com to be “the world's leading clinical organization.” 13 Drkoop.com failed, however, to reveal that it would receive 2% of any fees which Quintiles received for study subjects it would enroll through the site. 14

When faced with inquiries from ethicists and reporters, the website quickly renounced the commissions on advertised products and services and on clinical trial referrals. In addition, the site downgraded the description of the “community partners” from “the most innovative and advanced” to “prominent” health care institutions and noted that the institutions had paid a fee to be listed. 15

Loss of those revenues may have played a roll in drkoop.com’s financial demise. In April of this year, the accounting firm PricewaterhouseCoopers announced that drkoop.com had “sustained losses and negative cash flow from operations since its inception” and questioned its ability to continue as a going entity.” 16

In addition to these financial losses, Dr. Koop may have suffered a loss to his reputation. Critics have assailed Dr. Koop for compromising his ethics when he entered into these financial arrangements. And, they questioned whether he would lose credibility with the public. 17 Dr.

13 Id.

14 Id.

15 Id.

16 E-HEALTH: FINANCIAL FUTURE GRIM FOR DRKOOP.COM, AMERICAN HEALTH LINE, April 3, 2000. Drkoop.com also undertook greater expenses than other online health sites. See, eg., Karen Kaplan, The Cutting Edge: Focus on Technology; Pay-Per-Click concept Gets Goto.com Farther; Internet: Web-Search Firm Seizes Revenue Opportunities Every Time Users Leave Its Site to Link to Another, L.A. TIMES, April 3, 2000, C1.

17 See E-MEDICINE, supra note 5.
Koop, who in 1991 described himself as “America’s family doctor,” however, has expressed no doubt that his reputation will enable him to emerge from the controversy unscathed: “I have never been bought. I cannot be bought. I am an icon, and I have a reputation for honesty and integrity.”

This article examines the ethical consequences of the economic relationships which the Internet has facilitated in medicine. Part I provides a background to online medicine by describing the Internet medical sites and the consumer traffic which the sites attract. Part II analyzes the economic relationships which the Internet has fostered. Part III assesses the ethical consequences of these relationships and proposes a regulatory solution.

I. Online Medicine: the Cyberspace Landscape

A. The Traffic

A marketing research firm recently estimated that 43% of all Internet surfers access health care information online each year. Last year, more than 22 million people visited online health sites. And that figure is growing by 70% each year.

A significant amount of that traffic has produced online pharmacy sales. Industry analysts recently estimated that the Internet pharmacy market accounted for between 1% to 2% of the total pharmacy market in 1999. By 2001, annual sales will total between $1.4 billion to $2.8

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18 Id.


20 Drug Topics, November 15, 1999.
billion.\textsuperscript{21} And by 2005, annual sales will reach $6 billion.\textsuperscript{22}

\textbf{B. The Sites}

1. On-Line Pharmacies

In January 1999, the Internet hosted fewer than 30 online pharmacies. By July 30, 1999, more than 400 had appeared. 183 of those sites were devoted exclusively to prescribing and selling Viagra.\textsuperscript{23}

As of July, 1999, only 30 of the more than 400 online pharmacies were licensed. And one fifth of the sites investigators were able to ferret out were located outside the United States.\textsuperscript{24}

The sites which the National Association of Boards of Pharmacy believes to be legal “offer prescription medications in states where licensed or allowed by law, and when an original written prescription is provided or a verbal order, faxed prescription, or approved electronic prescription is obtained directly from the legally authorized prescriber with a valid patient prescriber-relationship.”\textsuperscript{25}

Illegal sites offer prescriptions based on answers to online questionnaires. The sites

\begin{flushright}
\textsuperscript{21} \textit{Id.}

\textsuperscript{22} \textbf{The NewsHour with Jim Lehrer, November 17,1999}

\textsuperscript{23} Carmen Catizone, R.Ph., Exec. Dir., National Association of Boards of Pharmacy, testifying on July 30, 1999 before House Commerce Committee’s Subcommittee on Oversight and Investigations (noting that 30 of 150 located sites were outside the U.S.).

\textsuperscript{24} \textit{Id.}

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represent that a physician reviews the questionnaires before prescribing, but investigators have discovered some merely “pirate” the names of physicians who are not involved with the site.

2. Professional Sites

The Internet is host to a variety of professional medical sites. These sites, such as the AMA’s ama-assn.org, the American Psychological Association’s apa.org, and the American Psychiatric Association’s psych.org, offer information on professional standards, professional organizations, and publications.

