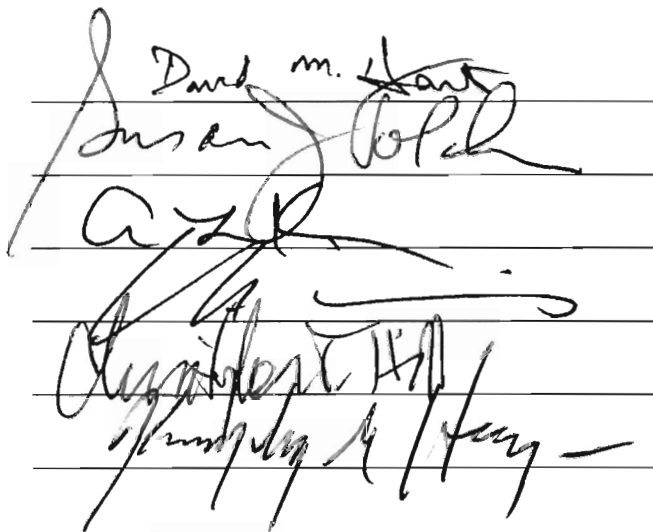


INTERNET DISSEMINATED MEDICAL INFORMATION: AN INVESTIGATION
OF THREE REGULATORY POLICY TOOLS

by

Kyle P. May
A Dissertation
Submitted to the
Graduate Faculty
of
George Mason University
in Partial Fulfillment of
The Requirements for the Degree
of
Doctor of Philosophy
Public Policy

Committee:

The image shows five handwritten signatures, each written over a horizontal line. From top to bottom, the signatures are: David M. Hart, Susan J. Tolchin, Gary L. Kreps, Linda M. Harris, and Christopher Hill. The signatures are written in dark ink and are somewhat stylized.

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An Investigation of Three Regulatory Policy Tools

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DEDICATION

This is dedicated to my parents Frank and Juliann. Without their unconditional and constant support and guidance, I would have struggled to complete this work. My two wonderful dogs, Abby and Griffin also provided loyal companionship through the long hours of research and writing.

ACKNOWLEDGEMENTS

I would like to thank the many friends, relatives, and supporters who have made this happen. Drs. Hart, Tolchin, Kreps, Harris, and the other members of the GMU School of Public Policy faculty were of invaluable help. Finally, thanks go out to the providers of high quality medical information that can be found on the Internet today. Their tireless dedication to providing users with up-to-date and relevant medical information allows consumers to play an important role in their personal health care.

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LIST OF ABBREVIATIONS

ACLU – American Civil Liberties Union
ACS – American Cancer Society
ACSI – American Customer Satisfaction Index
CAM – Complimentary and Alternative Medicine
CDA – Communications Decency Act of 1996
COPA - Child Online Protection Act of 1998
DOJ – Department of Justice
DSHEA - Dietary Supplement Health and Education Act
FDA – Food and Drug Administration
FFDCA – Federal Food Drug and Cosmetic Act
FTC – Federal Trade Commission
HON – Health on the Net Foundation
IDMI – Internet Disseminated Medical Information
ICRA – Internet Content Rating Association
IE – Microsoft Internet Explorer
IHC – Internet Health Care Coalition
JAMA – Journal of the American Medical Association
MICOM – Sundance Nachez Mineral Water
MSN – Microsoft Network
NCI – National Cancer Institute
NGO – Non-governmental Organization
NIH – National Institutes of Health
NLEA – Nutrition Labeling and Education Act
PSA – Public Service Announcement
SLD – Second Level Domain name
TLD – Top Level Domain name
UCLA – University of California at Los Angeles
URAC - Utilization Review Accreditation Commission
URL – Uniform Resource Locator
USDA – United States Department of Agriculture

ABSTRACT

INTERNET DISSEMINATED MEDICAL INFORMATION: AN INVESTIGATION OF THREE REGULATORY POLICY TOOLS

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George Mason University, 2008

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The advent of the Internet has been an information revolution that continues to have far reaching impacts on twenty-first century medical information consumers. Unlimited access to medical information may generally be considered a positive outcome of the Internet. However, when the information provided to users comes from questionable sources, provides intentionally or unintentionally inaccurate data or is otherwise tainted in its nature, questions arise over whether this type of medical information should be regulated. This work focused on three regulatory policy tools currently used to monitor Internet disseminated medical information, prohibition, information provision, and certification.

I. Introduction

The advent of the Internet has been an information revolution that has had and continues to have far reaching impacts on twenty-first century society¹. With a minimum of effort, an Internet user (user) can access a search engine and discover a wealth of information within a rapid period of time. All in all, access to information may generally be considered a positive outcome of the Internet. However, when the information provided to users comes from questionable sources, provides intentionally or unintentionally inaccurate data or is otherwise tainted in its nature, questions arise over whether this type of information should be regulated. This particular work is focused on Internet Disseminated Medical Information (IDMI) and the current prevalent regulatory mechanisms in place to monitor it.

Research Question

Regulation can play a key role in helping to ensure credible IDMI. Regulatory policy may take a variety of forms from highly restrictive to passive monitoring. The research question for this work is:

¹ Drucker, P.F., "The Second Information Revolution", *New Perspectives Quarterly*, 1997:14(2) pp 20-21.

Does current Internet regulation protect consumers from harmful medical information?

To answer this question, the author studied the effectiveness of three currently utilized policy tools. Empirical analysis of the prohibition, information provision, and certification tools aimed to answer:

- Is prohibition effectively preventing distribution of harmful medical information?
- Is information provision effectively promoting credible medical information?
- Is certification prevalent enough to effectively tell consumers the information they are gathering is credible?

Effectiveness for this work is defined as the ability to provide a desired outcome from a defined input. Effectiveness is a consensus determination that the intervention provides an acceptable result. For this work, the interventions are the policy tools: prohibition, information provision, and certification. The policy tools provided an acceptable result if the resultant consumer protection is at least as good as other alternative interventions. Alternative interventions may include user-applied tools and grass roots efforts discussed in the Regulatory Tools chapter. The interventions are studied individually and compared against each other.

Hypothesis

This investigation provides insight into the current regulatory nature of the Internet as it applies to medical information. The goal is to determine via an empirical analytical

method whether there is a significant difference in the data collected regarding the three policy tools under study. The three tools studied and their respective definitions follow:

Prohibition – This is the most restrictive policy tool available to regulators. It prevents the information from being distributed and aims to completely prevent the dissemination of the targeted information. The prohibition regulatory policy relies on compliance and enforcement to be effective.

Information Provision – Information Provision is accomplished by “functional” and “regulatory” forms. Functional information provision highlights the government’s duty to provide high quality information. Regulatory information provision focuses on ensuring the kind of data provided is within regulatory guidelines. This tool aims to provide credible information to users through sites that are actively monitored and maintained by experts in the medical community. Internet-provided information is also monitored by government agencies to ensure it is inline with established guidelines. It is not simply left to the discretion of the information provider to determine what is and what is not appropriate regarding the quality of information. The goal of information provision is to provide the user with the knowledge to potentially combat any faulty information available on the Internet. This tool relies on the user finding the specific sites containing the credible information and having the ability to differentiate credible and unreliable Internet sites.

Certification – This tool intends to provide an independent assessment of a site. The independent assessment provides the site a certificate that, when displayed, informs users what organization certified the site. The certificate tells the user that the site has

been reviewed by an independent organization and is required to provide information that is up to the standards of the certifying authority. The tool relies on the site remaining in compliance with the certifying organization after the certificate is granted. Additionally, the standards themselves must be adequate to credibly acknowledge good information from the bad thereby providing a worthwhile certification system.

Determining the efficacy of these three regulatory mechanisms was the focus of this work.

The author believes the following will result at the conclusion of the analysis:

Prohibition - This tool will be effective due to the reduction in the number of sites providing harmful IDMI. However, the author believes that due to vast nature of the Internet that information banned by the US Food and Drug Administration, US Federal Trade Commission or other US regulatory agencies will continue to be present on the Internet.

Information Provision - This tool will effectively provide useful IDMI to users in line with medical best practices and regulatory guidelines. It should be noted that user-entered search criteria will make the biggest impact upon the returned results of the search engines.

Certification – This tool will not effectively provide users with the guidance that sites displaying certification provide beneficial IDMI. This is because there will not be a significant number of IDMI sites that have a certification system in place.

In addition, the certification systems that are present will be a mixture of all of those available with no one system present on a clear majority of the sites.

The author hypothesized that, when viewed as independent policy tools, two of the three effectively regulate IDMI per the definition provided in the Research Question section of this chapter. Although the author believes that the certification tool will not be effective as a stand-alone policy tool, it will provide benefit to consumers as an additional protection when used in conjunction with other tools. The prohibition and information provision policy tools will demonstrate that they are each effective as stand-alone policy tools for IDMI consumer protection.

Evidence of the Problem

In this section, two specific examples are provided to demonstrate cases of actual harm befalling patients using health information they find on the Internet to remedy their maladies. The two cases mentioned below are specific to cancer as cancer was selected as the subject area of interest for this work. The reasoning for selecting cancer is detailed further in a later section “Selection of Cancer is IDMI Subject Area”.

- A death reported in a 2000 edition of the *Annals of Internal Medicine* was specifically attributed to the use of medical information and products gathered via the Internet. A 55-year-old cancer patient refused chemotherapy, radiation, and surgery to treat his condition and instead relied on hydrazine sulfate to self-treat his cancer. After four months the man presented at the hospital exhibiting

symptoms of liver and kidney failure due to the toxicity of the hydrazine sulfate.

He died one week after entering the hospital of multi-system failure.²

- In April of 2001, an unlicensed nurse was charged with manslaughter in the death of a cancer patient in Washington. The patient learned of the alternative cancer treatment through Internet marketing by the manufacturer and traveled from Louisiana to Washington for the MICOM treatment. The treatment was continued although the patient developed severe symptoms including chest pains, increased temperature, breathing difficulty, and decreased blood pressure. Five hours post-treatment initiation the patient's heart stopped.³ A physician testified during the successful prosecution of the nurse that high levels of potassium in the MICOM caused the patient's death⁴. The marketers of MICOM claim it is a "complex mineral solution" that increases intra-cellular oxygen preventing the growth of cancer. This claim that cancer was related to low cellular oxygen levels was studied and discounted years before this patient's death⁵.

A 2002 study published in JAMA suggested that there is a lack of evidence providing actual cases of harm to users of IDMI. However, the study authors go on to suggest that

² Hainer, M.I., N. Tsai, S.T. Komura, C.L. Chiu, "Fatal Hepatorenal Failure Associated with Hydrazine Sulfate." *Annals of Int Med*, v133 pp 877-880, Dec 2000.

³ "MICOM - alternative cancer treatment consisting of O2 MYGA III mineral water - contamination kills one and causes serious illness in another". *Townsend Letter for Doctors and Patients*. August 2001. FindArticles.com. accessed Jan 28, 2008.

http://findarticles.com/p/articles/mi_m0ISW/is_2001_August/ai_78177191

⁴ Barrett, S., "MICOM: A Simplistic Cancer "Treatment"", *Quackwatch* Jun 27, 2002, accessed Jan 2008 <http://www.quackwatch.com/01QuackeryRelatedTopics/Cancer/micom.html>

⁵ Green S. "Oxygenation therapy: Unproven treatments for cancer and AIDS", *Scientific Review of Alternative Medicine* 2(1):6-12, 1998.

this is not necessarily due to the actual low risk of harm to users but may in fact be due to the following reasons:

- Peer-reviewed literature provides a gross underestimate of harm as investigators focus on efficacy and effectiveness of treatment rather than harm or injury,
- Patients harmed by IDMI are not reporting their experiences out of a sense of shame or guilt for not relying on their primary caregivers,
- Healthcare professionals do not question patients about their Internet usage or the information they gather online subsequently missing any occurrence of harm,
- Healthcare professionals may in fact be aware of harm incurred by patients using inappropriate information from the Internet but are not submitting the cases for publication, and/or
- Cases of patients being harmed by IDMI are available but are secondary to the lead part of the investigation making them difficult to locate or they were simply not accepted for publication⁶.

The following paragraph provides additional insight into the problem.

Problem Statement

The principal benefit of using the Internet to disseminate medical information is that it is freely and easily available. The Internet provides a forum for discussion and coalition of

⁶ Crocco, A.G., Villasis-Keever, M., Jadad, A.R., “Analysis of Cases of Harm Associated With Use of Health Information on the Internet”, JAMA v287:21 p2869-2872 Jun 5, 2002.

persons with common (and sometimes rare) medical conditions to access and share information of critical interest⁷. However, it also provides a platform for anyone willing to make a medical claim. This may render the information questionable as it can be freely and easily produced and provided by anyone. A free and open forum may be desirable for encouraging unrestricted debate it is questionable whether the IDMI provided is safe and up to the standards set by the medical community. Suspect medical information may need greater oversight through regulatory policy to prevent harm to consumers. Currently, there are some regulatory mechanisms to monitor claims made by companies regarding their health products. Medical claims that are not supported by the product labeling are vigorously scrutinized⁸. The US Food and Drug Administration leads this effort although the sheer volume of web sites (estimated at greater than 100,000 health-related Web sites on the Internet) hinders thorough auditing and enforcement.⁹

The previous section illustrated two specific cases highlighting a growing concern in the medical community of consumers incurring harm by relying on unsafe IDMI¹⁰. The use of the Internet as a health communication channel continues to grow as users seek to gain more information regarding their medical welfare. Vast amounts of information are now

⁷ Dearlove OR, Sharples A, Stone C., "Internet Is Useful for Information On Rare Conditions [letter]", *BMJ* 1997;315 p491.

⁸ Food and Drug Administration White Paper, "Protecting the Public Health: FDA Pursues an Aggressive Enforcement Strategy", June 30, 2003.

⁹ Risk A., Dzenowagis J., "Review of Internet Health Information Quality Initiatives", *J Med Internet Res* 2001, December 26:3(4): e28.

¹⁰ Weisbord, S.D., Soule, J.B., Kimmel P.L., "Brief Report: Poison Online – Acute Renal Failure Caused By Oil of Wormwood Purchased Through the Internet", *N Eng J Med*, p825:337 1997.

immediately available by simply conducting an inquiry using any search engine.

However, the quality of this information ranges from very good to very bad. A very good resource may be equivalent to a peer reviewed journal article that has gone through extensive review by established experts in a field. Unsafe resources may come from individuals with hidden agendas including, anti-social, anti-government, and/or profiteering alignments. The sophisticated Internet user might discern the good from the bad by assessing the provider's information based on criteria such as; the website's affiliation, intended audience, timeliness, revision dates, and a multitude of other discriminators. However, assessment of information based on such criteria may not be enough. Consequently, users may need to rely upon regulatory practices for protection against poor information.

Regulation

The term regulation has come to have different meanings to different groups of people.

