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."[1]

When C. Everett Koop announced in 1989 that he would resign as U.S. Surgeon General, Secretary of Health and Human Services Louis W. Sullivan described him as "a voice of honesty, integrity, compassion and plain good sense."[2] Dr. Koop's colleagues reported that he intended to engage in scholarly pursuits, including writing books and speaking.[3]

Instead, Dr. Koop apparently focused his efforts on conquering the new medical frontier in cyberspace. In 1998, Dr. Koop became chairman and a shareholder in DrKoop.com.[4] At the outset, 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 company."[5]

DrKoop.com soon became the Internet's most successful medical site.[6] The site offers 80,000 electronic pages that reproduce recent health care news headlines and offer information on a variety of medical conditions including asthma, HIV/AIDS, cancer, depression, heart disease, and

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1 Sheryl Gay Stolberg, *From M.D. to I.P.O., Chasing Virtual Fortunes*, N.Y. TIMES, July 4, 1999 (quoting Dr. George D. Lundberg while editor of the Journal of the American Medical Association).

2 *Headliners: Changing a View*, N.Y. TIMES, May 7, 1989, § 4 (Week in Review Desk), at 9.

3 *Id.*

4 *See* DrKoop, *at* http://www.drkoop.com.

5 Holcomb B. Noble, *Hailed as a Surgeon General, Koop Is Faulted on Web Ethics*, N.Y. TIMES, Sept. 5, 1999, at A1, A20 (quoting DrKoop's prospectus).

6 *See* Bob Cook, AMA, *Specialty Societies May Collaborate on Internet Site*, 42 AM. MED. NEWS, Oct. 4, 1999, at 1 (indicating that DrKoop.com attracted more than twice as much Internet traffic as its nearest medical site competitor during May and August 1999).

mental health.[7] The site also offers a weekly "word from Dr. Koop," in which he proffers advice on conditions from flatulence to migraines.

Dr. Koop has indeed conquered cyberspace. In February 1999, less than a year after it went online, the site recorded over 369,000 visitors.[8] In May 1999, the site received over two million hits,[9] and in August 1999 the site witnessed nearly 3.5 million hits.[10] In comparison, aolhealth.com, the second most visited site, received 1.5 million hits in August 1999, less than half of DrKoop.com's traffic.[11] Other cyberspace health leaders also operate in DrKoop.com's shadow. For example, in the same month, onhealth.com received 1.4 million hits and webmd.com received 1.2 million.[12]

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."[13]

Nevertheless, cyberspace proved profitable for Dr. Koop, at least for a while. As chairman of the site, Dr. Koop receives a modest annual salary of $135,000 and his stock holdings in the site were worth more than $47 million in September of 1999.[14]

A number of ingredients in DrKoop.com's financial stew, including Dr. Koop's sources of revenue, have drawn criticism. For example, like most other websites, DrKoop.com features paid advertising. DrKoop.com runs ads for cyber-pharmacies, insurance companies, weight loss products, Internet servers, vitamins, and a "lifestyle" website devoted to improving one's "mental health."[15] DrKoop.com's initial public offering prospectus disclosed that in return for this advertising, the site 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."[16] However, DrKoop.com did not otherwise disclose this commission arrangement to the public.

DrKoop.com also features a "Community Partners Program," a list of hospitals and health centers that the site touts as "the most innovative

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7 *See* Noble, *supra* note 5, at A20.

8 AM. MED. NEWS, *supra* note 6, at 1.

9 *Id.*

10 *Id.*

11 *Id.*

12 *Id.*

13 Noble, *supra* note 5, at A20.

14 *Id.* The value of Dr. Koop's holdings, like the value of many dot-coms, has since dropped dramatically.