With the notable exception of linking to their own publishing arms, the professional sites rarely provide links to sites which attempt to sell products to consumers.

3. General Consumer Sites

General consumer sites, however, do link to sites which attempt to sell products and services to consumers. Indeed, as a financial analyst recently observed, sites such as drkoop.com, healthcentral.com, webmd.com, aolhealth.com, onhealth.com,

26 Id.
29 www.psych.org.
healtheon.com, and discoveryhealth.com premise their financial futures on just such links:

It’s far better … to draw 10,000 smokers who want information about how to give up their addiction and tie that information to a patch from an advertiser than it is for them to attract ‘100,000 users who don’t have any chronic diseases coming in from a sports Web site.’

In apparent recognition of the financial benefits of advertising links, the AMA recently joined with the American Academy of Ophthalmology, the American Academy of Pediatrics, the American College of Allergy, Asthma, and Immunology, the American College of Obstetrics and Gynecology, the American Psychiatric Association, and the American Society of Plastic Surgeons to form medem.com. Although still in its formative stage, medem.com promises soon to offer consumers “medical shopping”:

Consumers/patients will be provided the opportunity to easily access and purchase various medical and pharmaceutical products, including books and educational materials created by participating medical societies and other products made available through various partnerships established with e-commerce vendors.

4. Condition-Specific Sites

The Internet also offers a number of websites devoted to specific health conditions. Epotec.com, for example, represents that it “taps the speed and efficiency of the Internet, building


39 Id., as visited on April 13, 2000.
a powerful, cost-effective way of providing behavioral health services.”

The offered services include “private coaching from licensed professionals” which will enable patients to “[g]et information quickly and easily,” will be “[p]rivate and completely anonymous,” will feature “no cost [if sponsored by an employer], no hassle, no waiting” service, and will be “[a]vailable 24-hours a day, 7 days a week.”

Other sites offer sex-response enhancement. Menshealthonline, for example, offers to “Order your Sustain® Libido formula for men now, with this online order form. We will process your orders as quickly as possible. Please provide the following information as completely and accurately as possible.” The “patient” need only fill in his address and supply a credit card number.

Of course, Viagra has been most controversial on the Internet. Sites such as medicalcenter.net offer “an online consultation for a Viagra prescription.” The site promises that “[y]our medical history and patient profile will be reviewed by a Licensed Physician. If approved for a Viagra prescription, we will have your Viagra shipped to you.”

II. The Money

The Internet has facilitated consumer access to health information and health products. That access has also enabled sellers to track consumer behaviors, produced new transaction forms, and introduced new opportunities for health-related financial investment. The result is a

40 www.epotec.com, as visited on April 13, 2000.

41 Id.


43 www.medicalcenter.net, as visited April 13, 2000.
whole new financial vocabulary for the health care community.

A. Referral Fees, Commissions, Affiliate Fees, and Other Kickbacks

Drkoop.com has not been alone in its attempt to capture referral fees for linking visiting consumers to purveyors of health products. Indeed, nearly every Internet website benefits from some form of referral fee or commission arrangement with other sites.

A number of the Viagra sites feature “affiliate fees.” Any site which sends purchasers to the Viagra site receives a referral fee ranging from 2% to 7%. The referrer, too, may offer compensation to upstream “linkers.” The result is a complex financial network.

Sites may also pay for the privilege of being linked. For example, the search site goto.com\(^{44}\) consists of a series of links grouped by topic. Those paying fees get listed above non-paying sites and those paying the highest fees get listed first. For a fee of $1.01 per link, drkoop.com was ranked first in the medical information category. HealthAllies.com,\(^{45}\) a site which promises to link consumers with low-cost health products and services, paid $1 per link to be ranked second. The American Heart Association, however, did not pay any fee and, as a consequence, was listed forty sixth.\(^{46}\)

B. Professional fees

Physicians and other health care professionals who dispense advice on the Internet often charge for their services. And the fees can prove to be lucrative. One site’s Viagra sales provide

\(^{44}\) www.goto.com.

\(^{45}\) www.healthallies.com.

\(^{46}\) Karen Kaplan, The Cutting Edge: Focus on Technology; Pay-Per-Click concept Gets Goto.com Farther; Internet: Web-Search Firm Seizes Revenue Opportunities Every Time Users Leave Its Site to Link to Another, L.A. TIMES, April 3, 2000, C1.
an illustration.