Often the term is used to describe governmental action. To some this means enacting policies (legal rules, enforceable by the courts that are set forth through the legislative process) on corporations that dictate how certain aspects of the business should run. To others it means holding corporate America accountable for its actions regarding personnel, the environment and potentially hazardous products and information. Kenneth Meier defined regulation in 1985 as, "regulation is any attempt by the government to

control the behavior of citizens, corporations, or subgovernments.”¹¹ In 2000 Eisner et al. defined regulation in a narrower context arguing that Meier’s definition was too broad. They defined regulation as, “an array of public policies explicitly designed to govern economic activity and its consequences at the level of industry, firm, or individual unit of activity.”¹² Eisner et al. prefer to look at regulatory policy from a microeconomic perspective as opposed to the macroeconomic. For the purposes of this work, a combination of the Eisner and Meier regulatory definitions was used to investigate the regulation of IDMI. This work identified regulatory practices enacted by federal, non-profit and commercial institutions aimed to protect the medical information consumer.

More specifically the term “regulation” is used in this work to encompass the legally binding governmental actions of passing legislation to determine the types of information that can be provided on the Internet. It also takes into account the certification systems that are employed by different non-governmental institutions and the standards of those systems. With regard to Internet disseminated medical information, the government prohibits certain information from being provided to consumers via websites. If banned information is provided, there is legislation in place whereby the website owner is held legally responsible and may face criminal legal action. In contrast to the prohibition of information, the government also has mandates to provide high quality information to consumers. The E-Government Act of 2002 has as one of its provisions the following:

¹¹ Meier, K.J., “Regulation: Politics, Bureaucracy, and Economics.” New York, St Martins Press, 1985.

¹² Eisner, M.A., E.J. Ringquist, J. Worsham, “Contemporary Regulatory Policy”, Boulder CO, Lynne Rienner Publishers, 2000.

- *To promote access to high quality Government information and services across multiple channels*¹³

Regulation covering the certification systems focuses on the actions and standards of the non-governmental institutions that provide certificates to websites that meet a set of criteria outlined by these entities. While the certifying bodies develop and enforce their own set of standards, there remains government oversight as to the type of information that can be provided. For example, even if a site has a certificate it still must remain in compliance with the standards set forth by the governmental regulations.

General Methodology

The prohibition, information provision and certification policy tools were analyzed in a similar manner. Specifics regarding each methodology are provided in the chapter dedicated to the respective policy tool. This section provides a general view of the methodology from the perspective of analyzing the three policy tools.

The analysis started with a review of the relevant publications specific to the policy tool in question. This included such information gathered from court transcripts, papers released from regulatory agencies, and health care policy position papers. The next step was to enter in the selected search terms into the most highly used search engines.

¹³ US Office of Management and Budget, “The E-Government Act of 2002”, The White House, accessed Aug 2008, <http://www.whitehouse.gov/omb/egov/g-4-act.html>

Specifics regarding the selection of the search terms are provided below in the following “Selection of Search Terms” section. Specifics regarding the selection of the search engines are provided below in the “Selection of Search Engines” section. The top ten results of each of the five search terms for each of the three search engines were collected. As this work aimed to critique the effectiveness of each policy tool independently, there are 150 data points for each empirical section; 10 results per each of the 5 terms for each of the 3 search engines. Assessment of each of the sites was specific to the policy tool being studied. The specifics regarding the assessments are provided in the “Prohibition”, “Information Provision”, and “Certification” chapters.

Selection of Cancer as IDMI Subject Area

After consideration of the many highly searched medical topics typically entered by users into common search engines, cancer was selected as the primary topic of interest for this work. The specific types of cancer studied are described in detail in the Methods chapter. Cancer is the medical condition selected for testing of each of the three policy tools under investigation, prohibition, certification, and information provision, as it is a topic that has been exploited by the unscrupulous marketers of products with highly questionable clinical benefit¹⁴⁻¹⁵. Previous studies¹⁶⁻¹⁷ and the author’s preliminary research indicated

¹⁴ German, N.G., “Quack Healer Arrested”, Lancet 1997:349 p1679.

¹⁵ De Bousingen, D.D., “Austrian Cancer Patient’s Parents Sentenced”, Lancet 1996:348 p1440.

¹⁶ Impicciatore P., Pandolfini C., Casella N., Bonati M., “Reliability of Health Information for the Public on the World Wide Web: Systematic Survey of Advice on Managing Fever in Children at Home”, BMJ 1997:314 p 1875-81.

¹⁷ Culver, J.D., Gerr, F., Frumkin, H., “Medical Information on the Internet: A Study of an Electronic Bulletin Board”, J Gen Intern Med 1997:12 p 466-70.

that a user might find many sites providing information of questionable value to an individual seeking medical information. However, as cancer is the second leading cause of death in the US¹⁸, there is also a great deal of work being done to ensure that the information that is available:

- Does not provide guidance banned by regulatory agencies¹⁹,
- Conforms to the standards set forth by US regulatory agencies²⁰, and
- Is of high quality as perceived by independent oversight²¹.

In order to accurately assess the effectiveness of the policy tools under investigation in this work, the medical topic selected needed to have a high profile to the user population including: government agencies, the medical community, researchers, patients, and the general public. A less common medical condition may not warrant as much oversight from the aforementioned stakeholders and thus may not provide a good basis for analysis of the effectiveness of the policy tools. Low profile medical conditions may provide less analyzable data as there would be fewer sites dedicated to the topic. Cancer, on the other hand, has been a high profile topic for quite some time in the US as evinced by the over 30 year War on Cancer declared by President Nixon in 1971 when he signed the National

¹⁸ National Cancer Institute, “SEER Cancer Stats Fact Sheet”, Jan 2007, <http://seer.cancer.gov/statfacts/>

¹⁹ Eysenbach G., Diepgen, T.L., Muir Gray J.A., Bonati M., Impicciatore P., Pandolfini C., Arunachalam S., “Towards Quality Management of Medical Information on the Internet: Evaluation, Labelling [sic], and Filtering of Information”, BMJ 1998;317 p1496-1502.

²⁰ Ibid

²¹ Ibid

Cancer Act²². Recent findings released by the National Cancer Institute estimate 1.4 million new cancer cases in the US in 2006 (not including skin cancers which account for another 1 million cases)²³. There is considerable interest in the disease and it continues to draw significant resources in order to better diagnose, treat, and eventually identify a cure. It is highly likely that most US residents will either have cancer or be close to someone who has cancer. There is a lifetime incidence of cancer of nearly 1 in 2 for men and 1 in 3 for women²⁴.

Users rely on the Internet for cancer information. Eysenbach and Kohler found that 5% of all health related searches were specific to cancer²⁵. As an estimated 95 million users have used the Internet seeking health information²⁶ this equates to roughly 4.5 million users seeking cancer information online and thousands of searches on cancer per day. A 2003 Pew study reported that 80% of adult Internet users (estimated 93 million Americans) search for health information online. These respondents, “reported that their use of the Internet made them feel more independent from their physicians, empowered to ask more informed questions during patient visits, and allowed them to be less fearful

²² Haran, C., DeVita, V., “The View From the Top”, Cancer World, June–July 2005 pp38–43.

²³ National Cancer Institute, “SEER Cancer Stats Fact Sheet”, Jan 2007, <http://seer.cancer.gov/statfacts/>

²⁴ National Cancer Institute, “SEER Cancer Stats Fact Sheet”, Jan 2007, <http://seer.cancer.gov/statfacts/>

²⁵ Eysenbach, G., C. Köhler, “Health-related Searches On the Internet” JAMA. 2004 Jun 23;291(24):2946.

²⁶ Fox, S., “Health information online: eight in ten Internet users have looked for health information online, with increased interest in diet, fitness, drugs, health insurance, experimental treatments, and particular doctors and hospitals” Washington DC: Pew Internet & American Life Project; 2005.

of the unknown”.²⁷ As such, claims about prevention, treatment and cures receive quick and focused attention from users and regulators.

Unfounded cancer-curative claims may lead to regulatory action through the use of all three of the policy tools investigated in this work. Depending on the information provided, the authorized regulatory body may take action to prohibit the dissemination of the information in question. A second alternative is to combat suspect medical information with high-quality information. The purpose of information provision is to supply a wealth of credible knowledge with the expectation of drowning out the bad. Existing information about cancer prevention and treatment is established and provided via numerous commercial, educational, nonprofit, non-governmental organizations, and government institutions. Finally, the use of a third-party review system may offer users some assurance that a site displaying the certificate provides believable medical information. The use of one or some combination of the three policy tools provides users some regulatory protection against suspect cancer information.²⁸

This introductory chapter provided the reader with the problem, the author’s hypothesis, and why the author selected cancer as the IDMI subject area. The following chapters provide the reader with:

²⁷ Pew Internet and American Life Project, “Internet is Valued for Health Information Seekers”, *Drug Benefit Trends* 2003:15(8): pp 8-11.

²⁸ Charnock, D., Shepperd, S., Needham, G., Gann, R., “DISCERN: An Instrument for Judging the Quality of Written Consumer Health Information on Treatment Choices”, *J Epid Comm Health*, 1999:53 p105-111.

- The background of regulatory policy related to Internet information and user protection,
- The types of regulatory tools generally available as well as specific descriptions of the three tools studied in this work,
- The institutions that provide oversight of IDMI and the organizations providing the actual information itself,
- A detailed look at the methods developed for this work,
- One chapter for each of the three policy tools studied, prohibition, information provision and certification, investigating and discussing the results of each analysis, and
- Concluding remarks about the work.

II. Background

As the Internet continues to become an ever more prevalent medium of information exchange, more and more people are turning to it as a source for their medical information. A study performed by Peterson and Fretz in a Midwestern University hospital, published in 2003, indicated that, “the Internet was the most commonly used nonphysician resource”.²⁹ Another earlier study conducted by Peterson indicated that most sites providing medical information fail to meet “even minimum quality standards”.³⁰ Additional studies ranging on topics from orthopedic information to mammography to macular degeneration support Peterson’s conclusions that IDMI fails to consistently provide patients with high quality information.^{31,32,33,34} The conclusion reached from these studies is that the user has to take the responsibility to interpret IDMI to discern the good from the bad. Unfortunately, IDMI sites are often written at a reading

²⁹ Peterson, M.W., Fretz, P.C., “Patient Use of the Internet for Information in a Lung Cancer Clinic”, *Chest* 2003;123(2) pp 452-457.

³⁰ Peterson M.W., “Continuing Medical Education on the Internet”, *J Contin Educ Health Prof* 2000;19 pp 242-249.

³¹ Mclung, H.J., Murray, R.D., Heitlinger, L.A., “The Internet as a Source of Current Patient Information”, *Pediatrics* 1998;101 e2.

³² Tamm, E.P., Raval, B.K., Huynh, P.T., “Evaluation of the Quality of Self-education Mammography Material Available for Patients on the Internet”, *Acad Radiol* 2000;7 pp 137-141.

³³ Stone, T.W., Jumper, J.M., “Information About Age-related Macular Degeneration on the Internet”, *South Med J* 2001;94 pp 22-25.

³⁴ Beredjiklian, P.K., Bozentka, D.J., Steinberg, D.R., “Evaluating the Source and Content of Orthopaedic Information on the Internet: The Case of Carpal Tunnel Syndrome”, *J Bone Joint Surg Am* 2000;82A pp 1540-1543.

level significantly above the average reading level of the typical user.³⁵ It is possible then that the user might turn to the Internet and attempt to interpret the usefulness or quality of medical information that s/he may not be able to comprehend. The author believes the assessment by Peterson and others that users must take primary responsibility for information they gather is flawed. Consumers may be mistaken in their analysis of IDMI they gather or be duped in to believing sophisticated marketing campaigns. Possibly harmful IDMI requires regulatory oversight for adequate user protection.

Regulatory Policy

Prior to addressing the specifics of IDMI regulation, it is important to understand the purpose of regulatory policy. There are several theories regarding the purpose of governmental regulation. For this work, the most relevant theory of regulation is captured in the following ideology: policies attempting to correct and/or compensate for market failure. Market failure occurs due to the existence of imperfect competition, negative externalities, and/or the type of product or distribution having informational asymmetry resulting in inefficiency³⁶. For IDMI, market failure may occur due to the nature of the product and information asymmetry. The producer of harmful IDMI may have complete knowledge that the information provided is in fact erroneous and yet

³⁵ Graber, M.S., Roller, C.M., Kable, B., "Readability Levels of Patient Education Material on the World Wide Web", J Fam Prac 1999;48 pp 58-61.

³⁶ Williamson, O.E., "The Vertical Integration of Production; Market Failure Considerations", The American Economic Review, Vol. 61 v2, Papers and Proceedings of the Eighty-Third Annual Meeting of the American Economic Association. p112-123 May, 1971

provides it to a consumer who may not have the ability to comprehend the information is invalid.

Regulation of Pre-Internet Medical Information

The dissemination of credible medical information prior to the advent of the Internet relied on the actions of authoritative sources. Authoritative information is that which can be verified and documented and is produced by an individual (professional or otherwise) who is held responsible for the content. Typically this information was produced via professionals using the scientific method working at or in connection with accredited universities and/or government institutions. Wudka defines the scientific method as:

- Make an observation of a notable feature of the universe,
- Invent a tentative description (hypothesis) consistent with the observation,
- Make predictions based on the hypothesis,
- Test the predictions by experimentation or through additional observations,
- Modify the hypothesis based on the results of the experiments or observations,
- Repeat the intermediate steps until there are no discrepancies between hypothesis and experiment and/or observation.³⁷

Experts employed by universities or the federal government are generally considered as more authoritative when compared to those that are not. In addition to using the scientific method, this may be due to the reasoning that government and academic settings are more conducive to independent, objective thinking. Collin's book, The Credential Society sheds some light on society's acceptance of the university as respectable. By continually stating that earning degrees was the only route to the elite

³⁷ Wudka, J., "The Scientific Method", University of California, Riverside, Physics, Sep 1998.

positions in the professional world, the academic system realized a self-fulfilling prophecy. Universities grew and thrived until the undergraduate and graduate degrees were accepted to have specific payoffs.³⁸ As society accepted the university as a respectable institution of study, the authority of research and information stemming from university employees was set. This in turn led to the peer-review process whereby a university author's work was submitted to experts in the same or similar fields at other universities. Specific to medical information, peer-review became the standard for publishing in leading journals such as the Journal of the American Medical Association (JAMA).

The power of the university institution has survived the Internet revolution because as Agre notes, "Institutions are not driven in any direct way by technology. Institutions are political, and they change through a complicated and diffuse sort of collective bargaining among the various stakeholder groups."³⁹ Consequently, pre-Internet dissemination of credible medical information was reliant primarily on authoritative sources identified through their affiliations with institutions of higher learning. The traditional gatekeeper of pre-Internet medical information was the family doctor.⁴⁰ This physician had clear links to the institution of higher learning s/he attended for medical school as well as (presumably) ongoing continuing education to keep current with the changing nature of

³⁸ Collins, R., "The Credential Society", Academic Press Inc, NY, NY, 1979.

³⁹ Agre, P.E., "The Wired Car in the Wired World", Dep of Inf Studies, U of CA LA, Sep 2001.

⁴⁰ Arora, N.K., "Interacting with Cancer Patients: The Significance of Physicians' Communication Behavior", Soc Sci Med. 57:791-806, 2003.

the medical field. This established a pattern of trust between medical provider and patient and a trusted authoritative resource for treatment options.⁴¹ Additional avenues available to those seeking medical information included but were not limited to; personal physicians (and other health care providers), common knowledge from friends, family, and acquaintances (that included misinformation such as old wife's tales), the popular press, medical journals, public service announcements, distributed literature, advertising campaigns, and textbooks.