15 DrKoop, *supra* note 4 (last visited Apr. 2, 2000).

16 Noble, *supra* note 5. DrKoop officials said that Dr. Koop's contract has since been changed to eliminate the provision. *Id.*

and advanced health care institutions across the country."[17] What is unknown to visitors of the site, however, is that each of the 14 listed hospitals had paid a fee of $40,000 to be included on the list.[18]

The site also seeks to match visiting consumers to clinical trials that address the consumer's ailments.[19] The site originally referred consumers to Quintiles Transnational Corporation, a newly formed company that manages clinical trials for pharmaceutical companies. Quintiles declared itself on DrKoop.com to be "the world's leading clinical organization."[20] DrKoop.com failed, however, to reveal that it would receive 2% of any fees that Quintiles received for study subjects Quintiles enrolled through the site.[21]

When faced with inquiries from ethicists and reporters, DrKoop.com quickly renounced the commissions on advertised products and services and on clinical trial referrals. In addition, the site also downgraded the description of the "community partners" from "the most innovative and advanced" to "prominent" health care institutions, and further noted that the institutions had paid a fee to be listed.[22]

The resulting loss of "commission-based" revenues may have played a role in DrKoop.com's financial demise. In April 2000, 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."[23]

In addition to these financial losses, Dr. Koop may have tainted his professional reputation. Critics have assailed Dr. Koop for compromising his ethics when he entered into these financial arrangements. Moreover, they have questioned whether he would lose credibility with the public.[24] Dr. Koop, who in 1991 described himself as "America's family doctor,"[25] however, has expressed no doubt that his reputation will emerge from ethical controversy unscathed: "I have never been bought. I

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17 DrKoop.com, *supra* note 4 (last visited Apr. 2, 2000).

18 Noble, *supra* note 5.

19 A clinical trial is "[a]ny investigation in human subjects intended to determine the clinical pharmacological, pharmacokinetic, and/or other pharmacodynamic effects of an investigational agent, and/or to identify any adverse reactions to an investigational agent to assess the agent's safety and efficacy." CenterWatch, *at* http://www.centerwatch.com/patient/glossary.html.

20 Noble, *supra* note 5, at A20.

21 *Id.*

22 *Id.*

23 Bernhard Warner & Miguel Helft, *Portals Start to Feel the Heat*, INDUSTRY STANDARD, May 1, 2000, at 63. In April 2000, DrKoop.com's auditor, PricewaterhouseCoopers, expressed serious doubts about the company's ability to survive as a going concern. *See, e.g.*, Karen Kaplan, *Pay-Per-Click Concept Gets GoTo.com Farther*, L.A. TIMES, Apr. 3, 2000, at C1; *E-Health: Financial Future Grim for Drkoop.com*, AMERICAN HEALTH LINE, Apr. 3, 2000.

24 *See* Noble, *supra* note 5.

25 *Id.*

cannot be bought. I am an icon, and I have a reputation for honesty and integrity . . . ."[26]

This article examines the ethical consequences of the economic relationships that the Internet has created in the medical industry. Part I provides a background to online medicine by describing the Internet medical sites and the consumer traffic the sites attract. Part II analyzes the various economic relationships that 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.[27] Last year, more than 22 million people visited online health sites.[28] Furthermore, that figure is growing by 70% each year.[29] Some of this traffic has generated online pharmacy sales. Industry analysts recently estimated that the Internet pharmacy market will account for between 1 and 2% of the total pharmacy market in 2001.[30] By 2001, annual sales are expected to total between $1.4 billion and $2.8 billion.[31] By 2005, annual sales are expected to reach $6 billion.[32]

B. THE SITES

1. *On-Line Pharmacies*

In January 1999, the Internet hosted fewer than 30 online pharmacies.[33] By July 30, 1999, more than 400 had appeared.[34] One hundred eighty-three of these 400 sites were devoted exclusively to prescribing and selling Viagra.[35] Moreover, as of July 1999, 150 of these sites had

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26 *Id.* at A20.

27 *E-Drugs: Who Regulates Internet Pharmacies?: Hearing Before the Senate Comm. on Health, Education, Labor and Pensions*, 106th Cong. 7, 12 (2000) (testimony of Jane E. Henney, FDA Commissioner).

28 *Id.*

29 *Id.*

30 143 DRUG TOPICS 8, Nov. 15, 1999.

31 *Id.*

32 *The NewsHour with Jim Lehrer* (PBS television broadcast, Nov. 17, 1999).

33 *Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies: Hearing before the House Subcomm. on Oversight and Investigations of the Comm. on Commerce*, 106th Cong. 246 (1999) (testimony of Carmen A. Catizone, Executive Director, National Association of Boards of Pharmacy).