Approximately two years ago, directresponsemarketing.co (DRM) & Spar Pharmacy, both located in Jersey, England, began a joint venture in prescribing and selling Viagra. DRM runs an Internet site which writes prescriptions, which Star fills. In their first eighteen months of operation, the tandem generated $2.5 million in online sales, most of which was Viagra. In May 1999, for example, Star dispensed 3,698 Viagra pills. Twenty four of them went to Jersey residents.

Legitimate “brick and mortar” pharmacies typically charge $10 or less per Viagra pill. DRM has charged $20 per pill. Consumers are apparently willing to pay a premium for the confidentiality which the Internet provides.

DRM has arranged a split of the Viagra profits. DRM, the website, retains one third. The participating pharmacy and website designer share another third. The prescribing physician takes the remaining third. The physician’s take in the first full year of operation? $200,000.

C. Public Offerings


48 Id.

49 www.directmarketingresponse.com. DRM founder Tom O’Brien has stated that he “thought [he’d] be shut down by Pfizer” almost immediately. In preparation for a short business life, O’Brien only entered into a short-term lease and rented rather than purchased the computer equipment essential to conducting an online business. WALL ST. J., Nov. 29, 1999, p. 1. To date, O’Brien and his online counterparts have been pleasantly surprised. While continuing to press the FTC to shut down what Pfizer has characterized as illegal business enterprises, Pfizer has continued to supply them. Id. In March 2000, the FTC initiated an investigation into DRM’s activities. Alex Hannaford, No Prescription Needed on the Internet, EVENING STANDARD, March 14, 2000, 59.

50 Id.
Active participants are not the only individuals to profit from online medicine. At least until the recent grey days for technology stocks, as evidenced by NASDAQ’s precipitous fall, investors flocked to health sites. In November of 1999, for example, the Florida-based Nutriceuticals.com corporation, which offers a line of vitamins and other health products, sold 1.2 million shares at an initial offering price of $10 a share. As its president observed, “In Internet time, when you're dealing with Internet space, you've got to rush to capture as much of the market as you can.”

Similarly, Healthcentral.com, a general health information site, announced last fall a plan to raise $86.3 million in public offering. The company’s appeal derives from its lead public persona, Dr. Dean Edell. Edell hosts radio’s second most popular syndicated radio talk show. Edell owns 19.1% of healthcentral.com’s stock.

Recent news, however, has not been good for e-health care companies. The investment firm Goldman Sachs, for example, documented a 46% downturn in dot-com value from March through July 2000. Moreover, in July 2000, analysts estimated that sixty dot-coms had less than 12 months cash on hand.

Drkoop.com has not been immune from the dot-com woes. In April of this year, the

51 TAMPA TRIBUNE, 11-23-99


54 K.K. Campbell, Dot-Com Pendulum Swings Toward Gloom, TORONTO STAR, July 6, 2000
accounting firm PriceWaterhouseCoopers announced that drkoop.com had “sustained losses and negative cash flow from operations since its inception” and questioned its ability to continue as a going entity. 

In July, the site topped USA Today’s “worst of the Internet” list with an 84.5% loss since Dec. 31, 1999 and it reached number four on the Toronto Star’s “Internet Death Watch.”

More recently, drkoop.com has attempted a revitalization by trimming staff and luring new investors. Nonetheless, analysts remain convinced that the company’s “prognosis is bleak.”

That bleak future has spurred unrest among the investors which drkoop.com originally lured to fund its operations. Shareholders have charged that Dr. Koop, who remains chairman and a member of the board of directors, and other executives withheld from investors a negative auditor’s report until they sold their own shares.

The allegations stem from a February 1999 PriceWaterhouseCoopers report. Two weeks

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56 Matt Krantz, The Party’s Over, USA TODAY, July 5, 2000, 3B.

57 TORONTO STAR, July 6, 2000.

58 Andrew Park, Drkoop.com lays off 42 workers, Austin American-Statesman, August 31, 2000, C1.


60 Id.

61 Id.

62 Id.
after the report’s date and after the accounting firm had sent a letter to drkoop.com’s board of directors expressing “substantial doubt” about the company’s viability, Koop and three other board members sold substantial portions of their stock. Koop sold approximately 10% of his drkoop.com stock for $914,850.63 Only after the sales, shareholders allege, did drkoop.com reveal the audit report.64

PriceWaterhouseCoopers has since resigned as Drkoop.com’s auditor65 and the Securities and exchange Commission is currently investigating the allegations.66

III. A return to the Pre-Stark Years

Drkoop is a leading brand in what is the largest part of the economy that people care about. We believe with the right positioning and the right cleaning up of the company, you’ve got a real asset there that could be utilized in a lot of ways.