Though pre-Internet medical information was provided by a variety of sources, there were naturally instances of medical information dissemination of a questionable nature. One common term for such information and products in the US vernacular is snake oil commonly distributed during the course of US history by the disreputable snake oil salesman. The label of "snake oil" has come to mean, "any of various liquid concoctions of questionable medical value sold as an all-purpose curative, esp. by traveling hucksters"⁴². Spreading falsehoods, misrepresentations, and outright dishonest claims are activities of the dishonest, the frauds, and those that are corrupt. These are the attributes necessary in the snake oil trade. Rawls commented on the principles of fairness that can be applied to moral trade stating, "The question of fairness arises when free persons...engage in a joint activity [e.g. an exchange of information] will strike the

⁴¹ Eng, T.R., Maxfield, A., Patrick, K., Deering, M.J., Ratzan, S.C., Gustafson, D.H., "Access to Health Information and Support: A Public Highway or a Private Road?", JAMA 280:1371-1375, 1998.

⁴² Dictionary.com "Snake Oil." Unabridged (v 1.1). Random House, Inc. Feb 2007.
[http://dictionary.reference.com/browse/snake oil](http://dictionary.reference.com/browse/snake+oil)

parties as fair if none feels that, by participating in it, they or any of the others are taken advantage of...”⁴³ This speaks directly to distribution of false medical information with the primary goal of targeting people with serious health conditions and taking advantage of their situation. This occurred prior to the advent of the Internet and continues today via the Internet.

Internet Regulation

Regulatory policies for the Internet require special considerations. DeAngelo captures the challenges of Internet regulation stating, “Governing the Internet is an international effort, with organizations from around the globe contributing information and opinions... It is a complex, ongoing effort that requires constant effort to meet evolving technical and social requirements.”⁴⁴ It is questionable whether there can be global concurrence as to regulating the Internet.

The Internet has been referred to by Klein as the modern day “wild west”.⁴⁵ There is little effective regulation and even less enforcement. Due to its boundless nature, governance of the Internet should be an international effort. However, to date, the debates still continue regarding whose rule of law should be applied. Private groups such as the Internet Corporation for Assigned Names and Numbers (ICANN), formal

⁴³ Rawls, J., “Collected Papers”, edited by S. Freeman, Harvard Univ Press, 1999, p 59.

⁴⁴ DeAngelo, N., “Internet Standards and Controlling Bodies”, Faulkner Information Services, May 2005.

⁴⁵ Klein H., “ICANN Reform: Establishing the Rule of Law”, Internet and Public Policy Project, WSIS Policy Analysis, Atlanta GA, Nov 2005.

standards organizations such as the Internet Society (ISOC) and even international consortiums such as W3C have indicated they will provide foundational standards, protocols, and stability. However, the complexity of the effort due to the changing social and technical requirements requires constant vigilance and flexibility.

Good governance over the Internet, should the global community eventually decide that it is necessary and enforceable, should rely on the rule of law, as do other regulatory agencies. As of this writing, there has been no effective or enforceable regulatory body proposed for the Internet. ICANN, as a private entity, has attempted to fulfill this role but has been largely unsuccessful. Decision-making rules are changed, ignored, or not enforced. This has led to calls by many echoed through the sentiments of Baird, “A reliance on markets and self-policing has failed to address adequately the important interests of Internet users such as privacy protection, security, and access to diverse content”.⁴⁶

Regulation of non-Internet Dispersed Medical Information

This work focused on three specific regulatory tools, prohibition, information provision and certification. There are instances in non-Internet dispersed medical information where these tools are in force. In advertising for example, the FDA has mandated that certain medical claims about a product cannot be provided without prior investigation and

⁴⁶ Baird Z., " Governing the Internet: Engaging Government, Business, and Nonprofits", Council on Foreign Relations: Foreign Affairs Journal, Nov-Dec 2002.

authorization from the administration. A company is prohibited from making these claims through the media for consumer consumption without having first gone through a rigorous process of evaluation. Information is provided through a variety of public service announcements (PSA) on television, in magazines, on the radio and in newspapers to impart on consumers important information relevant to their overall health. These PSAs have covered a variety of topics and employed well-known celebrities and cartoons to relate information on the dangers of smoking, wearing seatbelts, to a satirical look at a human brain on drugs. Certification of information has also occurred through the self-regulatory tool of reporting conflicts of interest and credentialing.

According to a recently released report by the National Cancer Institute, many Americans continue to receive their medical and health information via the news media⁴⁷. The report studied the use of TV, radio, magazines, and newspapers by seekers of health information. With the inaccuracies that are inherent in these mediums of information provision, it is important to understand regulatory policy for the media ensuring consumer protection. One avenue of regulatory policy for non-Internet disseminated medical information is through the adoption of a set of criteria or guidelines that outline the type of information that can be provided to consumers. This is a form of self-regulation and is described in more detail in the form of journalistic oversight in the following paragraph. Haufler notes that technically, regulation is an act or behavior that

⁴⁷ Rutten L.F., Moser R.P., Beckjord E.B., Hesse B.W., Croyle R.T.. “Cancer Communication: Health Information National Trends Survey”, Washington, D.C.: National Cancer Institute. NIH Pub. No. 07-6214 2007.

is mandated by government institutions and consequently cannot be considered voluntary⁴⁸. However, taking the term self-regulation in a wider context it can be understood to include entities adhering to a set of standards and following (sometimes unwritten) guidelines voluntarily. These are adopted where the industry believes additional guidelines are needed and to potentially prevent additional governmental action. Enforcement of self-regulatory policies is handled by the industry itself. Chayes describes industry self-regulation agreements in the following:

The agreements vary widely in scope, number of parties, and degree of specificity, as well as in subject matter. Some are little more than statements of principle or agreements to agree. Others contain detailed prescriptions for behavior in a defined field. Still others may be umbrella agreements for consensus building in preparation for more specific regulation later. Often they create international organizations to oversee the enterprise⁴⁹.

The guidelines are employed to assist the information provider to remain within the regulatory standards set forth by legislative mandates.

Another method for monitoring non-Internet dispersed medical information is through journalistic oversight. Leading peer-reviewed science and medical journals have in place the policy to report any potential conflicts of interest. The lay press is slowly adopting this as well. In 2004, the New York Times issued a memo to reporters that encouraged them to reveal apparent conflicts of interest in their medically related stories.⁵⁰ However,

⁴⁸ Haufler, V., "A Public Role for the Private Sector: Industry Self-Regulation in a Global Economy", Carnegie Endowment For International Peace, Washington DC 2001.

⁴⁹ Chayes, A., A.H., Chayes, R.B., Mitchell, "Managing Compliance: A Comparative Perspective", Brown, Weiss and Jacobsen, Engaging Countries, Cambridge, MA, 1999.

⁵⁰ Okrent, D., "Analysts Say Experts Are Hazardous to Your Newspaper", New York Times, Oct 31, 2004: Sect 4: 2.

in deference to First Amendment of the United States Constitution rights to freedom of the press, these are “encouragements” and not regulations. Since regulation would potentially be in conflict with the First Amendment, there is a call for credentialing of medical journalists. ABC News’ Dr. Timothy Johnson and University of Minnesota School of Journalism’s Gary Schwitzer are championing this call. As Schwitzer points out, “some meteorologists are credentialed. Are personal health decisions less important than the weather?”⁵¹

IDMI Regulation

There are calls for additional protections for consumers of Internet disseminated medical information. Beyond the three policy tools that are the focus of this work, prohibition, information provision and certification, some experts call for patient education as a primary consumer protection tool. It is argued that a properly implemented patient education and/or consumer awareness campaign may be more beneficial than legislative action.

Many experts such as Medscape’s Dr. Lundberg have called for some form or other of regulation to assist users in determining credibility of IDMI. However, they tend to agree that this should not stem from governmental action. Lundberg points out that

⁵¹ Schwitzer, G., “Ten Troublesome Trends in TV Health News”, BMJ 329, 2004: 1352.

governmental regulation of information provision leads to “total censorship”.⁵² Kassirer notes that while, “The federal government has an obligation not only to provide reliable Web sites from its outstanding health and medical institutions but also to educate the public about how to identify erroneous and misleading material... [however] a full-fledged regulatory system with legal restrictions, surveillance mechanisms, and punishments to cope with medical sources on the Internet is unworkable and probably unconstitutional”.⁵³ The emphasis is placed on training the user to be able to understand and appreciate the differences in the quality of information presented on the Internet. This presents quite a challenge and may require a great deal of effort on the part of physicians, scientists, and government educators to implement.

Warnock, writing for Project HOPE, suggests that the physician will take a primary responsibility for patient education on IDMI, “One of the most important jobs of the primary care physician, in a Web-enabled health care system, will involve helping patients differentiate good [Internet] information from bad”.⁵⁴ This relates directly to the information provision and certification policy tools studied in this work. Providers can tell their patients about certified websites where the patient can access medical information provided as a public service. Such sites as those hosted by the National Institutes of Health and the Centers for Disease Control (to name just a couple) may

⁵² Guadagnino, C., “Using Medical Information on the Internet”, *Phys News Dig*, Jul 2000.

⁵³ Kassirer, J.P., “Patients, Physicians and the Internet”, *Health Aff* 2000:19(6) pp 115-23.

⁵⁴ Warnock III, A., “Vaporware.com: Why the Internet Will Be the Next Thing Not to Fix the US Health Care System”, *Health Aff* 2000:19(6) pp 57-71.

provide the patient with the appropriate resources necessary to review all Internet medical information with a critical eye. As more patients turn to the Internet for their health care concerns, it becomes very important to train them to interpret what they find or at least read with an attitude of skepticism. From a larger perspective, patients using information provided by uncertified sites may attempt to self-diagnose with little to no ability to make sound medical judgments. An inaccurate self-diagnosis with resulting unwanted results is the type of situation that consumer protection regulatory policy may address. Self-diagnosis by patients should not be condoned and is one of the hallmarks of certified medical sites. For example, the National Institutes of Health site makes the following statement:

It is not the intention of NIH to provide specific medical advice, but rather to provide users with information to better understand their health and their diagnosed disorders. Specific medical advice will not be provided, and NIH urges you to consult with a qualified physician for diagnosis and for answers to your personal questions.⁵⁵

Instead of simply dismissing a patient's search for IDMI, the physician (scientist or government educator) must provide the criteria necessary for a patient to understand that some IDMI is, in fact, not only questionable, but can actually be dangerous.

According to Kassirer, the courts system will become involved as lawsuits begin to appear regarding the provision of substandard medical advice via Internet sites. The resulting malpractice lawsuits, Kassirer argues, will not be an adequate tool to contend

⁵⁵ US Department of Health and Human Services, "National Institutes of Health Disclaimer", Apr 2007, Jun 2007 <http://www.nih.gov/about/disclaim.htm>

with the quality of IDMI and will instead be a clumsy and ineffective method. To date, there have been a few successful legal attempts to proactively address the dissemination of bad IDMI. This issue is addressed in more detail in the Prohibition section of this work.

User Protection

Through the course of this research the question of why users trust the information they gather via the Internet arose time and again. There may be many reasons. It may be due to the fact that users hope to find the answer to a personal, family member's, or friend's medical condition. Sites using medical jargon may allow the user to feel s/he has found a reputable site and subsequently believe what they read. Testimonials on a site from other patients that the information is true and alleviated their condition allow the user the hope to believe they have identified the answer. It may be argued that some patients are willing to try anything they see as potentially beneficial if their traditional therapies are not producing the desired results. Users that fall prey to medical misinformation disseminated via the Internet fail to grasp the fact that just because something is online, does not make it true. It is unfortunate, but non-scientist users typically do not apply sound principles when deciding on the trustworthiness of IDMI. Dr. Michael Lundberg, former editor-in-chief of the Journal of the American Medical Association and current editor-in-chief of Medscape, offers the following comments that users should follow when determining IDMI credibility:

First, "Who wrote what they're reading?" A lot of sites don't even have the names of who wrote it. Second, you ought to be able to tell where that person works so you can find them if you need them. Third, if information has come from somewhere else, it should be attributed as to what its origin was. Fourth, you need to be able to tell quickly who owns the site and where the money comes from to keep it going. And fifth, the timing of material that's put there and if it's been updated should be clearly stated. So these five questions—authorship, institution, attribution, financing and timing—are the key points to look at on a medical Internet site.⁵⁶

Lundberg's points are a good guideline that may be used by the user to help determine credibility in a general sense. They however, may be difficult to apply, as the answers to his questions may not be readily available without undue effort on the part of the user. A user going to the American Cancer Society's (ACS) page at www.cancer.org would not be able to quickly answer the five questions posed by Lundberg depending on the article selected. A recent visit to the ACS site provided an article on colon cancer that provided some but not all of the information for Lundberg's criteria. The article, "What You Eat May Influence Colon Cancer Relapse"⁵⁷ did not provide an author or where the author worked but did provide a date, citation to a JAMA article, and it is possible to find out where ACS funding comes from though the user would have to search elsewhere on the site.

Additional User Protection Guidelines

Lundberg's five criteria were not the only attempt at lending credibility and authority to IDMI. The US Government also provided guidelines for users to determine the level of authority any such website content may have. Work completed in 1999 by the

⁵⁶ Guadagnino, C., "Using Medical Information on the Internet", Phys News Dig, Jul 2000.

⁵⁷ American Cancer Society, "What You Eat May Influence Colon Cancer Relapse", Aug 2007, Jan 2008 http://www.cancer.org/docroot/NWS/content/NWS_1_1x_What_You_Eat_May_Influence_Colon_Cancer_Relapse.asp

Department of Health and Human Services' Scientific Panel on Interactive Health Communication called for a number of factors to assist in determining the authority of IDMI. Some of these factors included; credibility, content, disclosure, and linking. Credibility arose from citing trustworthy sources. Content focused on accuracy based on evidence and verification. Disclosure clearly informed the user of the site's purpose. Links within and without the site must be clear and easy to navigate with vigilant oversight.⁵⁸ The implementation of these factors to allow users to form opinions regarding the authority and credibility of a site may come to fruition based on regulatory action.

Other non-governmental organizations have attempted to establish criteria aimed at protecting the user from unreliable or at the very least, unsubstantiated information concerning human health. One of the organizations is Quackwatch. Quackwatch's mission statement is:

Quackwatch, Inc., which was a member of Consumer Federation of America from 1973 through 2003, is a nonprofit corporation whose purpose is to combat health-related frauds, myths, fads, fallacies, and misconduct. Its primary focus is on quackery-related information that is difficult or impossible to get elsewhere. Founded by Dr. Stephen Barrett in 1969 as the Lehigh Valley Committee Against Health Fraud, it was incorporated in 1970. In 1997, it assumed its current name and began developing a worldwide network of volunteers and expert advisors.⁵⁹

Another is the National Council Against Health Fraud. Their mission statement is similar to that of Quackwatch:

⁵⁸ Rippen, H.E., "Criteria for Assessing the Quality of Health Information on the Internet", May 1999 <http://hitiweb.mittek.org/iq/onlycriteria.html> 2004.