34 *Id.*

35 *Id.* at 247.

been identified as to the registrant state of origin.[36] One fifth of the sites were registered outside the United States.[37]

The National Association of Boards of Pharmacy (NABP) believes some sites are legal: "[some cyber-pharmacies] 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."[38] Illegal sites, on the other hand, offer prescriptions based on answers to online questionnaires. These sites represent that a physician has reviewed the questionnaires before he or she prescribed drugs.[39] However, investigators have discovered that some of these sites merely "pirate" the names of physicians who are not involved with the sites.

2. *Professional Sites*

The Internet hosts a variety of professional medical sites. These sites, such as the AMA's ama-assn.org,[40] the American Psychological Association's apa.org,[41] and the American Psychiatric Association's psych.org,[42] 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 that attempt to sell products or services to consumers.

3. *General Consumer Sites*

General consumer sites, however, frequently link to sites that attempt to sell products and services to consumers. Indeed, as one financial analyst recently observed, sites such as DrKoop.com,[43] healthcentral.com,[44] webmd.com,[45] aolhealth.com,[46] onhealth.com,[47] healtheon.com,[48] and discoveryhealth.com,[49] premise their financial futures on just such links:

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36 *See id.*

37 *See id.*

38 *E-Drugs: Who Regulates Internet Pharmacies?: Hearing before the Senate Comm. on Health, Education, Labor and Pensions*, 106th Cong. 34 (2000) (testimony of Carmen A. Catizone, Executive Director/Secretary National Association of Boards of Pharmacy).

39 *See id.*

40 American Medical Association, *at* http://www.ama-assn.org.

41 American Psychological Association, *at* http://www.apa.org.

42 American Psychiatric Association, *at* http://www.psych.org.

43 DrKoop.com, *supra* note 4.

44 Healthcentral, *at* http://www.healthcentral.com.

45 WebMD, *at* http://www.webmd.com.

46 AOL Health Web Channel, *at* http://www.aol.com/webcenters/health.

47 OnHealth, *at* http://www.onhealth.com (site no longer exists).

48 Healtheon, *at* http://www.healtheon.com (site no longer exists).

49 Discovery Health, *at* http://health.discovery.com.

> [I]t'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."[50]

Apparently recognizing 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.[51] Although still in its formative stage, Medem.com promises to offer consumers "medical shopping" in the future: "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."[52]

4. *Condition-Specific Sites*

The Internet also offers a number of websites devoted to specific health conditions. Epotec.com, for example, claims that it "taps the speed and efficiency of the Internet, building a powerful, cost-effective way of providing behavioral health services."[53] This site offers services such as "private coaching from licensed professionals" which will enable patients to "[g]et information quickly and easily," which 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."[54]

Other "condition-specific" sites offer sex-response enhancement. Menshealthonline, for example, offers: "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

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50 Tyler Chin & Bonnie Booth, *Can Medem be Profitable and Ethical?*, AM. MED. NEWS, Nov. 15, 1999, *available at* http://www.ama-assn.org/sci-pubs/amnews/pick_99/orl21115.htm (partially quoting financial analyst Stephen DeNelsky commenting on Medem.com).

51 Medem, *at* http://www.medem.com; Medical Societies, *at* http://www.medem.com/corporate/corporate_societies_founding.cfm (listing Medem's seven founding medical societies).

52 *Id.* (last visited Apr. 13, 2000).

53 Epotec, *at* http://www.epotec.com (last visited Apr. 13, 2000).

54 *Id.*

as completely and accurately as possible."[55] The "patient" need only fill in his address and supply a credit card number to receive the product.

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."[56]

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 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.

For example, a number of the Viagra sites feature "affiliate fees." Under an affiliate agreement, any site which sends purchasers to the Viagra site receives a referral fee ranging from 2 to 7% of the sale. The referrer, too, may offer compensation to upstream "linkers." The result of this referral scheme is a complex financial network.

Individual sites may also pay for the privilege of being linked. For example, the search site goto.com[57] consists of a series of links grouped by topic. Within these series, the search site lists other sites that pay fees above sites that do not pay. For a fee of $1.01 per link, DrKoop.com was ranked first in the medical information category. HealthAllies.com,[58] 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.[59]

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55 http://www.menshealthonline.com (last visited Apr. 13, 2000) (site no longer exists).