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Dr. Koop is an American icon. If you talk with anyone in the medical profession or you speak to any doctor or patients or consumers, everybody knows and loves Dr. Koop. They trust him; they grew up with him. He was the first one on television to really fight back against smoking when no one else wanted to talk about it. He was the first one to support AIDS research and make it a national issue. Everyone believes in him.67

Drkoop.com CEO, September 2000

A patient's choice can be affected when physicians steer patients to less

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64 Id.


66 See, Troubled Drkoop.com, supra note 59.

convenient, lower quality, or more expensive providers of health care, just because the physicians are sharing profits with, or receiving remuneration from, the providers.\footnote{Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1662 (1998).}

HCFA on the enactment of Stark I

The premise for drkoop.com was simple. Consumers who knew and trusted the name of the former Surgeon General would be drawn to a website bearing his name. And, those trusting consumers could then be linked to product and service vendors who would compensate drkoop.com for sending Internet business their way.\footnote{“The new idea was to create ‘Dr. Koop's Community,’ a collection of chat rooms, support groups and health information that would make money through advertising and e-commerce.” The Life and Near Death of Drkoop.com, supra note 63.} As Dr. Koop put it in his 1991 biography, he knew that he “had gained the public's trust.”\footnote{The Life and Near Death of Drkoop.com, supra note 14.} And if Dr. Koop did not intend solely to capitalize financially on that trust,\footnote{Koop has stated, “I wanted to make sure that I did not use that trust only for private gain. Like many Americans, I was disgusted with the way retired politicians - even presidents - cashed in on their celebrity status.” Id.} the website’s new CEO makes no bones about his plan: “This organization that we inherited was not focused on any one goal, We want to refocus the company around sales.”\footnote{Drkoop.com Lays Off, supra note58 .}

Congress has enacted two sets of laws to address similar economic relationships in the “brick and mortar” sector of health care. Both sets of statutes – the Anti-Kickback law\footnote{See infra text 7 notes .} and the
Stark laws\textsuperscript{74} – seek to prevent physicians from profiting simply by steering a patient to another provider of health care services. Yet, that is precisely what drkoop.com’s CEO proposes: “There are also a lot of partners in the health-care space who want to use Drkoop's content and its 1.4 million registered users to create transactions. We will benefit by getting a small piece of those transactions.”\textsuperscript{75}

This part of this article addresses the advisability and feasibility of applying these federal laws to Internet health care.

\textit{A. Secret Remuneration}

1. Premises for the Stark and Anti-Kickback laws

Congress enacted the first version of the Anti-Kickback statute in 1972. The statute prohibited anyone from soliciting, offering or receiving “any kickback or bribe in connection with” providing Medicare or Medicaid services.\textsuperscript{76} Congress subsequently broadened the statute’s scope to include kickbacks in all federal health care programs.\textsuperscript{77} Conversely, Congress narrowed the statute by limiting its application to the “knowing[] and wilfull[ ]” payment or receipt of kickbacks or bribes.\textsuperscript{78} Simply put, the statute bars physicians and other health professionals from receiving fees for referring federal health care program patients to hospitals or other facilities.

\textsuperscript{74} See infra text 7 notes - .

\textsuperscript{75} The Life and Near Death of Drkoop.com, supra note 63.

\textsuperscript{76} P.L. 92-603 (1977), codified at 42 U.S.C. §1395nn(b) (1977) (Medicare) and §1396h(b) (1977) (Medicaid).

\textsuperscript{77} P.L. 95-142, 91 Stat. 1183 (1977), codified at 42 U.S.C.

\textsuperscript{78} P. L. No. 96-499 , codified at 42 U.S.C.A. 1320a-7b. (1980).
Although the Anti-Kickback statute may have addressed some of the more overtly illicit financial arrangements in federal health care programs, Congress remained concerned about the covert. In 1988, the Office of the Inspector General reported that Medicare “patients of referring physicians who owned or invested in independent clinical laboratories received 45% more laboratory services than all Medicare patients in general.” Moreover, all patients of physicians who had any compensation arrangement with laboratories received statistically more laboratory services than those with physicians who received no compensation.