⁵⁹ Quackwatch, "Mission Statement", Jul 2007, Aug 2007, <http://www.quackwatch.com/00AboutQuackwatch/mission.html>

The National Council Against Health Fraud is a nonprofit, tax-exempt voluntary health agency that focuses its attention upon health fraud, misinformation, and quackery as public health problems. It is private, nonpartisan, and nonsectarian. Its members are health professionals, educators, researchers, attorneys, and other concerned citizens. Its officers and board members serve without compensation. This site contains hundreds of articles that can help people evaluate health claims. The Council originated in 1977 as the Southern California Council Against Health Fraud, Inc. and became the California Council Against Health Fraud in 1978. The council became national in 1984. It is now incorporated in California and has members in all 50 states, the District of Columbia, and several foreign countries. Nearly all of our funding comes from membership dues and individual contributions.⁶⁰

Both Quackwatch and the National Council Against Health Fraud are private non-profit organizations dedicated to dispelling the prevalence of medical misinformation.

However, non-profit organizations have limited regulatory and enforcement capabilities. Consequently it is *caveat emptor* as FDA's Bill Rados notes, "you must protect yourself by carefully checking out the source of any information you obtain."⁶¹

First Amendment Consideration

There exists an issue with the publication of medical misinformation on the Internet. One issue that arises with any published material is freedom of speech. Some might argue that persons should be free to publish and speak whatever they wish. The US takes great care to protect the first amendment to the US Constitution that reads in part "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press..."⁶² Regardless of one's

⁶⁰ National Council Against Health Fraud, "NCAHF Mission Statement", Jun 2001, Aug 2007, <http://www.ncahf.com/about/mission.html>

⁶¹ US FDA, "Health Information Online", Food and Drug Administration Consumer Magazine, Apr 1999.

⁶² U.S. Const. amd. I

feelings towards free speech, officials at the US Food and Drug Administration consider the spread of medical misinformation concerning. A compliance officer in FDA's division of labeling and nonprescription drug compliance relates the following story:

A physician was browsing the Web when he came across a site that contained a fraudulent drug offering. He called us to report it. The person who maintains the site claimed he had a cure for a very serious disease, and advised those with the disease to stop taking their prescription medication. Instead, they were told to buy the product he was selling, at a cost of several hundred dollars.⁶³

Such instances are not isolated on the Internet and users are exposed to claims both more and less serious than this FDA anecdote.

The expansive nature of the Internet has provided significant regulatory challenges for policy makers wishing to decrease abuses such as defrauding or misleading consumers. Information is provided from all over the world leading to many problems regarding jurisdiction and enforcement. The first attempt at US Internet regulation was the Communications Decency Act of 1996 (CDA)⁶⁴. Through the CDA, Congress aimed to respond to increasing reports of the availability of Internet pornography to minors. The CDA was contested by civil liberties groups on the grounds it violated the First

⁶³ Bren, L., "Agencies Team Up in War Against Internet Health Fraud", Food and Drug Administration Consumer Magazine, Sep-Oct 2001.

⁶⁴ CDA Title V of Telecommunications Act of 1996, Pub L No 104-104, 110 Stat 56, 47 United States Code.

Amendment⁶⁵. The US Supreme Court subsequently declared that the majority of the Act was unconstitutional⁶⁶.

A second attempt at the protection of children through Internet regulation was made when Congress enacted the 1998 Child Online Protection Act (COPA). COPA criminalized Internet commercial distribution of content considered harmful to minors. The Act required discouragements and warnings to minors to not enter sites that provide such content. It required the user to verify that s/he was 18 or older by clicking on a link. An additional link was provided for the underage user to click that would redirect a user to a site without potentially harmful content. Once again, civil liberties groups challenged this Act as an infringement on First Amendment protections. In 2002 the Supreme Court did not decide on the core legal questions and ordered the Third Circuit Court of Appeals to decide the case. The Third Circuit Court ruled COPA unconstitutional in its March 2003 decision. In June of 2004 the Supreme Court upheld the lower court's ruling stating "there is a potential for extraordinary harm and a serious chill upon protected speech" if COPA had gone into effect⁶⁷.

⁶⁵ Cannon, R., "The Legislative History of Senator Exon's Communications Decency Act: Regulating Barbarians on the Information Highway", 49 Fed Comm LJ 51, 1996.

⁶⁶ Supreme Court of The United States, "RENO, ATTORNEY GENERAL OF THE UNITED STATES, et al. v. AMERICAN CIVIL LIBERTIES UNION et al.", June 1997.

<http://www.law.cornell.edu/supct/html/96-511.ZS.html>

⁶⁷ Mark, R., "Supreme Court Upholds COPA Ban", Ecommerce, Jun 29, 2004, accessed Jan 2008
<http://www.internetnews.com/ec-news/article.php/3375001>

While attempts at US Internet regulation routinely face challenges on constitutional grounds, other countries have successfully banned their citizens from accessing certain information or from accessing the Internet altogether. China, Cuba, Egypt, and Myanmar are all examples of countries whose governments limit Internet access for their citizens.

- China – Blocks any Internet information deemed inappropriate and promotes user self-censorship.
- Cuba – Restricts Internet usage to individuals and organizations supportive of the regime. It is possible that in the future, citizens will gain access but only to pre-approved sites.
- Egypt – Does not actively promote a coordinated censorship regulation but closely monitors Internet activity and makes arrests of users providing a dissenting online voice.
- Myanmar – Severely restricts freedom of speech with minimal Internet usage allowed. Extreme punishments keep the citizens from attempting unauthorized access.⁶⁸

Even with the power that these governments have over their citizen's Internet usage, the advance of the information age will probably require a shift in the regulatory policies.

This is already being seen in China where there is a freer information environment for the online environment when compared to the print and broadcast media. Authoritarian

⁶⁸ Kalathil, S, "Dot.Com for Dictators", Foreign Policy 135 p42-49, Mar 2003.

regimes will most likely never allow the type of free and open information exchange enjoyed by US citizens under the First Amendment.

III. Regulatory Tools

There are many tools that policymakers may use to regulate market behaviors. Eisner et al. notes that the nine most common are: prohibitions; licensing; price, rate, and quantity restrictions; product standards; technical production standards; performance standards; subsidies; information provision; and assigning property rights and liability.⁶⁹ Of these nine, three are currently commonly used for IDMI regulatory policy. They are prohibition, information provision, and certifications. The direct correlation between these tools and the common regulatory mechanisms currently in place for IDMI will be discussed later in this chapter. There are other regulatory methods in place for IDMI, such as user-applied tools like the Validity Wizard and grass roots efforts such as the Credibility Commons. However, initial research into these alternate policy mechanisms indicated that they are not as effective and limited in scope as compared to the three selected for this work. Following is a more detailed look at the less commonly employed policy tools.

⁶⁹ Eisner, M.A., E.J. Ringquist, J. Worsham, “Contemporary Regulatory Policy”, Boulder CO, Lynne Rienner Publishers, 2000.

User Applied Tools

The Validity Wizard⁷⁰ was an attempt to create an automated tool (a scale that ranks the validity of sites based on a user-entered set of criteria) that would allow the user to estimate validity of the resource. For example, John Q. Public reads online that he should be very concerned about some component in his environment that causes cancer. Because John Q. isn't a chemist and consequently does not recognize the element in question, he may feel inclined to be worried about this issue. Through the use of a tool-based evaluation model such as the Validity Wizard, John Q may learn that the information ranks a 1 out of 10 on the validity scale. John may consequently learn that the professionals who created the validity scale would consider the information provided by the website highly suspect. The tool-based self-regulation model in this case may calm his fears, created by an alarmist, spoofed, or hoaxed newsletter.

The Validity Wizard is self-described as:

...designed to aid you in assessing the validity of information you will find on the World Wide Web through the use of the Web Validity Wizard (VWiz). The VWiz will walk you through a variety of steps. You will be asked a series of questions... The VWiz will result in three estimate coefficients, each of which will be a value somewhere between zero and one. The three estimates measure internal validity, external validity, and overall validity. If either of your internal or external validity coefficients is low, then your overall validity will be low, and there is a good chance the source is not very valid. If both of your internal and external validity coefficients are high, then your overall validity will be high, and chances are that the Web source is a good one.⁷¹

While a noteworthy effort, the Validity Wizard itself has not been updated since 2000 and is a good example of an abandoned experiment at rating the validity of Internet information. Validity is of importance to all fields touched by the Internet including;

⁷⁰ StyleWizard.com, "Validity Wizard", 2000, Apr 2006, <http://www.stylewizard.com/val/vwiz.html>

⁷¹ StyleWizard.com, "Validity Wizard", 2000, Apr 2006, <http://www.stylewizard.com/val/vwiz.html>

lyrics of popular songs, do it yourself instructions on landscaping, the latest findings of prominent scientists, and of course, medical information. The creation of a tool to assess the validity of Internet information is admirable and should be further investigated for viability and application, especially as it applies to human health.

Preliminary research for this work into IDMI regulation using a user-applied tool such as the Validity Wizard involved application of pre-selected search criteria. A set of sites was identified that were noted in the literature to have directly caused physical or mental harm to a user(s). Although not updated since 2000, the Validity Wizard remains an active site and provides results when the appropriate criteria are entered as of September 2007. Using the information from the sites under study, the author entered in the requested criteria from the site into the Validity Wizard website. The results were inconclusive as to whether or not the user-applied tool would appropriately discriminate high and low quality IDMI. This may be due to the rapid advance of the skills of webmasters in building sites to purvey lower quality IDMI in conjunction with the lack of update to the Validity Wizard site. In addition, entering in the required criteria before the Wizard provides its assessment is a burdensome task on the user. It is unlikely that many users would employ this tool due to the extra effort involved. An automated system to provide instant credibility ratings to users through the search results page of their selected search engine may prove to be of much greater utility.

Grass-roots Efforts

As noted earlier one example of grass-roots regulatory effort for improving Internet information quality is the Credibility Commons. This is a joint effort currently operated by the University of Washington and Syracuse University. The goal of the Commons is to “improve access to credible information on the Internet”.⁷² Over the course of 2005, the MacArthur Foundation funded work by the American Library Association’s Office of Information and Technology Policy and the University of Washington. The goal was to investigate the issue of credibility of Internet information and ascertain the scope of the problem, uncover existing knowledge of the issue, and develop a system for addressing it. The work resulted in the release of white papers, a symposium, development of a tool and the recommendation for a series of follow up meetings. A few of the main findings include: 1) Internet information credibility is a controllable issue when given proper attention by government, industry, education, and nonprofit institutions, 2) currently, there is a scarcity of online resources addressing the issue, and 3) users typically lack the skills and/or motivation necessary to determine the credibility of information found online. Tools may be employed to assist the user’s quest for reliable information.

Current research being conducted by the Credibility Commons is specific to the credibility of health-related material disseminated on the Internet. Similar to the work conducted for this manuscript, the Credibility Commons researchers investigated the results of automatically generated search results from Internet based search engines used

⁷² Credibility Commons, “About the Commons”, Feb 2006, Jan 2007 <http://credibilitycommons.org/>

to identify health-related websites. They identified four different search engines and had 28 physician assistant graduate students rate the material the search engines identified. Though not yet published the initial findings indicate that government sponsored search engines consistently provide more credible information than more commonly used search engines such as Google⁷³.

While the Credibility Commons and other grass roots efforts for managing the issue of Internet information credibility are well intentioned, they do not yet provide enough data in order to objectively quantify the effectiveness of their actions. As the Credibility Commons is a fairly new campaign, future research may warrant a review of their work. In January 2007 the Commons released a credibility tool that runs in the background while users search for online information. However, this version is limited to working with the lesser-used Mozilla Firefox browser and consequently will have a subtle effect on overall information quality. Perhaps if the Commons releases a tool compatible with the more heavily employed browsers such as Microsoft's Internet Explorer, a larger and measurable effect will occur. Future research might well look at this.

⁷³ Eisenberg, M., S.Kane, P. Lin, "Credibility Commons Annual Report for MacArthur Foundation", Aug 2007, <http://credibilitycommons.org/index.php/publications/>

Selected IDMI Regulatory Policy Tools

The three policy tools of interest for this work are prohibition, information provision and certification. The specifics regarding each tool will be discussed next. In general, these three were selected due to prior research conducted by the author investigating Eisner's nine most common policy tools to determine which if any currently apply to IDMI.

While it may be argued that all nine apply in some way to the topic of study all but the selected three do not provide adequate data for quantitative analysis. In addition to Eisner's nine commonly used policy tools, the previous section identified others such as user-applied tools and grass roots efforts. These are not yet providing the quantitative data necessary to draw conclusions. The Credibility Commons is moving towards providing research specific to IDMI but has not yet provided the details of their work for review and/or replication. Their work will provide future research opportunities.

Prohibition

Prohibition is the most powerful tool policy makers may use to protect users from unsafe IDMI. As the majority of IDMI available to consumers is largely unregulated almost any individual with Internet access and a modicum of information technology knowledge is free to create a web page. The content of these pages is at the discretion of the creator. While the motivation behind the publication of information on the Internet may be positive, the information itself may be flawed. On the other hand, medical information may be provided with the express intent to instill fear or doubt with the ultimate goal of

selling a product. When misleading or incorrect IDMI is published, are users affected by this poor information? The FTC, FDA and Health Canada say yes. Based on reports of user harm due to poor quality IDMI, these institutions have created a multinational effort named Operation Cure. All to stop purveyors of unsafe IDMI. As noted in the Introductory chapter, there are instances of hazardous IDMI identified by government organizations and in the literature. One of the examples related the instance of a physician finding a site that informed users to stop taking the medication their physicians prescribed and instead buy the site's product to cure a serious disease. The other example is of a death attributed directly to a user relying on the medical information and products he found on the Internet. The author will therefore take as fact that poor quality IDMI can do actual harm to users. Organizations such as the FTC and FDA directly regulate content on the Internet by prohibiting some types of information.

Deterrence Theory and Prohibition

Another aspect by which prohibition may be a more widely spread and consequently more effective regulatory tool is through the indirect deterrent effect it has on others that may wish to commit similar prohibited actions. One component of deterrence theory stems from the notion that the punishment of committing a certain prohibited act will keep future individuals or institutions from committing that act⁷⁴. The particular aspect

⁷⁴ Clarke, R.V., Felson M. (Eds.) "Routine Activity and Rational Choice. Advances in Criminological Theory", New Brunswick, NJ: Transaction Books Vol 5. 1993.

of deterrence theory relevant to this work is generalized or indirect deterrence. This aspect of the theory focuses on prevention of crime by would-be wrongdoers due to the public punishment received by others that have been convicted of committing the prohibited act. This aspect of deterrence theory is different that the other components of the theory of specific deterrence and incapacitation. Specific deterrence focuses on the individual that committed the act attempting to prevent future misdeeds by that specific entity. Incapacitation removes the individual from society and places him or her in custody where s/he is unable to commit future prohibited acts.