56 Medicalcenter, *at* http://www.medicalcenter.net (last visited Apr. 13, 2000) (site no longer exists).

57 GoTo.com, *at* http://www.goto.com.

58 HealthAllies, *at* http://www.healthallies.com.

59 Kaplan, *supra* note 23, at C1.

B. PROFESSIONAL FEES

Physicians and other health care professionals who dispense advice on the Internet often charge for their services as well. As the following example shows, these fees can prove to be quite lucrative.

Approximately two years ago, Direct Response Marketing[60] (DRM) and Spar Pharmacy, both located in Jersey, England, began a joint venture in prescribing and selling Viagra.[61] DRM runs an Internet site that writes prescriptions, which Star Pharmacy then fills. In their first eighteen months of cooperation, the tandem generated $2.5 million in online sales, most of which was attributable to Viagra. In May 1999, for example, Star dispensed 3,698 Viagra pills. Twenty-four of these pills went to Jersey residents.[62]

While legitimate "brick and mortar" pharmacies typically charge $10 or less per Viagra pill, DRM charged its customers $20 per pill.[63] One explanation for this inflated price may be that consumers are willing to pay a premium for the confidentiality that the Internet provides.

DRM has arranged a system through which to divide the Viagra profits. DRM, the website, retains one third and the participating pharmacy and website designer share another third. The prescribing physician takes the remaining third, which was $200,000 in DRM's first full year of operation.[64]

C. PUBLIC OFFERINGS

Active participants are not the only individuals to profit from online medicine. Before the conditions for technology stocks turned bearish, 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."[65]

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60 *Formerly* at http://www.directmarketingresponse.com (site no longer exists).

61 *See* Laurie P. Cohen, *Drug Maker Protests Dispensing via Internet, But Practice Flourishes*, WALL ST. J., Nov. 29, 1999, at A1.

62 *Id.*

63 *Id.* at A16. DRM founder Tom O'Brien has stated, "I thought we'd be shut down by Pfizer." *Id.* 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. *Id.* While still pressuring the FTC to shut down what it has characterized as an illegal business enterprise, Pfizer has not attempted to stop DRM from gaining access to Viagra. *Id.* at A1.

64 Cohen, *supra* note 61, at A16.

65 *Business Today*, ST. PETERSBURG TIMES, Nov. 23, 1999, at 1E.

Similarly, in Fall 2000 Healthcentral.com, a general health information site, announced a plan to raise $86.3 million in an initial public offering. The company's appeal derives from its lead public persona, Dr. Dean Edell, who hosts the second most popular syndicated radio talk show. Coincidentally, Edell owns 19.1% of heathcentral.com's stock.[66]

Recent news, however, has not been promising for e-health care companies. The Goldman Sachs Internet index fell 46% between March and June 2000.[67] Moreover, in July 2000, analysts estimated that sixty out of two hundred dot-coms had less than 12 months cash on hand.[68]

DrKoop.com has not been immune from the dot-com woes. In April 2000, the accounting firm PricewaterhouseCoopers announced that DrKoop.com had suffered "substantial ongoing losses" and expressed "serious doubts about the company's survival as a 'going concern.'"[69] In July, the site topped USA Today's "Worst-Performing stocks of the Internet 100" list with an 84.5% stock price loss since December 31, 1999.[70] In addition, DrKoop.com made the Toronto Star's "Death Watch Top 10" list.[71]

More recently, DrKoop.com has attempted to revive itself by trimming staff[72] and luring new investors.[73] Nonetheless, analysts remain convinced that the company's "prognosis is bleak."[74]

Meanwhile, shareholders have charged that Dr. Koop, who remains chairman and sits on the board of directors,[75] and other executives withheld a negative auditor's report from investors until the executives sold their own shares.[76] The allegations stem from a February 1999 PricewaterhouseCoopers report. Two weeks 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

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66 Bob Cook, *Celebrity Doctor Hopes His Name Will Enrich Web Site,* AMA NEWS, Oct. 18, 1999, *available at* http://www.ama-assn.org/sci-pubs/amnews/pick_99/bizb1018.htm.