Other studies have reached similar conclusions. For example, Mitchell and Scott found both higher utilization rates and charges for ambulatory surgical centers and diagnostic imaging where referring physicians have ownership interests. Hillman and his co-researchers found that physicians with imaging equipment in their offices use that equipment more often and charge more for its use than physicians who refer patients to unaffiliated facilities. And Swedlow found that self-referral led to both increased costs and utilization of physical therapy, psychiatric evaluation, and MRI tests in the California workers’ compensation.


80 Id.


In response to the evidence of the relationship between physician remuneration and referral, in 1989 Congress enacted the Ethics in Patient Referral Act,\textsuperscript{84} colloquially known as “Stark I,” in reference to the legislation’s sponsor, representative Pete Stark of California. In 1993, Congress enacted the sequel, “Stark II.”\textsuperscript{85}

Stark I prohibited self referral to clinical laboratories.\textsuperscript{86} Stark II extended the self-referral ban to ten additional health services, including physical and occupational therapy services, radiology services, and the provision of prescription drugs.\textsuperscript{87}

Although the Stark laws have on occasion been criticized as being overly broad and complex,\textsuperscript{88} they have, in the main, achieved their goal. Physicians have ceased investing in the entities to which they refer their patients.\textsuperscript{89}

2. Premises for application the Anti-Kickback and Stark laws to online medicine

Two characteristics of medical commerce facilitated the financial arrangements which led


\textsuperscript{87} 42 U.S.C. 1320 a-b7b (95nn(h)(6) (2000).


\textsuperscript{89} See Stark Raving Mad, supra note 88.
to the enactment of the Anti-Kickback and Stark laws. First, the arrangements could be accomplished very efficiently. Physicians with spare office space could simply purchase and install imaging equipment. Those lacking space might rent the office down the hall. In either event, the referral would simply involve walking the patient to the equipment. In effect, the patient was a “captured” customer.

Second, the economic arrangement could be secreted from the patient. Especially when the diagnostic equipment was not housed within the physician’s office, the patient would have no reason to suspect the compensation arrangement. As a result, self-referral flourished.

The Internet is even more conducive to efficient and secretive compensation arrangements. The “referral” is accomplished with a link. And, unlike Stark-like diagnostic referrals, the referrals involve no capital expense. Indeed, the advertiser will likely pay the health site for the privilege of posting an advertising banner and link. And, as drkoop.com proved, at least until reporters began an inquiry, the arrangements can easily be kept from site visitors.90

The result is complex and secretive referral network which dwarfs the self-referral problem which the OIG highlighted in its 1988 study. Physician owned or sponsored websites can refer visitors, by hyperlink, to pharmacies, pharmaceutical companies, health product sellers, hospitals, clinics, and clinical trials. The referral may include a recommendation, such as drkoop.com’s characterization of sponsor hospitals as “innovative and advanced health care institutions across the country.”91 And the possibility of the referral fees generated by these arrangements can be used to entice investors to buy shares.

90 See supra text & note .

91 See supra text & note .
What makes the Internet particularly effective is its ability to track downstream and upstream referrals. Web sites can track and count traffic. Site one can link a visitor to site two, which can link to site three, and so on. The ultimate seller can pay a commission or affiliate fee to the immediate, upstream link, and that site can pay referrers farther upstream. The effect is a web of financial incentives which stretches as far as the mouse can click.

3. Impediments to extension of Anti-Kickback and Stark laws

There are two impediments to extending the Anti-Kickback and Stark laws to cyberspace. The first is practical. The second involves the relationships to which the statutes apply.

First, both sets of federal laws apply only to federal health care programs. That limitation, of course, provides the basis for asserting federal authority over health care arrangements. Moreover, the limitation has not significantly diminished the impact of the statutes. Medicare, Medicaid and other federal programs constitute a significant portion of “brick and mortar” health care. In addition, physicians have found it nearly impossible to enter into referral or self-referral arrangements which segregate federal program and non-federal program patients. Physicians have been unwilling to invest in laboratories and other clinical services to which they can refer only their non-federal program patients. As a result, most kick-back and self-referral behavior has ceased.

Even if applicable in cyberspace, the Anti-Kickback and Stark laws would not likely have

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92 See, e.g., the “affiliate” fee pay schedule at footnote , supra.

93 Health Care Finance Administration, Office of the Actuary, figure 7.1 (1996) (reporting the federal government supplies 34% of the financing for health care).