General deterrence theory is a main pillar of Rational Choice Theory. The main premise of this theory is that a given rational individual will select the choice that causes the least pain and maximizes gain. Therefore, regulators may influence the actions of that individual through the promise of delivering enough pain to allow the potential offender to decide not to commit the prohibited act. The promise of pain dispensation is recognized by potential offenders through observation or knowledge of the punishment of convicted offenders.

Critics of indirect deterrence theory argue that the experiential effect, having actually had the experience of being caught and punished for a bad act, makes any indirect deterrent

effect negligible by comparison⁷⁵. In one longitudinal study looking at criminal activity from 1972 to 1986, indirect deterrence did not show any causal relationship in preventing future bad acts by individuals prone to do so⁷⁶.

The line between specific and indirect deterrence blurs somewhat in the arena of the Internet. Due to its virtual nature, it is sometimes very difficult for enforcement actions against Internet-based companies to have much effect. There is little pain involved when a virtual-only site receives a notification from the government that they are in noncompliance with a certain regulation. The site can easily shut down and open again using a different URL. Without having a permanent address and only resident in the virtual world of the Internet, an Internet-only business is relatively free to move and only needs to update links to its site and its respective ranking in search engines to again begin conducting business at a new Internet address. While the action of the government is specific to that company, it may be argued that the virtual company may simply close that site and then open a new site using a different company name with little or no consequences. This type of virtual company that can quickly change names and Internet addresses may be thought to have been subject to both specific and indirect deterrence. The information is once again provided, so it cannot be truly thought of as specific deterrence as the offending company is not prevented from providing this information

⁷⁵ Saltzman, L., Paternoster R., Waldo, G.P., Chiricos, T.G., "Deterrent and Experiential Effects: the Problem of Causal Order in Perceptual Deterrence Research", *J of Res in Crime and Delinquency* 1982 v19:2 pp 172-189.

⁷⁶ Paternoster, R., "The Deterrent Effect of the Perceived Certainty and Severity of Punishment: A Review of the Evidence and Issues", *Justice Quarterly* Jun 1987 v5:2

again. Furthermore, the “new” company may have modified their site in order to avoid governmental notification of a violation that is one of the tenets of indirect deterrence.

Traditional brick-and-mortar producers of medical information and products may very well feel the pain of providing prohibited medical information if they receive notification from an institution such as the FDA or FTC. As an example, the FDA ruled in 2004 that products and information promoting the use of ephedra should be banned. On April 12, 2004 the prohibition against the promotion of ephedra went into effect⁷⁷. This subsequently led to multiple seizures of ephedra containing products dispensed through commercial and Internet stores. One seizure netted the US Marshals over \$3,000,000 in ephedra containing products from Hi-Tech Pharmaceuticals⁷⁸. The loss of \$3 million received swift attention of the Hi-Tech Pharmaceutical executives. A court battle ensued that Hi-Tech eventually lost, and some of its executives are now facing criminal charges.

⁷⁷ US FDA Statement, “FDA Announces Rule Prohibiting Sale of Dietary Supplements Containing Ephedrine Alkaloids Effective April 12”, US Food and Drug Administration, Apr 2004
<http://www.fda.gov/bbs/topics/NEWS/2004/NEW01050.html>

⁷⁸ US FDA News, “FDA Requests Seizure of More Dietary Supplements Containing Ephedrine Alkaloids”, US Food and Drug Administration, Feb 2006,
<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01325.html>

Information Provision

Mazis et al. presented three principles that guide the provision of information in a 1981 Journal of Marketing study. The authors note that the three principles are incentive compatibility, communication effectiveness, and First Amendment protections⁷⁹.

- Incentive compatibility is attuned to the seller's incentives. Most regulations work through market incentives. A seller is incentivized to refrain from providing prohibited information for fear of lawsuits, financial judgments, or even possible incarceration. Such is the situation with the cases of Lane Labs and Hi-Tech Pharmaceuticals. In contrast, incentive compatibility works as a positive reinforcement of a seller's desire to provide marketable information about their good to the consumer. The now familiar miles per gallon rating for automobiles provides an example of incentive compatibility. The seller knows that certain segments of the consumer market want certain fuel economy. They are consequently incentivized to provide the information about the efficiency of their automobiles in a cost-effective manner as a part of their promotion campaigns.
- Communication effectiveness is the idea that when the government sets standards for information provision, it should ensure that the information provided is done in such a way as to benefit the consumer. The consumer must have access to the information, understand what is being provided, and subsequently use the information in the decision making process.

⁷⁹ Mazis, M.B., Staelin R., Beales, H., and Salop S., "A Framework for Evaluation Consumer Information Regulation", J of Marketing, 1981 v45:1 pp11-21.

- First Amendment protections relate to the general principle of unimpeded flow of information. For the information to enjoy protection under the First Amendment, it must be nondeceptive. This concept is further explored in the following section on the protection of information provision (aka commercial speech) by the Supreme Court.

Information Provision as Regulation

As a policy tool, information provision should be seen from two perspectives. These perspectives are not mutually exclusive and can be seen working in concert or working independently. Information provision may be the undertaking of the government to mitigate the wealth of misleading information by providing high quality information to the user. The idea is to drown out the bad with the good. In this work, the author refers to this aspect of information provision as the “functional form”. The second perspective is seeing information provision as it works under the regulatory guidelines of overseeing agencies. Governmental institutional guidelines provide for the types of claims that companies can make on their websites about their products. This is the “regulatory form” of information provision. In summary, functional information provision is the government’s duty to provide high quality information while regulatory information provision focuses on ensuring the kind of data provided is within regulatory guidelines.

An important regulatory mechanism for IDMI is the provision of balanced information to users by the government and/or other professionally credentialed institutions. As the least intrusive policy tool, there have been appeals from the medical community for the government to take an active role in information provision⁸⁰. Eysenbach noted that for those institutions providing IDMI the quality should first and foremost follow the dictates of the Hippocratic injunction to, “First, do no harm.”⁸¹ Gray acknowledged that the quality of the information on the web is both extremely variable and difficult to assess due to the lack of available evidence to determine credibility⁸². Consequently, organizations providing IDMI should provide the data necessary for users to make reasonable assumptions about the provider. Jadad et al. stated that then currently available (1998) tools to rate Internet information do not necessarily measure what they are supposed to measure and questioned whether they should even exist. They consequently call for the providers of IDMI to supply credible information, thereby alleviating the need for any form of censorship. From a broader perspective, the emphasis is placed on the government directly or indirectly to provide reliable information and training the user to be able to understand and appreciate the differences in the quality of information presented on the Internet.

⁸⁰ Jadad, A.R., Gagliardi, A., “Rating Health Information on the Internet. Navigating to Knowledge or to Babel?”, JAMA 1998 v279 pp611-614.

⁸¹ Eysenbach, G., Diepgen, T.L., “Towards Quality Management of Medical Information on the Internet: Evaluation, Labelling [sic], and Filtering of Information”, BMJ Nov 1998 v317 pp1496-1500.

⁸² Gray, J.A., “Hallmarks for Quality of Information”, BMJ Nov 1998 v317 pp1500-1501

The information provision regulatory tool plays an important role in health communication and particularly IDMI⁸³. Users wish to have unrestrained access to whatever information they seek, pursuant to the rationale of freedom of the press. Yet yelling fire in a crowded theater is not protected by the first amendment, according to the US Supreme Court⁸⁴. Should not medical protection fit into the same category? Nevertheless, as mentioned in the Background chapter the Constitution protects free speech and freedom on the press. The Supreme Court has upheld that these freedoms also apply to the Internet in a 1997 case⁸⁵. In *Reno v. ACLU* the Court declared;

the Internet to be a free speech zone, deserving of at least as much First Amendment protection as that afforded to books, newspapers and magazines. The government, the Court said, can no more restrict a person's access to words or images on the Internet than it could be allowed to snatch a book out of a reader's hands in the library⁸⁶.

Consequently the Internet remains relatively unrestricted under the provisions of the first amendment.

Unsafe Information

An individual may publish a site based on claims regarding scientific studies that may or may not exist. Even if they do exist, the studies may not have been conducted according to the scientific method and subsequently crumble under the scrutiny of peer review.

⁸³ Viscusi, W.K., Magat, W.A., Huber, J., "Informational Regulation of Consumer Health Risks: An Empirical Evaluation of Hazard Warnings", *RAND J Econ Aut* 1986, v17:3, pp 351-365.

⁸⁴ Farber, D.A., Nowak, J.E., "The Misleading Nature of Public Forum Analysis: Content and Context in First Amendment Adjudication", *Virginia Law Review*, Sep 1984, v70:6, pp 1219-1266

⁸⁵ Supreme Court of The United States, "*RENO, ATTORNEY GENERAL OF THE UNITED STATES, et al. v. AMERICAN CIVIL LIBERTIES UNION et al.*", June 1997.

<http://www.law.cornell.edu/supct/html/96-511.ZS.html>

⁸⁶ ACLU, "Internet Free Speech", <http://www.aclu.org/privacy/speech/index.html> accessed Sep 2007.

Such studies exist and have changed the way health care is viewed in this country. One such example is a study of the intrauterine birth control device published in 1981 that reported IUD use greatly increased chances of pelvic infection. This study was reanalyzed in 1991 with the conclusion that the 1981 study, “showed an almost complete disregard for epidemiologic principles in its design, conduct, analysis, and interpretation of results”.⁸⁷ While this was before the advent of the Internet as it is now known, the multitude of claims of cures to a whole host of diseases is growing rapidly, with some Internet health communication claims stating their information is based on scientific studies. Regarding prevention of and cures for cancers Lundberg notes, “If you look up shark cartilage, you find 275 sites on shark cartilage and they’re all complete tripe”.⁸⁸

Certification

Certification Systems

This work studied functional third party evaluative certification systems. There are a number of other methods by which the certification policy tool has been used for IDMI. In order to provide a basis for the study of the certification system selected for this work, the other certification systems are briefly outlined in this section.

⁸⁷ Kronmal RA, Whitney CW, and Mumford SD., “The Intrauterine Device and Pelvic Inflammatory Disease: The Women’s Health Study Reanalyzed”, J of Clin Epidem, Feb 1991:109-22.

⁸⁸ Guadagnino C., “Using Medical Information on the Internet”, Physicians News Digest, July 2000, Jan 2006, <http://www.physiciansnews.com/spotlight/700.html>

The first certification systems arrived in 1996 and provided a code of conduct for IDMI. Jadad et al. published a study in JAMA in 1998 rating the fourteen systems available at that time that to determine their efficacy. They concluded that though there were a large number of certification systems available, most were incompletely developed and they questioned whether users would even notice a certification on a site.⁸⁹ Incomplete Internet regulatory tools were also identified during the course of this work such as the credibility commons. The question as to whether or not users take notice of the certification is one for future research.

Other techniques for the application of the certification tool involved setting ethical standards for providers of IDMI and allowing them to self-regulate. The site could then make a claim to follow the principles and guidelines of the standard producing institution and subsequently claim certification without any third party review process. Wilson noted that this type of regulation was simply, “promoting the good” and hoping that providers would follow a set of guidelines for the sake of doing what was right.⁹⁰ Without any oversight however, there was little incentive for a site to simply claim the certificate without actually following the guidelines.

⁸⁹ Jadad A, Gagliardi A., “Rating Health Information on the Internet: Navigation to Knowledge or to Babel”, JAMA, 1998; 279(8): 611-614.

⁹⁰ Wilson, P., “How to Find the Good and Avoid the Bad or Ugly: A Short Guide to Tools for Rating Quality of Health Information on the Internet”, BMJ Mar 9, 2002;324:598-602.

Another process for the certification system involved identifying means for working with the large amount of medical information available. This system focused on breaking down the data into manageable sizes and concentrating on the principals of delivering it to users. The integrity of data was then reviewed to certify the existence of the entire volume. The certificate provided the user the knowledge that s/he was receiving the whole of the information as opposed to just certain parts of the data. However, these certificates did not provide a user with any sense that the information provided followed any institutional guidelines relating to the provision of IDMI.

This work analyzed the third party certification systems functioning at the time of the study. Of the aforementioned types of certification systems, the third party system is the most rigorous as it calls for a review by an independent party in order to receive the credential. The granting institution that conducts an investigation of the site's content to determine eligibility governs the quality criteria needed to obtain the certificate. Professionals and experts in the medical field typically standardize the criteria.

Third Party Certification System

The adoption and use of a 3rd party certification system provides an avenue of regulatory oversight for the Internet as well as for the press. As noted earlier many Americans receive their medical and health information via the news media. At the moment they are protected by editorial oversight and journalistic integrity, a combination of 3rd party and self-regulation. Leading peer-reviewed science and medical journals have instituted

policies to catch any potential conflicts of interest. Specific to IDMI there are many organizations that provided certifications via a 3rd party system. They include but are not limited to the American Medical Association, Internet Health Care Coalition (IHC), Hi-Ethics, Health on the Net Foundation (HON), URAC, and MedCERTAIN. These organizations create guidelines for IDMI with some that review sites using exacting standards. For example, in 2000 IHC launched a regulatory initiative whereby sites should perform self-assessments and comply with stated standards.

The 3rd party certification process has existed for some time in the US, long before the dawn of the Internet. Taylor in 1958 and later Parkinson in 1975 defined the use of the 3rd party certification system as institutions granting certification marks to products and services that meet predetermined standards⁹¹. The institutions included consumer magazines, independent testing laboratories, professional and technical organization, unions, and government agencies⁹². In 1981 Laric noted that certification systems might be classified in three major categories:

Factual certification – certifies the presence of a specific characteristic such as specific materials such as 14k gold

Evaluative certification – the certifier provides an evaluation of the product or service and confirms that it conforms to appropriate standards, and

⁹¹ Taylor, D.A., “Certification Marks – Success or Failure”, Journal of Marketing, 22 Jul 9-46 1958.

⁹² Parkinson, T.L., “The Role of Seals and Certifications of Approval in Consumer Decision Making”, Journal of Consumer Affairs, 9 i-14 1975.

Warranty certification – the certifier presents their responsibility regarding the purchase of a product or service⁹³.

For the purpose of this work, the evaluative certification category is most relevant. The author's interest lies in determining if evaluative 3rd party review systems that specifically investigate the content of IDMI sites provide adequate consumer protection.

An 8-year longitudinal study conducted from 1972 to 1980 aimed to determine the success or failure of evaluative 3rd party certification systems. The study concluded that although policy changes occurred from the implementation of the certification system in 1972 and the final review in 1980, consumers continued to have misperceptions regarding what the certificate actually meant⁹⁴. The study cautioned that consumers begin to rely on longstanding certifications and do not adjust their perceptions accordingly when policy changes are made that alter the meaning or the evaluative system. Herein is a concern for IDMI 3rd party certifications in that once vetted and instituted, they should refrain from change, as consumers may not appreciate the consequences of any change.

There may be multiple certifications applied to an individual site depending on its profile in the online community. A certification standard, adopted by each site is designed to

⁹³ Laric, M.V., D. Sarel, "Consumer (Mis)Perceptions and Usage of Third Party Certification Marks, 1972 and 1980: Did Public Policy Have an Impact?", *Journal of Marketing*, vol45(3) pp135-142, 1981.