67 *See* Fred Vogelstein, *Dot-Com Gallows Humor*, U.S. NEWS & WORLD REP., July 10, 2000, at 41.

68 K.K. Campbell, *Dot-Com Pendulum Swings Toward Gloom*, TORONTO STAR, July 6, 2000, at H1.

69 Warner & Helft, *supra* note 23, at 63.

70 Matt Krantz, *'The Party's Over': Sell-off Thumps Dot-Coms*, USA TODAY, July 5, 2000, at 3B.

71 Campbell, *supra* note 68, at H3. The article forecasted that DrKoop.com, along with the others on the list, would "run out of cash within a month or three."

72 Andrew Park, *Drkoop.com Lays off 42 workers*, AUSTIN AMERICAN-STATESMAN, Aug. 31, 2000, at C1.

73 Kathleen Ohlson, *Troubled Drkoop.com Is Barely Breathing; Despite New Cash, Analysts Say Site Has a Bleak Future*, COMPUTERWORLD, Aug. 28, 2000, at 12.

74 *Id.*

75 *Id.*

76 *Id.*

sold approximately 10% of his DrKoop.com stock for $914,850.[77] Shareholders allege that DrKoop.com did not reveal the audit report until after the insider sales.[78] PricewaterhouseCoopers has since resigned as DrKoop.com's auditor and the Securities and Exchange Commission is currently investigating the allegations.[79]

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.
>
> 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.[80]

"A patient's choice can be affected when physicians steer patients to less convenient, lower quality, or more expensive providers of health care, just because the physicians are sharing profits with, or receiving remuneration from, the providers."[81]

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. Those trusting consumers could then be linked to product and service vendors who would compensate DrKoop.com for sending Internet business their way.[82] As Dr. Koop put it in his 1991 biography, he knew that he "had gained the public's trust."[83] If Dr. Koop did not intend solely to capitalize financially on

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77 Todd Woody, *The Life and Near Death of Drkoop.com*, INDUSTRY STANDARD, July 31, 2000 at 123, 139-40, *available at* http://www.lexis.com.

78 *Id.*

79 Ohlson, *supra* note 73.

80 Ashley Dunn, *Drkoop.com Chief Diagnoses Firm's Ailments*, L.A. TIMES, Sept. 4, 2000, at C1, C4 (quoting Richard Rosenblatt, CEO of DrKoop.com).

81 Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1659, 1663 (proposed Jan. 9, 1998).

82 "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." Woody, *supra* note 77, at 129.

83 *Id.* at 124.

that trust,[84] the website's new CEO makes no bones about his new plan: "This organization that we inherited was not focused on any one goal. We want to refocus the company around sales."[85]

Congress has enacted two sets of laws to address similar economic relationships in the "brick and mortar" sector of health care. Both statutes, the Anti-Kickback law and the Stark laws, 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."[86]

The following section of this article addresses the advisability and feasibility of applying the Anti-Kickback law and the Stark laws to Internet health care.

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.[87] Congress subsequently broadened the statute's scope to include kickbacks in all federal health care programs.[88] Conversely, Congress narrowed the statute by limiting its application to the "knowing[ ] and willful[ ]" payment or receipt of kickbacks or bribes.[89] Simply put, the statute bars physicians and other health professionals from knowingly or willfully receiving fees for referring federal health care program patients to hospitals or other facilities.

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 more covert kickback arrangements. In 1988, the Office of the Inspector General (OIG) reported that Medicare "patients of referring physicians who owned or invested in

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84 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.*

85 Park, *supra* note 72.

86 Woody, *supra* note 77.

87 Pub. L. No. 92-603, 86 Stat. 1329 (1977), codified at 42 U.S.C. § 1395nn(b) (1977) (Medicare) and § 1396h(b) (1977) (Medicaid).