94 See Stark Raving Mad, supra note 88.
the same impact as they have had in the “brick and mortar” sector. Many of the services and products to which Internet medical sites link customers are not the medical services contemplated by the Anti-Kickback 95 and Stark 96 laws. Again, drkoop.com provides an example. The site provides advertiser links to nutritional and health supplement vendors, book sellers, and other, sundry products 97 which would not be deemed medical care. Similarly, Medem.com, the commercial website created by the AMA and other physician organizations, contemplates linking visitors to a variety of “consumer sites” offering services and products which are not provided by health care professionals. 98

Moreover, many Internet health care sites cater to consumers who pay out-of-pocket for the services and products they purchase. Witness the requirement that purchasers tender a credit card number to purchase Viagra from the Internet’s many Viagra vendors. 99 Federal programs simply do not have as significant a role in Internet medicine referral fees and kickbacks.

A second, and more significant limitation precludes the Stark laws from applying even to purchases through federal programs of conventional medical services and products. Stark I and II apply to physicians’ referrals of their patients. 100 Regardless of the definition of physician/patient...

95 See supra text & notes - .
96 See supra text & notes - .
100 See, e.g., 42 U.S.C. § 1395nn. The section prevents “physician” referrals.
relationship one employs, it is doubtful that many, if any, of the millions who visit drkoop.com or healthcentral.com are patients of Drs. Koop or Edell.

In effect, these good doctors have lent their names to the creation of a health care system which delivers its goods and services in the absence of either a physician/patient relationship or federal regulation.

B. A Ban on Affiliate Fees, Commissions, and the Like

1. The proposal

The Stark and Anti-Kickback laws are premised on the discovery that money corrupts. Simply put, physicians’ decisions about their patients’ medical needs vary with payment. If physicians own x-ray machines, their patients are more likely to receive x-rays.

Although there are no broad Internet studies which mirror the OIG’s investigation of self-referral, the anecdotal evidence is clear. There is no reason other than for compensation for drkoop.com to tout the standing of the “innovative and advanced health care institutions” to which it referred consumers. The site offered no testimonials, quality reviews, or association certifications to corroborate the description. And neither did it offer information to support the

101 See, e.g., Barbara Tyler, Cyberdoctors: the Virtual Housecall – the Actual Practice of Medicine on the Internet is Here; Is it a Telemedical Accident Waiting to Happen?, 31 IND. L. REV. 259, 265 (1998). The author suggests that “no touch” physician/patient relationships may exist when the patient seeks the physician’s individual advice. See, id. The millions of patients who “surf” through drkoop.com and other sites each month do not seek or receive Dr. Koop’s individual advice.


104 See supra text & notes - .
claim that the start-up clinical trials manager also listed on the site was “the world's leading clinical organization.”\textsuperscript{105}

Of course, once challenged, drkoop.com either renounced financial ties or disclosed to consumers its arrangements financial arrangements. But, as Congress apparently concluded in enacting the Stark laws, disclosure, alone, will not address the problem. Unless patients refuse the advice of their physicians, disclosure will not change the referral pattern. And, indeed, drkoop.com was formed on the theory that “consumers [would] associate the trustworthiness and credibility of Dr. C. Everett Koop with our company,”\textsuperscript{106} and, presumably, the services and products it touted.

Just as self-referral led to questionable treatment decisions, so has the Internet compensation scheme led to questionable links. And given the amount of health-related Internet traffic, the current financial web surely does not serve the public health.

The solution mirrors the Stark laws. Like drkoop.com, websites affiliate physicians to gain credibility for their health recommendations. But, the financial arrangements threaten to corrupt physicians’ judgment. To avoid this corruption, Congress should bar physicians from receiving affiliate fees or commission for providing links to medical-related sites on the Internet.

For purposes of simplicity and consistency, the ban would apply only to those sites offering the services addressed in the Stark laws: clinical laboratories, physical and occupational therapy services, radiology services, and the provision of prescription drugs.\textsuperscript{107} The last, which

\textsuperscript{105} See supra text & notes - .

\textsuperscript{106} See supra text & notes - .