⁹⁴ Laric, M.V., D. Sarel, "Consumer (Mis)Perceptions and Usage of Third Party Certification Marks, 1972 and 1980: Did Public Policy Have an Impact?", *Journal of Marketing*, vol45(3) pp135-142, 1981.

provide a standard basis for the quality of IDMI on that individual site. The use of a certification is a way for a site to provide users assurance of the provision of reliable IDMI. Unsafe information should not be available assuming the site strictly adheres to the standards of the certification system.

IV. IDMI Oversight and Providers

Institutions that have legal authority over IDMI are the government agencies that have enforcement capabilities. For the sake of this research, the main agencies of interest are the FDA and the FTC. Each has a role in ensuring IDMI providers stay within the constraints of the law. However, there is also collaboration as seen through the Operation Cure.All effort. The FDA specifically targets violators of the FFDCA including manufacturers that make unsubstantiated claims regarding their products. FDA enforcement actions include warning letters, recalls, arrests, and convictions of violators. The FTC is charged with consumer protection and ensuring fair competition. FTC enforcement actions target businesses engaged in anticompetitive, deceptive, or unfair practices. This includes the area of health care fraud. As fraud in the health information section is similar to the FDA enforcement of violations of the FFDCA, the FTC launched Operation Cure.All as a combined effort to coordinate the enforcement actions of the agencies.

IDMI Oversight

Federal Trade Commission

As one of the lead agencies involved in invoking Internet regulatory tools, it is important to have an understanding of FTC's regulatory efforts regarding consumer protection. A shift in the FTC's regulatory process occurred from the reforms of the 1970s with the emergence of consensus building in the 1980s. During the 1970s there arose a concept to include underrepresented stakeholders (e.g. consumers) in the policy formulation process. Stewart notes that this was based on the notion that these participating interest groups should be given equal access to and fair representation in the process.⁹⁵ In the early 1980s Harter noted that this idea was mostly abandoned in place of a new process for regulatory formation that came to be known as "reg neg".⁹⁶ This negotiation process helped to break the impasse during adversary regulatory proceedings.

The FTC played a key role in the move to "reg neg" policy formulation. The regulation negotiation policy process allowed stakeholders and the government to work together to create new rules. This process was intended to decrease the adversarial nature of rule making and thereby allow for greater expediency. However, in the case of IDMI, a site's author may not have the resources to fully participate in regulatory negotiations. A site containing information that the government deems unacceptable and consequently

⁹⁵ Stewart, R., "The Reformation of American Administrative Law", Harvard Law Review 80, 1975: 1667-1711.

⁹⁶ Harter, P.J., "Negotiating Regulations: A Cure for Malaise", Georgetown Law Journal 71:1, 1982.

prohibited may deem it easier to seek resolution through the courts instead of participating in the negotiations. In this instance, the site manager may provide very limited information, only that necessary to allow a verdict. In extreme cases, the site manager may withhold information and/or hide any areas where compromise may occur⁹⁷.

Food and Drug Administration

The case study in the Prohibition chapter directly relates to the supplement industry. To properly frame the case study, some history of the regulatory policy surrounding this industry follows as shark cartilage is now considered a dietary supplement under the current DSHEA. The specifics regarding shark cartilage and Lane Labs are discussed in additional detail in the Prohibition chapter.

FFDCA and DSHEA

In 1958 Food Additive Amendments were made to the Federal Food, Drug, and Cosmetic Act (FFDCA).⁹⁸ This was an important step allowing the FDA to evaluate all new additives or ingredients for safety. This included ingredients used in dietary supplements. The FDA had, for decades, regulated dietary supplements as foods in order to ensure their safety and prevent deceptive labeling.

⁹⁷ Woods, R., “Regulatory Negotiation: Early Involvement Ensures Rules People Can Live With”, BBB Solutions 5v3, 2003. http://www.dr.bbb.org/Autoline/pub_regneg.asp

⁹⁸ Federal Register: Oct 25, 2006 V71(206) pp 62400-62407, Nov 2006, www.wais.access.gpo.gov

In 1994, President Clinton signed the Dietary Supplement Health and Education Act (DSHEA).⁹⁹ Through the DSHEA Congress amended the FFDCA to include provisions applied to only dietary supplements and their ingredients. The result was that the ingredients used in dietary supplements were no longer subject to pre-market safety evaluations of other food ingredients. The ingredients must meet the requirements of other safety provisions. DSHEA was Congress' attempt to meet the concerns of consumers to ensure that appropriately labeled and safe supplements remained available to consumers. In their research, Congress determined that there might be a positive relationship between the ingestion of dietary supplements and the overall good health of consumers.¹⁰⁰ They acknowledge that more scientific research is required but the potential for reduced health-care costs and disease prevention outweigh any potential risk from ingestion of dietary supplements under the new DSHEA guidelines.¹⁰¹

During the early years of the dietary supplement industry, the FDA considered them to be composed only of essential nutrients such as minerals, proteins and/or vitamins. In 1990, the Nutrition Labeling and Education Act added "herbs, or similar nutritional substances"¹⁰² to the term dietary supplement. The DSHEA established a formal

⁹⁹ US FDA "Dietary Supplement Health and Education Act of 1994 Public Law 103-417 103rd Congress", Oct 1994, Nov 2006, <http://www.fda.gov/opacom/laws/dshea.html#sec3>

¹⁰⁰ Barrett, S., "Major Recommendations from the Dietary Supplement Commission", Nutrition Forum 14:28, 1997.

¹⁰¹ Bureau of Consumer Protection, "Dietary Supplements: An Advertising Guide for Industry", Washington, DC: Federal Trade Commission, 1998.

¹⁰² US FDA, "Guide to Nutrition Labeling and Education Act (NLEA) Requirements" Office of Reg Affairs, Aug 1994.

definition based on several criteria. Summarized from the Dietary Supplement Health and Education Act of 1994 Public Law 103-417 103rd Congress a dietary supplement has the following characteristics;

Is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients. Is intended for ingestion in pill, capsule, tablet, or liquid form. Is not represented for use as a conventional food or as the sole item of a meal or diet. Is labeled as a dietary supplement.¹⁰³

Congress thereby expanded the term dietary supplement to include substances such as garlic, fish oils, enzymes, ginseng, and any mixtures of these.

Under DSHEA the adulteration provisions of the FFDCa were amended to reflect that adulteration occurred if the supplement or one of its ingredients presented a significant risk of illness or injury when used according to the labeling instructions. Furthermore, a supplement may be considered adulterated if it contains a new ingredient for which there is inadequate research to determine a reasonable assurance that the ingredient will not produce a significant risk of illness or injury. A “new ingredient” is an ingredient that was not marketed for dietary consumption in the US prior to Oct 15, 1994 the date President Clinton signed the DSHEA. Manufacturers that intend to use a new ingredient are required to inform the FDA at least 75 days before they begin marketing the product.

¹⁰³ US FDA “Dietary Supplement Health and Education Act of 1994 Public Law 103-417 103rd Congress”, Oct 1994, Nov 2006, <http://www.fda.gov/opacom/laws/dshea.html#sec3>

In addition, they must provide the FDA with the information used to determine that the dietary supplement's new ingredient will reasonably be expected to be safe.

The DSHEA allowed that third party publications might be provided to consumers to help them make informed decisions regarding the potential health benefit of dietary supplements. The materials would include book chapters, articles, abstracts, websites, and other third-party material. However, the literature could not be false or misleading, must promote a specific brand, must promote with similar material to provide a balanced view, must be separated from the area supplements are provided, and cannot have product promotion literature or other information attached.

Statements regarding diagnosing, curing, treating, or preventing a specific disease cannot be included on the label of dietary supplements. A claim of "cures cancer" is prohibited by the DSHEA. There are appropriate health claims that can be made by manufacturers on the labels of their supplements presuming the product qualifies to bear the claim. For example, a claim that calcium may reduce the risk of osteoporosis may be used on a calcium-containing supplement. Use of such claims by manufacturers requires that the statement "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Use of this statement requires the manufacturer to notify the FDA no later than 30 days after the product has reached the market.

On October 2, 1995, almost one year after the DSHEA was signed into law, the White House appointed the seven-member panel that would form the Commission required under the Act. The appointments were confirmed on Nov 9, 1995 and the Commission received its charter from the Secretary of Health and Human Services on Feb 13, 1996.¹⁰⁴ The purpose of the Commission was to conduct a study in order to make recommendations on the regulation of label claims and statements by manufacturers and designate procedures for the evaluation of the claims. DSHEA required that the Commission present its findings in a final report to be submitted to the President within two years of convening.

The Commission held nine meetings between Feb 1996 and Aug 1997 in order to create, populate, and revise its list of key issues. The key issues were then parceled to subcommittees and staff for additional investigation before incorporation into the final report. The Commission delivered its report to the Office of the President, the Congress, and the Secretary of the Department of Health and Human Services on Nov 24, 1997. The seven key areas identified were in the areas of safety, health claims, statements of nutritional support, notification letters, substantiation files, publications used in connection with sales, and some special considerations regarding botanical products.¹⁰⁵ In brief, these key items raised concerns that some of the statements of nutritional support

¹⁰⁴ Commission on Dietary Supplement Labels, “Commission Procedures”, Dec 1997, Nov 2006, <http://www.health.gov/dietsupp/appc.htm>

¹⁰⁵ Commission on Dietary Supplement Labels, “Major Issues and Recommendations Related to Labeling of Dietary Supplements”, Nov 2006, <http://web.health.gov/dietsupp/TOC.HTM>

were in fact very similar to drug claims. Some members believed that the DSHEA created a loophole that allowed manufacturers to make claims related to organ and organ systems. In addition, they raised concerns regarding the use of third-party publications as applied to dietary supplements. As noted earlier, the DSHEA has four requirements regarding the use of third-party materials. However, the Commission concluded that these criteria would be very difficult to apply especially the one requiring provision of balanced information. In addition, members warned that no federal agency has the resources to regulate what individual retailers do in their stores. This is subsequently true with what retailers do with information provision on their websites as well as what links and meta-tags they may use to increase the number of visitors.

FTC, FDA and Operation Cure.All

Operation Cure.All is “a partnership of the Federal Trade Commission, the Food and Drug Administration, Health Canada (the Canadian federal health department), and various state attorneys general and state health departments, combining law enforcement efforts with a consumer education campaign.”¹⁰⁶ The partnership is working to take action against large targets and has intensified its efforts since December 2002. As of October 2003, Operation Cure.All has issued more than 200 warning letters, cyber letters, and e-mail advisories to companies marketing dangerous or fraudulent medical and

¹⁰⁶ Food and Drug Administration Consumer Magazine, “Agencies Team Up in War Against Internet Health Fraud”, Sept-Oct 2001, Feb 2006, http://www.fda.gov/fdac/features/2001/501_war.html

health products online.¹⁰⁷ The first phase of Operation Cure.All began with an Internet search in 1997 repeated in 1998. During this search, users sought out information using common search engines for medical products making questionable claims of treatment or curative properties for a host of diseases including cancer and heart disease. Within three hours of searching, the users conducting the study identified 1600 sites worldwide with 800 identified as being located in North America making the questionable claims¹⁰⁸. In early 1999, the FTC performed an Internet search that turned up greater than 400 sites that made doubtful claims about products sold to treat various diseases. In the four years that passed since the FTC's search and Operation Cure.All's letter issuing campaign, one might rightly assume that the number of sites making bogus health claims has increased due to the vast increase in the number of Internet sites and pages.

Some of the claims targeted by Operation Cure.All present on the sites and subsequently challenged by the FTC included:

- THIS IS NOT A TREATMENT FOR CANCER: IT IS A CURE!... It takes 5 days to kill the parasites that cause intestinal cancer. The cancer is then killed...
- Herb Veil 8 has been used in the successful removal of carcinoma, adenocarcinoma, and melanoma.

¹⁰⁷ Food and Drug Administration White Paper, "Protecting the Public Health: FDA Pursues an Aggressive Enforcement Strategy", June 30, 2003.

¹⁰⁸ Beales, H., "Health Fraud and the Elderly: A Continuing Epidemic", Prepared Statement of the FTC Before the US Senate Special Committee on Aging, Washington DC Sep 2001.

- This formula is a “power house” and has been used on (and restored to health), cancer of the spine, arthritis, and polio, and has helped rebuild torn cartilage and sinews, fractures, etc. etc...¹⁰⁹

There are critics of the Operation Cure.All program. James, of International Advocates for Health Freedom, is one example of the types of conspiracy theorists behind the movement against the placement of infrastructure or mechanisms to ensure that there is some type of regulatory oversight of IDMI. In an attempt to undermine FTC’s rules of endorsement for testimonials and endorsements of products, James notes, “Most of us are not qualified to do scientific research, nor do we have the money to hire a scientist to do it for us every time we want to give a testimonial.”¹¹⁰ James argument stems from the rationale that since some individuals and/or small businesses cannot afford to test their products, they should be exempt from the regulations requiring this process. Similar to other critics, James’ anti-government deregulation philosophy falls short of providing a valid argument to remove the limited protections currently in place for users of IDMI.

Health On The Net Foundation

HON was created in 1995 and launched in 1996 with the mission to guide both the lay public and medical professionals to authoritative and valid IDMI. The reason that HON

¹⁰⁹ Beales, H., “Health Fraud and the Elderly: A Continuing Epidemic”, Prepared Statement of the FTC Before the US Senate Special Committee on Aging, Washington DC Sep 2001.

¹¹⁰ James R., “Operation Cure All – But Who’s Cure?”, The Commentary, September 2001. May 2005, <http://www.tpromo.com/gk/sep01/092201.htm>

was initiated was due to the concerns by medical professionals and users regarding the questionable quality of IDMI on an ever-expanding number of sites. The lack of scientific evidence backing up some of the claims made on certain sites was a cause for growing concern. HON began formal discussions with IDMI purveyors and the webmasters of some of these sites. It was determined that reputable sites would follow a set of accepted criteria regarding the content of the site. This resulted in the first version of HONcode, the HON Code of Conduct in July 1996¹¹¹. The HONcode was slightly modified almost a year later in 1997 but has remained unchanged since then.

According to the HON website, the HONcode focuses on:

- the authority of the information provided,
- data confidentiality and privacy,
- proper attribution of sources,
- transparency of financial sponsorship, and
- the importance of clearly separating advertising from editorial content¹¹².

These translate further into a set of guidelines for site developers based on the above criteria. The following is a paraphrased suggested code of conduct (HONCode) from HON that should be applied to IDMI:

¹¹¹ Health On The Net Foundation, “How It Started”, <http://www.hon.ch/HONcode/background.html> Mar 2006, Feb 2007.

¹¹² Health On The Net Foundation, “How It Started”, <http://www.hon.ch/HONcode/background.html> Mar 2006, Feb 2007.