88 Medicare-Medicaid Anti-fraud and Abuse Statutes, Pub. L. 95-142, 91 Stat. 1175 (1977).

89 Omnibus Reconciliation Act of 1980, Pub L. 96-499, 94 Stat. 2599 (1980) (codified at 42 U.S.C. § 1320a-7b (2000)).

independent clinical laboratories received 45% more laboratory services than all Medicare patients in general."[90] Moreover, all patients of physicians who had any compensation arrangement with laboratories received statistically more laboratory services than patients with physicians who received no compensation.[91]

Other studies have reached similar conclusions. For example, Jean Mitchell and Elton Scott found both higher utilization rates and charges for ambulatory surgical centers and diagnostic imaging where referring physicians have ownership interests.[92] Moreover, Bruce Hillman and his co-researchers found that nonradiologist physicians with imaging equipment in their offices use that equipment more often and charge more for its use than nonradiologist physicians who refer patients to unaffiliated facilities.[93] Meanwhile, Alex Swedlow found that self-referral led to both increased costs and utilization of physical therapy, psychiatric evaluation, and MRI tests in California workers' compensation cases.[94]

In response to the evidence of the relationship between physician remuneration and referral, in 1989 Congress enacted the Ethics in Patient Referral Act,[95] 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."[96] Stark I prohibited self-referral to clinical laboratories.[97] 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.[98]

Although the Stark laws have on occasion been criticized as being overly broad and complex, they have in the main achieved their goal.[99]

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90 Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg., at 1661.

91 *Id.*

92 Jean M. Mitchell & Elton Scott, *New Evidence of the Prevalence and Scope of Physician Joint Ventures*, 268 J.A.M.A. 80, 83 (1992).

93 Bruce J. Hillman, et al., *Physicians' Utilization and Charges for Outpatient Diagnostic Imaging in a Medicare Population*, 268 J.A.M.A. 2050, 2050 (1992).

94 Alex Swedlow, et al., *Increased Costs and Rates of Use in the California Workers' Compensation System as a Result of Self-Referral by Physicians*, 327 NEW ENG. J. MED. 1502 (1992).

95 Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2239 (1989) (codified at 42 U.S.C. § 1395nn (2000)).

96 Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312 (1993) (codified at 42 U.S.C. § 1395nn (2000)).

97 42 U.S.C. § 1395nn (2000).

98 42 U.S.C. § 1320 a-7b (2000).

99 *See, e.g.*, Francis J. Serbaroli, Noose Around Self-Referrals Pulled Tighter: Congress Steps up War on Practice, 210 N.Y.L.J. 113, at 9 (1993); Molly Tschida, *Stark Raving Mad: Beaten Down by Ambiguous Self-Referral Laws, Providers Now Face the Prospect of Harsh Penalties*, MOD. PHYSICIAN, May 1999, at 28 (quoting Stark as saying, "I hope that HCFA will also consider and propose ways to simplify this law and its regulations.").

Physicians no longer invest in the entities to which they refer their patients.[100]

2. *Premises for Applying the Anti-Kickback and Stark Laws to Online Medicine*

Two characteristics of medical commerce facilitated the financial arrangements that led 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 physicians 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 kept secret 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" process is accomplished with a link. And, unlike Stark-like diagnostic referrals, the referrals involve no capital expense. At most, the advertiser will pay the health site for the privilege of posting an advertising banner and link. Moreover, as DrKoop.com proved, at least until reporters began an inquiry, the arrangements could easily be kept secret from site visitors.

The result is a complex and secretive referral network that dwarfs the self-referral problem that 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 even include a recommendation, such as DrKoop.com's characterization of sponsor hospitals as "innovative and advanced health care institutions across the country."[101] Furthermore, the possibility of the referral fees generated by these arrangements can be used to entice investors to buy stock in the referring site.

What makes the Internet particularly effective in this arena 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

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100 *See* Tschida, *supra* note 99.

101 *See* DrKoop, *supra* note 4.

farther upstream. The effect is a complex web of financial incentives that stretches as far as the mouse can click.

3. *Impediments to Extending 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.[102] In addition, physicians in the "brick and mortar" sector have found it nearly impossible to enter into referral or self-referral arrangements that 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 in the traditional health care market.[103]

Even if applicable in cyberspace, the Anti-Kickback and Stark laws would not likely have 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 and Stark laws. Again, DrKoop.com provides an example. The site provides advertiser links to nutritional and health supplement vendors, book sellers, and other, sundry products[104] which would not be deemed medical care under the statutes. 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.[105]

Moreover, many Internet health care sites cater to consumers who pay out-of-pocket for the services and products they purchase. For example, many Viagra vendors require purchasers to tender a credit card

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102 HEALTH CARE FINANCE ADMIN., OFFICE OF THE ACTUARY, NATIONAL HEALTH EXPENDITURES AMOUNTS, PERCENT DISTRIBUTION AND AVERAGE ANNUAL PERCENT CHANGE, BY SOURCE OF FUNDS: SELECTED CALENDAR YEARS 1970-2007, figure 7.1 (1996) *at* http://www.hcfa.gov/stats/nhe-proj/tables/t01.htm (reporting that the federal government supplies 34% of the financing for health care).