\textsuperscript{107} See supra text & notes - .
would encompass cyberpharmacies, would address the largest financial issue presented by online medicine.\textsuperscript{108}

Penalties should also mirror those provided in the Stark laws. The Stark laws provide a civil penalty of up to $15,000 for each referral which violates the statutes.\textsuperscript{109} In addition, physicians and others that “enter into a circumvention scheme that the physician or entity knows or should know has a principal purpose of assuring referrals” which violate the Stark laws may be assessed civil penalties of up to $100,000.\textsuperscript{110} Finally, providers who fail to comply with the laws’ reporting requirements are subject to a civil penalty of a maximum of $10,000 for each day of non-compliance.\textsuperscript{111}

Application in cyberspace of the reporting requirements might be particularly beneficial. The statute requires that covered entities “shall provide the Secretary (of HHS) with the information concerning the entity's ownership, investment, and compensation arrangements, including ... the covered items and services provided by the entity, and [identification] of all physicians with an ownership or investment interest ... or with a compensation arrangement ... in the entity.\textsuperscript{112}

Application of the reporting requirements in cyberspace would assist regulators in

\textsuperscript{108} See supra text & notes - (predicting that by 2001, annual sales will total between $1.4 billion to $2.8 billion and that by 2005, annual sales will reach $6 billion.)


\textsuperscript{110} 42 U.S.C. § 1395nn(g)(4) (2000).


\textsuperscript{112} 42 U.S.C. § 1395nn(f) (2000).
detecting the payment of affiliate fees, referral fees, and product kickbacks from website to physicians. Websites which enlist physicians to provide advice to visiting consumers would have to disclose details of the physicians’ compensation packages. The attendant administrative burden has proven controversial in the world of brick-and-mortar medicine. That burden, however, should be less problematic in cyberspace. Health-related websites, unlike brick-and-mortar practices, can operate without physician participation. Thus, those wishing to avoid the burden may do so by offering information services, links, and products and services without attaching a physician’s name or reputation to the operation of the website. Presumably, then, consumers seeking a physician about appropriate provider/manufacturer choices could consult their personal physicians.

2. The case for federal regulation

States, too, could attempt to regulate online medicine. Indeed, many have begun to assert jurisdictional authority over online pharmaceutical prescription. Any extensive attempt by states to regulate online medicine, however, faces two difficulties.

The first is a matter of pragmatic difficulty. Were each state to act independently, online physicians would face fifty different variations on the theme. Any effort to develop a cohesive, consistent policy regarding physician cyberspace financial relationships would likely prove futile.

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113 For criticism of the administrative burden which attends the reporting Stark laws’ reporting requirement, see, e.g., Note: The Stark Laws: Conquering Physician Conflicts of Interest?, 87 GEO. L.J. 499 (1998).

Moreover, the physicians would likely have great difficulty in complying with a multitude of laws.

The second, and, perhaps more formidable difficulty is embodied in the dormant Commerce Clause of the United States Constitution. The Commerce Clause provides that "the Congress shall have Power... To regulate Commerce ... among the several States ...." As the Supreme Court recognized in General Motors Corp. v. Tracy, the “dormant” attribute of the Clause limits the ability of states to impede the flow of interstate commerce: “the negative or dormant implication of the Commerce Clause prohibits state taxation or regulation that discriminates against or unduly burdens interstate commerce and thereby ‘impedes free private trade in the national marketplace.’”

In American Libraries Association v. Pataki, Judge Loretta A. Preska of the United States District Court for the Southern District of New York recently applied the “undue burden” component of dormant commerce clause theory to grant a preliminary injunction against the enforcement of a New York state “Internet Decency” statute. At the outset of her decision, Judge Preska observed:

115 U.S. CONST. art. I 8, cl. 3.
119 Id. at 184. The court failed to reach a First Amendment challenge to the same statute. Id. at 183.
The borderless world of the Internet raises profound questions concerning the relationship among the several states and the relationship of the federal government to each state, questions that go to the heart of `our federalism.'

That “borderless” nature makes any state attempt to regulate Internet per se violative of the dormant commerce clause:

New York has deliberately imposed its legislation on the Internet and, by doing so, projected its law into other states whose citizens use the Net. ... This encroachment upon the authority which the Constitution specifically confers upon the federal government and upon the sovereignty of New York's sister states is per se violative of the Commerce Clause.

Similarly, any state attempt to regulate physician Internet financial arrangements would necessarily impact physicians in other states. Thus, under the rationale of American Libraries v. Pataki, the attempt would be barred by the dormant commerce clause power.