- Authority – advice provided only by medically trained and qualified professionals.
- Complementary – information designed to support user-physician relationship.
- Confidentiality – honors privacy requirements for patient confidentiality.
- Attribution – clear references to source data and recent updates.
- Justifiability – claims must be supported by unbiased research and reports.
- Transparency of authorship – provision of contact information for all authors.
- Transparency of sponsorship – clearly identify commercial and non-commercial sponsors.
- Honesty in advertising & editorial policy – the advertising policy shall be posted and advertising sources clearly stated.¹¹³

Sites that adhere to the criteria set by HON are authorized to use the HONcode Valid and



Official Certificate¹¹⁴

The author contacted Celia Boyer , Executive Director of HON, for additional detail regarding: how the criteria were developed and are modified over time, how enforcement occurs, and efficacy of enforcement. Boyer confirmed the information gathered by the author using the HON website that in 1996 a consensus of webmasters agreed to accept a

¹¹³ HON Code of Conduct (HONCode) for Medical and Health Websites, v1.6 Apr 1997, May 2005, <http://www.hon.ch/HONcode/Conduct.html>

¹¹⁴ Health on the Net Foundation, “Sample of HONcode valid and official certificate”, Apr 2006, Aug 2006, http://www.hon.ch/HONcode/sample_certificate.html

set of rules and guidelines for content provision. The principles listed above were addressed in the first HON Code of Conduct. After adoption, due to the “swift evolution of the Internet technologies”¹¹⁵ the principles were expanded in 1997 to include sponsorship and advertising. Boyer noted that modifications to the principles requires consensus from all webmasters involved.

Sites using the HON certificate are subject to enforcement actions by HON. Boyer noted that there are three distinct warnings and corresponding changes to the HON certificate given to webmasters of sites that are in violation of the HON principles. **Graphic 4.1** provides examples of the changes to the HON certificate in response to violations. The different warning labels depict the three progressive warnings given to webmasters should they be unresponsive to requests from HON to become compliant with the rules and guidelines for content provision. If a Webmaster continues to be non-responsive to repeated requests from HON to make the appropriate corrections, the site is deemed in noncompliance and can no longer be considered a member of the HON community. Furthermore, a user clicking on the “invalid” certificate will be provided a display that indicates the site is not compliant with the standards of HON.

Boyer states that these enforcement actions are effective due to the voluntary nature of obtaining an HON certificate. A Webmaster must contact HON and agree to remain in

¹¹⁵ Boyer, C, HON Executive Director, Personal Communication, Feb 2008.

compliance with the rules and guidelines. If it is deemed that a site is noncompliant, the Webmaster is contacted and informed of the problem. Boyer indicated that, “in the majority of the cases, they [webmasters] are willing to do the changes to prevent withdrawal of the HONcode [certificate]”¹¹⁶. HON measures enforcement efficacy by the fact that most sites that are contacted will make the necessary changes. Specific numbers regarding sites contacted and those that made the appropriate modifications were not available. However, Boyer believes that their enforcement actions are effective which thereby allows HON to, “provide quality health information on the internet [sic] which we do by reviewing sites according to the quality code of conduct, the HONcode”¹¹⁷.

¹¹⁶ Boyer, C, HON Executive Director, Personal Communication, Feb 2008.

¹¹⁷ Ibid

New generation of HONcode seal

Ways of fighting against the misuse of the HONcode:

Different warning levels



HON automatically displays the HONcode seal and shows its validity in real time

Figure 4.1. HONcode Seals

Additional detail regarding HON is provided in the Certification chapter.

IDMI Providers

This section details information about selected information providers discovered through the course of the research for this work. The goal is to provide a background of these organizations as examples of the overall data set. The information provided below was gathered through personal correspondence with the points of contact provided on the sites through telephone and e-mail communication and through a thorough review of the sites themselves to corroborate any personal correspondence received. The background

information requested related to the uncovering the organization's history, funding, and mission. The providers below were selected to represent commercial (.com), governmental (.gov), and nonprofit (.org) sites. Wikipedia.org was included as it was highly represented in the search results for a user seeking cancer information on the Internet. As its content is provided and reviewed by users, it is a unique site.

Cancer.org

Cancer.org is the web site of the American Cancer Society (ACS). ACS began in 1913 under a different name, the American Society for the Control of Cancer (ASCC). It started as a collaboration of the medical and business communities in New York City. In 1945, the ASCC underwent a reorganization and name change to what is now known as the ACS. Development efforts to promote the information provision efforts of the organization began in earnest in 1946 through recruitment of volunteers who raised more than \$4 million for ACS. Public awareness operations led to the provision of such information as the CAUTION campaign used from the late 1960s through the 1980s. CAUTION was the acronym for the warning signs of cancer that included:

- Change in bowel or bladder habits
- A sore that does not heal
- Unusual bleeding or discharge
- Thickening or lump in the breast or elsewhere
- Indigestion or difficulty in swallowing
- Obvious change in wart or mole

- Nagging cough or hoarseness¹¹⁸

The ACS launched its first website in 1995 with the goal to provide the public comprehensive information regarding the fight against cancer. ACS believes that the early detection of cancer gives patients the best chance of survival. Consequently, the Society wanted to provide the public and medical providers the latest cancer resources available to aid in making informed decisions. One way to accomplish this was through their site at www.cancer.org. The site went through multiple revisions with a doubling of the resources in 1999 and a completely retooled site in 2001¹¹⁹.

The ACS has two governing bodies that oversee its operations. There is a national assembly and a national board of directors composed entirely of volunteers that include medical experts. The national assembly oversees corporate guidelines including funding. The board of directors sets policy, goals, and monitors progress.

ACS conducts ethical and funding operations using a publicly traded for-profit governance model. The code of ethics details mechanisms for managing conflicts of interest and confidentiality for staff and volunteers. Funds are managed through a series of committees overseeing audits, financing, and compensation. The author was unable to determine through personal communications or through a review of the ACS 2006

¹¹⁸ American Cancer Society, “ACS History”, About ACS, Oct 2006, Oct 2007
http://www.cancer.org/docroot/AA/content/AA_1_4_ACS_History.asp?

¹¹⁹ American Cancer Society Public Information Officer, personal e-mail communication in response to email request for information.

financial statement the exact amount of funding used to operate the ACS website. However, the site falls under that category of “prevention – programs that provide the public and health professionals with information and education to prevent cancer occurrence or to reduce risk of developing cancer”¹²⁰ that consumed over \$186 million in 2006. The percent of the \$186 million used for the maintenance of cancer.org is difficult to determine.

Cancer.gov

The National Cancer Institute (NCI) is the provider of the cancer.gov website. The NCI began in 1937 with the passing of the National Cancer Institute Act. The Act led to the formation of the NCI and mandated that it focus on:

- conducting and fostering cancer research,
- reviewing and approving grant-in-aid applications to support promising research projects on the causes, prevention, diagnosis, and treatment of cancer,
- collecting, analyzing, and disseminating the results of cancer research conducted in the United States and elsewhere, and
- training and instruction in the diagnosis and treatment of cancer¹²¹

¹²⁰ Ernst & Young, “ACS Combined Financial Statements, 2005, 2006”, Feb 2007.

http://www.cancer.org/docroot/AA/content/AA_1_7_2006_Combined_Financial_Statements.asp

¹²¹ Niederhuber, J.E., “Celebrating 70 Years of Excellence in Cancer Research”, Oct 2007 www.cancer.gov

As a part of the National Institutes of Health (NIH) the NCI is one of eight agencies that make up the Public Health Service in the Department of Health and Human Services.

The NCI is the US Government's primary agency for the dissemination of cancer information to the public and health care practitioners. In 1971, the National Cancer Act increased the responsibilities of the NCI and the pattern of increasing authority and responsibility has continued with additional legislative amendments including adding new information dissemination mandates. The NCI:

- Supports and coordinates research projects conducted by universities, hospitals, research foundations, and businesses throughout this country and abroad through research grants and cooperative agreements.
- Conducts research in its own laboratories and clinics.
- Supports education and training in fundamental sciences and clinical disciplines for participation in basic and clinical research programs and treatment programs relating to cancer through career awards, training grants, and fellowships.
- Supports research projects in cancer control.
- Supports a national network of cancer centers.
- Collaborates with voluntary organizations and other national and foreign institutions engaged in cancer research and training activities.
- Encourages and coordinates cancer research by industrial concerns where such concerns evidence a particular capability for programmatic research.
- Collects and disseminates information on cancer.

- Supports construction of laboratories, clinics, and related facilities necessary for cancer research through the award of construction grants.¹²²

Specifically regarding information provision, the NCI has led an effort to explore new dissemination channels including the use of the Internet. The NCI's site www.cancer.gov recently won an award in the international 9th Annual Webby Awards. In 2005 the site was selected as the winner in the government websites category. The Webby Awards are considered a prestigious honor and given based on the site's usability, functionality, creativity, and design. It is an annual competition with the 2005 awards covering over 4,300 sites from over 40 countries. The NCI's winning of the award provides international recognition of the site's leadership in the IDMI arena. Though the Internet was not in widespread use as it is today, the NCI provided the first online publicly available database with the NCI's Physician Data Query in 1982. Since then, the online resources have been continuously updated to reflect the growing number of users accessing health information via the Internet.

As a Federal Agency, NCI funding is obtained through budget requests. The 2008 budget request for the NCI is \$5.8 billion. Of this, 10%, \$585 million, is allocated to cancer prevention and control. A portion of these funds is used to maintain and update the site as needed. The exact amount spent on the site alone was not available through requests to NCI for this information nor is it a specific line item in the budget. The following is

¹²² National Cancer Institute, "NCI Mission Statement", Oct 2007, www.cancer.gov

the information provided regarding a funding for cancer.gov, “cancer prevention and control funds are used to support research, communication, and other activities to reduce cancer risk, incidence, morbidity, and mortality and improve the quality of life for cancer patients.”¹²³

Wikipedia.org

Wikipedia is nonprofit website run by a foundation with the goal of providing an Internet-based free encyclopedia. The content comes from an international collaboration of volunteers. The site started as an offshoot of an abandoned project called Nupedia. Nupedia was to provide thoroughly reviewed information from an elaborate system of peer review with content from experts in their respective fields. However, the provision of information was determined to be too slow via this mechanism with less than 15 articles completed during the first year. In 2000 the Nupedia concept was rethought and in 2001 Wikipedia launched with an open content concept.

Currently, Wikipedia has over 75,000 active contributors working on over five million articles from all over the world. Edits to the articles content are made daily with an average editing rate of 10,000 per day. Contributors do not need any specialized training or background to provide information to the Wikipedia site. Any individual that visits an article on Wikipedia is free to add to or change the content of the article. The site does employ an automated system to check edits and references and retains the right to remove

¹²³ National Cancer Institute, “NCI Budget Request for FY 2008”, Oct 2007, www.cancer.gov

content deemed inappropriate, inaccurate, or otherwise contrary to the site's editing policies.

Due to the open nature of the site's content, Wikipedia does caution users about the information provided. The site provides the following:

However, like all sources, not everything in Wikipedia is accurate, comprehensive, or unbiased. Many of the general rules of thumb for conducting research apply to Wikipedia, including:

- Always be wary of any one single source (in any medium—web, print, television or radio), or of multiple works that derive from a single source.
- Where articles have references to external sources (whether online or not) read the references and check whether they really do support what the article says.¹²⁴

There are both strengths and weaknesses with an open content site such as this. Some of the strengths are; speed in reporting breaking news on items of interest, provision of information from international sources allowing a wider range of perspective, and the large number of active editors presumably may provide neutral and objective coverage as well as increasing the likelihood of correcting factual errors or misleading statements.

The weaknesses include; the open content allows for a user to provide misinformation at

¹²⁴ Wikipedia, "Researching With Wikipedia", Oct 2007
http://en.wikipedia.org/wiki/Wikipedia:Researching_with_Wikipedia

any given moment that may or may not be immediately corrected, the information provided may not be balanced such as that provided on other reviewed-content sites, and many contributors do not use references for their sources of information making it difficult for a user to assess the credibility of the information provided. From an academic perspective, the weaknesses of the site outweigh the strengths, and consequently most universities and peer-reviewed journals do not accept the use of Wikipedia as a reference. For the sake of this work, Wikipedia is used as a data point due to its being a site identified via the commonly used search engines when searching for cancer information on the Internet.

Funding for Wikipedia is provided mainly through donations that are requested through its site. At this time it does not engage in advertising as a means for revenue generation. Donations come from over 50 countries and are generally small in nature. However, due to the extensive reach of the site, the Wikimedia Foundation¹²⁵ has been successful in continuing operations based on the large number of donations. The costs to provide Wikipedia are estimated to exceed \$2.5 million in 2007¹²⁶. The majority of the expense is the computer hardware. Additional costs are for hosting, bandwidth, and office staff.

¹²⁵ The Wikimedia Foundation, Inc. is a nonprofit charitable organization dedicated to encouraging the growth, development and distribution of free, multilingual content, and to providing the full content of these wiki-based projects to the public free of charge. The Wikimedia Foundation operates some of the largest collaboratively edited reference projects in the world, including Wikipedia, one of the 10 most visited websites in the world. – accessed Jan 2008 <http://wikimediafoundation.org/wiki/Home>

¹²⁶ personal e-mail communication, Wikipedia Public Information Officer, Oct 2007

MedicineNet.com

As an example of information provision from a commercial site (.com) the author selected MedicineNet.com. This site is owned and operated by WebMD.com.

Consequently, WebMD dictates the business practices. MedicineNet.com started in 1996 and provides health information to the general public that is easily accessible, comprehensive and reliable based on the internal and external review mechanisms employed. Though a commercial site, it is not engaged in directing users to any particular product but instead aims to provide a better understanding of the health topic of interest.

An editorial board that selects topics considered suitable for the user determines site content. The board also responds to user and staff requests regarding topics of interest. Subjects that are included in the site are kept separate from the commerce and advertising divisions of MedicineNet. Thereby helping to prevent any commercial influence over site content. The site uses a multi-step process to control article content outlined below:

- Approval is given by the Medical Editorial Board for new content, or to update/review existing content.
- A specific medical editor is assigned to work with each writer.
- After approval, a Producer assigns a task to a writer.
- A writer receives the assigned task, interacts with the assigned medical editor, and submits a draft of the text in a Word document (with track changes on) to the assigned medical editor.
- The medical editor critically reviews the text and returns comments, questions, and deletions as well as revisions and specific requests to the author. The medical editor may also seek the input of other members of the writing staff or Medical Editorial Board or outside reviewer.
- A revised version of the text is reviewed by the medical editor who then performs initial formatting and transfers the text to the lay editor.

- The lay editor critically reviews all aspects of the content for logic, clarity, and presentation.
- The lay editor returns the revised text to the medical editor for review.
 - The medical editor interacts with the lay editor as needed to produce the final copy.
- When the final copy of the text is ready, the article is "released" and ready for publication (posting) via the TMS.
- The medical editor performs all database relational coding for the final publication of the article. The text appears as new or updated content on MedicineNet.com.
- Newly and updated posted articles are finally reviewed in presentation at regularly scheduled meetings of the MedicineNet.com Medical Editorial Board.
- After the Medical Editorial Board meeting, another member of the Medical Editorial Board is assigned to review the published article.¹²⁷

Funding for MedicineNet is provided through commercial advertising on its site. The site follows the guidelines of its corporate parent, WebMD. The advertising rules are a comprehensive set of guidelines that govern how advertising is accepted, how advertising is displayed, and removal of advertising. In general, WebMD does not endorse its advertisers, will not provide advertising for alcohol, tobacco, firearms, gambling, or pornography, and reserves the right to reject or remove any advertising for any reason at any time. For year-end 2006, WebMD generated overall revenue of \$254 million with \$170 million of that coming directly from advertising. WebMD stated their operating costs at \$106 million.