103 *See* Tschida, *supra* note 99.

104 *See* DrKoop.com, *supra* note 4.

105 *See* Medem, *supra* note 51.

number to purchase Viagra on the Internet.[106] Thus, the statutory limitation that makes the statute applicable only to federal health care programs acts to exclude on-line credit card purchases from the statute's coverage. Ultimately, federal programs 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.[107] Regardless of the definition of physician/patient relationship one employs,[108] it is doubtful that many, if any, of the millions who visit DrKoop.com[109] or healthcentral.com[110] are patients of Drs. Koop or Edell.

In effect, these good doctors have lent their names to the creation of a health care system that 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 philosophy that money corrupts. Simply put, physicians' decisions about their patients' medical needs vary with the physicians' capabilities and equipment. If physicians own x-ray machines, their patients are more likely to receive x-rays.

Although there are no broad Internet studies that mirror the OIG's investigation of self-referral, the anecdotal evidence is clear. There is no motivation 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. Neither did it offer information to support the claim that the start-up clinical trials manager also listed on the site was "the world's leading clinical organization."[111]

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106 *See, e.g.*, http://www.phentermine.net; http://www.directmarketingresponse.com. Consider also the many other Viagra-selling sites that a search on GoTo.com yields.

107 42 U.S.C. § 1395nn (2000) (limiting certain physician referrals).

108 *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.

109 DrKoop.com, *supra* note 4.

110 Healthcentral, *supra* note 44.

111 *See supra* note 17 and accompanying text.

Of course, once challenged, DrKoop.com either renounced financial ties or disclosed its financial arrangements to consumers. But, as Congress apparently concluded in enacting the Stark laws, disclosure, alone, will not address the problem. Unless patients affirmatively act to refuse the advice of their physicians, disclosure will not change the referral pattern. Indeed, DrKoop.com was founded on the theory that "consumers [would] associate the trustworthiness and credibility of Dr. C. Everett Koop with our company,"[112] 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 to this lack of attention to the public health mirrors the Stark laws. Like DrKoop.com, websites affiliate with physicians to gain credibility for their health care recommendations. But, the financial arrangements made with the sites threaten to corrupt physicians' judgment. To avoid this corruption, Congress should bar physicians from receiving affiliate fees or commission payments 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.[113] The last, which would encompass cyberpharmacies, would address the largest financial issue presented by online medicine.[114]

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 that violates the statutes.[115] 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.[116] 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 noncompliance.[117]

Application in cyberspace of the reporting requirements might be particularly beneficial. The statute requires that covered entities "shall

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112 Noble, *supra* note 5 and accompanying text.

113 *See supra* notes 87-89, 95-98 and accompanying text.

114 *See supra* notes 30-32 (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).

115 42 U.S.C. § 1395nn(g)(3) (2000).

116 42 U.S.C. § 1395nn(g)(4) (2000).

117 42 U.S.C. § 1395nn(f)(1)-(2), (g)(5) (2000).

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."[118]

Application of the reporting requirements in cyberspace would assist regulators in detecting the payment of affiliate fees, referral fees, and product kickbacks from websites to physicians. Websites that enlist physicians to provide advice to visiting consumers would be forced to disclose details of the physicians' compensation packages to the Secretary of HHS. Admittedly, the attendant administrative burden has proven controversial in the world of brick-and-mortar medicine.[119] 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's advice 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.[120] 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 variants of regulation. Any effort to develop a cohesive and consistent policy regarding physician cyberspace financial relationships would likely prove futile. Moreover, physicians would have great difficulty complying with a multitude of state approaches.

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 . . . ."[121] As the Su-

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118 42 U.S.C. § 1395nn(f) (2000).