Not all commerce clause scholars would take such a broad view of the dormant commerce clause power. Justice Antonin Scalia, for example, has argued that “‘negative’ Commerce Clause jurisprudence” implicates courts in improper “prospective decisionmaking [which] is incompatible with the judicial role, which is to say what the law is, not to prescribe what it shall be. ... Weighing the governmental interests of a State against the needs of interstate commerce is ... a task squarely within the responsibility of Congress.”

Regardless of the outcome of the dormant commerce clause debate, at this time the doctrine presents a significant question about the validity of state attempts to regulate online commerce.

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121 969 F. Supp. at 177.

medicine. Moreover, the practical difficulties inherent with state regulation are undeniable. Thus, effective regulation will require federal participation.

III. Conclusion

As I came to the end of my surgeon general years, I felt that I had gained the public's trust and that I should do something with it.123

C. Everett Koop speaking about founding drkoop.com.

Despite its financial woes, drkoop.com continues to attract health care consumers. In August 2000, the website ranked seventh on the “PC Data Online Top 10 Hit Lists,” garnering over six hundred thousand hits by “unique individuals” in a single week and obtaining nearly 1% of the Internet “health and family” traffic.124 By contrast, the National Institutes of Health ranked tenth, with four hundred fifty two thousand hits.125

What Dr. Koop has done with the public’s trust is to profit from it. Perhaps Dr. Koop harbored some altruistic goals at the foundation of drkoop.com, but he consented to the formation of a company premised on the goal of “establish[ing] the DrKoop.com brand so that consumers associate the trustworthiness and credibility of Dr. C. Everett Koop with our company.”126 Moreover, he recently assented to new management bent on the single goal of generating sales by

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123 The Life and Near Death of Drkoop.com, supra note 14.

124 Drkoop.com Chief Diagnoses Firm’s Ailments, supra note 67. Presumably, the “unique individuals” measure does not count multiple visits by a single individual.

125 Id.

126 AMA News, Oct. 4, 1999 (indicating that drkoop.com attracts over twice the Internet traffic as its nearest competitor).
capitalizing on consumers’ views of Dr. Koop as an icon of medical integrity.127

Dr. Koop, of course, although possessing the most recognizable name, is not the only physician to profit from the cyberspace referral web. Dr. Dean Edell, for example, has done well by healthcentral.com.128 And the “cyberdocs” associated with cyberdocs.com not only “are always in,” but appear to have prospered, as well.129

The issue has not gone unrecognized by professional organizations. The AMA ethics rules, for example, provide that “payment by or to a physician solely for the referral of a patient is fee-splitting and is unethical.”130 But, the AMA’s rule is as ineffective in cyberspace as are the Stark laws. The consumers from the referral of whom physicians prosper are not often the physicians’ patients.

And the problem which the Stark laws target exists, at least in cyberspace, even in the absence of a physician/patient relationship. As drkoop.com demonstrated in listing hospitals and clinical trial organizations as “leaders” in exchange for a fee, money can corrupt judgment. And when consumers rely on website judgments because of affiliation with a well-known physician, following those judgments may not serve their health. Moreover, the AMA’s ethical premise has not, apparently, discouraged the likes of Dr. Koop from profiting from the selling of services and products to consumers who place their trust in the physicians’ implicit endorsements of links on

127 See supra text & notes .

128 See supra text & notes .

129 At $50 to $100 a session, the site has been scheduling 3,000 online visits each day. Marissa Melton, Online Diagnoses Finding More than a Doc-in-the Box, U.S. News 7 World Report, as reproduced at www.cyberdocs.com.

130 E-MEDICINE, supra note 5.
their sites.

Of course, online medicine is not all bad. “Online medicine can mean high-quality advice, affordable drugs and more control over your own records.” But, it is problematic when money corrupts professional judgment.

Applying the Stark laws to cyberspace will address the problematic attribute of online medicine while allowing the beneficial aspects to continue to exist. The website can offer information and link consumers to useful products and services. Physicians just cannot profit from the linkage. Moreover, physicians may offer services and advice online, even for a fee, but may not refer for a “kickback” or receive any sort of referral fee or affiliate fee.

As one commentator recently put it, “Online medicine can mean high-quality advice, affordable drugs and more control over your own records. But, as with most things in cyberspace, what you see is not always what you get.”

Applying the Stark laws in cyberspace will at least make it more likely that consumers get what they see. And then, perhaps, Net surfers will be able to distinguish “science and snake oil.”

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133 *Need a Doctor in a Hurry?*, supra note 1 (Quoting Dr. George D. Lundberg when he was the editor of the Journal of the American Medical Association).