119 For criticism of the administrative burden which attends the Stark laws' reporting requirement, *see* Jo-Ellyn Sakowitz Klein, Note, *The Stark Laws: Conquering Physician Conflicts of Interest?*, 87 GEO. L.J. 499 (1998).

120 *See, e.g.*, Joan R. Rose, *Are Doctors Who Affiliate with Internet Pharmacies Asking for Trouble?*, 77 MED. ECON. 33 (2000); Amy Lane, *Task Force Asks Comment on Regulating Internet Pharmacy Services*, CRAIN'S DETROIT BUS., Sept. 11, 2000, at 49.

121 *See* U.S. CONST. art. I, § 8, cl. 3.

preme Court recognized in *General Motors Corp. v. Tracy*,[122] 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.'"[123]

In *American Libraries Association v. Pataki*,[124] Judge 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.[125] At the outset of her decision, Judge Preska observed: "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.'"[126]

That "borderless" nature makes any state attempt to regulate the 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.[127]

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 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

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122 *See* General Motors Corp. v. Tracy, 519 U.S. 278 (1997).

123 *Id.* at 287 (citations omitted) (quoting Reeves, Inc. v. Stake, 447 U.S. 429, 437 (1980)). For a general discussion of the "Dormant Commerce Clause," *see* Lawrence H. Tribe, AMERICAN CONSTITUTIONAL LAW § 6-5 (2d ed. 1988).

124 969 F. Supp. 160 (S.D.N.Y. 1997).

125 *Id.* at 184. The court declined to reach a First Amendment challenge to the same statute. *Id.* at 183.

126 *Id.* at 168, *quoting* Younger v. Harris, 401 U.S. 37, 44 (1971).

127 Am. Libraries Ass'n v. Pataki, *supra* note 124, at 177.

interstate commerce is . . . a task squarely within the responsibility of Congress . . . ."[128]

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

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."[129]

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.[130] By contrast, the National Institutes of Health ranked tenth, with four hundred fifty two thousand hits.[131]

Dr. Koop has profited from the public's trust in him. 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."[132] Moreover, he recently assented to new management bent on the single goal of generating sales by capitalizing on consumers' views of Dr. Koop as an icon of medical integrity.[133]

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.[134] And the "cyberdocs" associated with cyberdocs.com not only "are always in," but appear to have prospered, as well.[135]

The issue has not gone unrecognized by professional organizations. The AMA ethics rules, for example, provide that "payment by or to a

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128 Bendix Autolite Corp. v. Midwesco Enters., 486 U.S. 888, 895-98 (1988) (Scalia, J., concurring).

129 Woody, *supra* note 77.

130 *See* Dunn, *supra* note 80. Presumably, the "unique individuals" measure does not count multiple visits by a single individual.

131 *Id.*

132 Noble, *supra* note 5, at A20.

133 *See* Park, *supra* note 72.

134 Healthcentral, *supra* note 44.

135 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 & WORLD REP., June 21, 1999, at 61.

physician solely for the referral of a patient is fee-splitting and is unethical."[136] But, the AMA's rule is as ineffective in cyberspace as are the Stark laws. It is ineffective because physicians prosper by referring consumers who often are not their patients.

Moreover, the Stark laws target a problem that 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. When consumers rely on website judgments because the sites are affiliated with a well-known physician, following those judgments may not best serve the consumers' health. Furthermore, the AMA's ethical premise has not 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 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."[137] It is problematic, however, when money corrupts professional judgment.

Applying the Stark laws to cyberspace will address the problematic attributes of online medicine while allowing the beneficial aspects to continue to exist. Websites can continue to offer information and link consumers with useful products and services, yet, physicians will not be able to profit from this 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 stated, "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."[138]

Applying the Stark laws in cyberspace will at least increase the likelihood that consumers get what they see. And then, perhaps, Net surfers will be able to distinguish "science and snake oil."[139]

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136 Noble, *supra* note 5, at A20.

137 *See* Claudia Kalb & Deborah Branscum, *Doctors Go Dot.Com?*, NEWSWEEK, Aug. 16, 1999, at 65.

138 *Id.*

139 Stolberg, *supra* note 1.