Comparison of .com .org and .gov

¹²⁷ MedicineNet, "Content Production" Oct 2007, <http://www.medicinenet.com/script/main/hp.asp>

The IDMI providers above offer specific examples of the type of sites that this work identified as providing users with information about cancer. However, some general concepts can be formed regarding their operation that may be considered applicable to similar institutions. As a general rule, sites with a .gov address are funded through the US Federal Government. There is typically a substantial and easily identifiable history associated with the organization providing the information. The mission is well defined and specific to the topic of interest, cancer in the case of this research. Sites with the .org address are usually nonprofit organizations that hold a special tax status to act in this capacity from a business perspective. Their funding is generated through fundraising efforts and/or donations. The content may be thoroughly reviewed but may not be up to the standards set by a .gov site. The two .org sites reviewed in detail show the range of information that may be provided. Cancer.org supplies information that undergoes content review prior to provision while Wikipedia.org provides information that is user generated and may or may not be reviewed for accuracy. .com websites generate a large portion of their revenue through advertising. In the case of the parent company (WebMD) of MedicineNet.com, advertising revenue accounted for over 67% of the total revenue generated for 2006. It may be argued that it is in the site's interest to provide quality information, drawing a large number of users and subsequently generating a high rate of hits on advertisers links.

V. Methods

The methods chapter provides the reader some of the background regarding; how search engines were selected, how the specific types of cancers were selected, and the type of quantitative study performed.

Previous work done by the Pew Internet and American Life Project provided a wealth of information regarding how users access Internet information via search engines. This work was used as a basis for determining the selection of the search engines due to the actions of users. As noted in the Introduction, cancer was selected as the health topic of interest due to the prevalence of searches on this topic. However, it is rare that a user searches for the generic term “cancer”. Moreover, a user will seek out information on specific types of cancer personally relevant to their situation. This chapter identifies how the five specific search terms were selected. Finally, this study was analyzed using a cross sectional methodology. The reason was to capture a snapshot of what is currently happening with IDMI as opposed to a longitudinal analysis.

Background

Pew Internet and American Life Project

The way users employ search engines has been studied over the years through the Pew Foundation's Internet and American Life Project. The Pew Foundation began in 1948 through the creation of the Pew Memorial Foundation¹²⁸. The Foundation serves as a nonprofit institution dedicated to enhancing knowledge through providing information to organizations and individuals based on scientifically conducted research seeking to advance practical solutions to complex problems. The Internet and American Life Project is one of many parts of the foundation that is dedicated to furthering knowledge about the influence of the Internet on America. The Project is designed to conduct research into, "families, communities, work and home, daily life, education, health care, and civic and political life"¹²⁹. The Project conducts the work through telephone and online surveys. It typically releases around twenty original research works annually that vary in size and scope. The work provides insight into how Americans behave when they are online as individuals and in groups.

Many researchers as well as those working on the Project have released numerous works that relate directly to how users employ search engines. As the percent usage of the Internet has grown over the years, so has the way that users exercise search engines. This

¹²⁸ The Pew Charitable Trusts "About Us", Jan 2007, <http://www.pewtrusts.com/about/index.cfm>

¹²⁹ Pew Internet and American Life Project, "About Us", 2005, Jan 2007, <http://www.pewinternet.org/about.asp>

may be due to the increasing sophistication of the online community, increasing popularity and subsequent knowledge of search engines, and increased presence of search engines on popular sites.

Studies released by the Project have conducted detailed analyses of how search engines were used and by what kind of user. A 2002 study looked at four specific types of searches; searching for an individual, searching for health information, searching for government information, and searching for religious information¹³⁰. A 2005 study focused on the emotions users expressed about a search engine and compared it to their actual knowledge of how search engines operate and the compiled results displayed to users¹³¹. Following is a list of information that is collected from the various studies released by the Project. The list focuses on the parts of the studies most relevant to creating the methodology used in this work. The Project found that:

- A user went to a typical search engine first, as opposed to a specialty site like WebMD.com when looking for health information,
- A user visited two to five sites during a single search session,
- A user found what they are seeking 87% of the time,
- A user reported few cases of harmful effects by acting on bad information,

¹³⁰ Pew Internet and American Life Project, “Search Engines: A Pew Internet Project Data Memo”, July 2002, Jan 2007.

¹³¹ Fallows, D., “Search Engine Users: Internet Searchers are Confident, Satisfied, and Trusting – but They are Also Unaware and Naïve”, Pew Internet and American Life Project Jan 2005, Jan 2007, http://www.pewinternet.org/PPF/r/146/report_display.asp

- 45% of users started at the top of the results page and worked their way down,
- 39% searched the results for the links they deemed most relevant,
- 12% clicked on a search result because they recognized the name or sponsor of the site,
- A user picked one search engine and consistently used it rather than comparing results between search engines, and
- Only 18% of users could tell the difference between a sponsored result and an unpaid result.

The results of the Pew Internet and American Life project were considered when creating the methodology for studying the policy tools within this work. The later empirical chapter's methods sections elucidate specifically how they relate to each policy tool. In general, the data provided by the Pew Project suggest that a study design that is focused on information provided via the Internet needs to take into account how users access that information. The points above lead to the conclusion that the average Internet user going online in search of health and medical information is most likely:

- Going to use only one of the most popular search engines for the search,
- Visiting only a few of the sites in the search results to review the requested information,

- Not paying a great deal of attention to whether the result is a paid sponsor and therefore listed on the first page of the search results due to advertising dollars as opposed to relevancy to search terms, and
- Feeling confident about the information and not concerned about potentially harmful effects of using that information.

Selection of Search Engines

A 2002 Pew Internet and American Life project study found that Google was the most popular search engine at that time¹³². Other more recent studies have indicated that Google, Yahoo!, and MSN take the top spots as the Internet's most popular search engines. A 2004 study indicated that these three search engines are the top three as defined by market share and have the greatest loyalty among users; Google with 65.8%, Yahoo! with 55.2% and MSN with 53.7%¹³³. Loyalty provides an indication that users will return to the same search engine time after time when seeking information on the Internet. For the sake of this research, the author uses Google, Yahoo!, and MSN as the engines to search the Internet for the presence or absence of information related to the policy tools of interest; prohibition, information provision, and certification.

¹³² Pew Internet and American Life Project, "Search Engines: A Pew Internet Project Data Memo", July 2002, Jan 2007. http://www.pewinternet.org/PPF/r/64/report_display.asp

¹³³ iProspect, "Search Engine Marketing Firm iProspect Survey Confirms Search Engine Loyalty Exists", Apr 2004, Jan 2007, http://www.iprospect.com/media/press2004_04_14.htm

Selection of Search Terms

A general search for the term “cancer” is not what a typical user would enter into a search engine when accessing the Internet. Numerous previous studies have surveyed users and researched the logs of individual search engines to determine the most widely searched terms. For this analysis the method to investigate each policy tool adopts the same strategy with respect to the search terms entered into the three search engines. Based on work done by Bader and Theofanos in 2003¹³⁴ and follow up work by Doolittle and Spaulding in 2005¹³⁵, the five most searched terms regarding cancer are:

- 1) Breast cancer
- 2) Lung cancer
- 3) Leukemia
- 4) Colon cancer
- 5) Prostate cancer

These are the five search terms that will be entered into the Google, Yahoo!, and MSN search engines to determine the results for each of the policy tools. The specific data points gathered resulting from these search terms are further discussed in the methods sections of the chapters specific to each of the policy tools.

¹³⁴ Bader, J.L., Theofanos, M.F., “Searching for Cancer Information on the Internet: Analyzing Natural Language Search Queries”, J Med Int Res, 2003:5(4) e31 Jan 2007 <http://www.jmir.org/2003/4/e31>

¹³⁵ Doolittle, G.C., Spaulding A., “Online Cancer Services: Types of Services Offered and Associated Health Outcomes”, J Med Int Res, 2005:7(3) e35 Jan 2007 <http://www.jmir.org/2005/3/e35>

Search Terms Leading a User to Complementary and Alternative Medicine

A user searching for medical information about the five most commonly searched cancer terms would not immediately identify complementary and alternative medicine (CAM) information. CAM information covers the areas of information this work sought to uncover in searches for specific types of cancer information. Cassileth et al. note that the use of alternative therapies by cancer patients is quite high and ranges from 31% to 64% depending on how the researchers defined CAM¹³⁶. Barnes et al. identify the following as the top ten most commonly used CAM therapies along with the frequency of usage among over 31,000 adults in a 2002 CDC survey:

- Prayer specifically for one's own health (43%)
- Prayer by others for one's own health (24.4%)
- Natural products (18.9%)
- Deep breathing exercises (11.6%)
- Participation in prayer group for one's own health (9.6%)
- Meditation (7.6%)
- Chiropractic care (7.5%)
- Yoga (5.1%)
- Massage (5.0%)

¹³⁶ Ernst, E., Cassileth, B.R., "The Prevalence of Complementary/Alternative Medicine in Cancer: A Systematic Review", *Cancer* 1998;83 pp 777-82.

- Diet-based therapies (3.5%)¹³⁷

It is therefore curious as to why this work did not identify the type of information that might be construed as CAM therapy that falls outside of the guidelines of regulatory agencies. It seems to be highly sought by users seeking cancer information. The author suggests that it is due to user's entering in information about the disease itself as opposed to treatment options. If a user is seeking information only about a specific disease and does not enter any treatment criteria, it is unlikely that CAM information will be found. However, when the user seeks treatment information, the purveyors of questionable CAM therapy information abound whether or not the information provided is appropriate and within US regulatory agency guidelines. This was noted by Biermann et al. who performed an Internet search in 1998 using six common search engines at that time with the objective to ascertain the quality of the information available about a relatively rare form of cancer. They concluded that, "Had we performed our study by searching therapies, rather than by searching a disease, we would have found abundant information regarding such alterative medicines as hydrazine sulfate, shark cartilage, and coffee enemas."¹³⁸ This work is not suggesting that all CAM information is of questionable value. In fact, there is a wealth of clinical data that suggests that CAM therapies such as acupuncture¹³⁹ and massage¹⁴⁰ may provide significant benefit to cancer patients. The

¹³⁷ Barnes, P.M., Powell-Griner, E., McFann, K., Nahin, R.L., "Complementary and Alternative Medicine Use Among Adults: United States 2002", *Adv Data*, May 2004:343 pp 1-19.

¹³⁸ Biermann, J.S., Golladay, G.J., Greenfield, M.L., Baker, L.H., "Evaluation of Cancer Information on the Internet", *Cancer Aug* 1999:86(3) pp 381-90.

¹³⁹ Alimi, D., Rubino, C., Pichard-Leandri, E., "Analgesic Effect of Auricular Acupuncture for Cancer Pain: A Randomized, Blinded, Controlled Trial", *J Clin Oncol* 2003:21 pp 4120-26.

author does suggest that the use of herbs and supplements requires close scrutiny as they may interfere with conventional treatments¹⁴¹.

It is recognized that other search terms might provide results with links to sites that do not follow the guidelines. Although not included in this work, the #6 result on Google for the search term “cancer cure” was <http://www.elbeeglobal.com/>. This site states: “Natural Alternative Cancer cure / cures: Natural, Safe, Effective & Scientifically Results Proven by the Ministry of Health of China --- Cure for Cancer!” and sells two products, cessoriac and yuccalife. Dr. Ziment, professor of medicine at UCLA made the following remarks regarding this claim:

There are numerous allegedly effective cures or even relievers of cancer that lack any validity. To prove a drug or a mixture of herbs have any useful benefits can take years of scrupulous research and usually is enormously expensive. Unfortunately many fake remedies are sold, and many other cures are promoted without justification. There is always a story about a miraculous response to a traditional or secret remedy but all the evidence is that such products are useless or possibly harmful. The old adage is that if it sounds too good to be true it very probably is not true. The other important adage is buyer beware¹⁴².

As the model for this work did not enter the term “cancer cure” into the three search engines used, this result is outside of the scope of this investigation. However, it is important to note that there is a great deal of information available on the Internet that

¹⁴⁰ Grealish, L., Lomasney A., Whiteman, B., “Foot Massage: A Nursing Intervention to Modify the Distressing Symptoms of Pain and Nausea in Patients Hospitalized With Cancer”, *Cancer* 2003:98 pp 2723-29.

¹⁴¹ Labriola, D., Livingston, R., “Possible Interactions Between Dietary Antioxidants and Chemotherapy”, *Oncology* 1999:13 pp 1003-8.

¹⁴² Ziment, I., “Can Chinese Products Like Cessoriac and Yuccalife Cure Cancer?”, *Doctor NDTV*, Nov 2004, Dec 2006, <http://www.doctorndtv.com/faq/detailfaq.asp?id=5605>

provides information that is outside of regulatory agency guidelines. A user starting an initial inquiry into the most highly searched cancer terms would not immediately find this information. That is the stage that this work tested. However, a user who searched alternative remedies and/or therapies outside the realm of traditional medicine would soon find information making claims far outside those approved by the FDA and FTC.

Cross Sectional Analysis versus Longitudinal Study

This work is conducted as a cross-sectional analysis instead of as a longitudinal study. The nature of a cross-sectional analysis is to explore the topic areas of interest at a particular moment in time as opposed to the longer-term multi-year timing of a longitudinal study. The point-in-time nature of this work aims to provide an analysis of the effectiveness of these policy tools as they relate to IDMI when this work was conducted in the early part of 2007. Further research conducted as a longitudinal study may well provide additional insight as to the effectiveness of policy tools on IDMI as the prevalence of regulation and Internet usage increases. This cross-sectional analysis investigates the individual effectiveness of prohibition, information provision, and certification as well as comparing the relationship between these tools as a snapshot. The model can be run periodically and this work can be used as a baseline for future research. When future Internet regulatory actions are implemented, the model can be run to investigate the effects.

VI. Prohibition Policy Tool

As a means to investigate the prohibition policy tool regulating IDMI, the author conducted a case study analysis on the case of US vs. Lane Labs-USA, Inc. In the 1990s the Food and Drug Administration and Federal Trade Commission acting through the Operation Cure.All campaign contacted Lane Labs, Inc to inform them to cease providing information to consumers that their products were cures for cancer. Lane Labs did not do so and was ultimately called into court resulting in a \$1 million judgment against Lane Labs and its president Andrew J. Lane. In addition, Lane Labs was directed to provide \$8 million in consumer redress to customers who purchased the purported cancer cure products.¹⁴³ As of this writing, Lane Labs has appealed the ruling in federal court.¹⁴⁴ Lane Labs continues to provide the products it had heretofore claimed to cure cancer via its website, www.lanelabs.com however, subsequent to the decision against them in the case, Lane Labs has removed the information that makes claims regarding the prevention, treatment, and cure for cancer of its products.

¹⁴³ US FTC "'Operation Cure.all" Nets Shark Cartilage Promoters: Two Companies Charged with Making False And Unsubstantiated Claims for Their Shark Cartilage And Skin Cream as Cancer Treatments", Federal Trade Commission, Jun 2000, Nov 2006, <http://www.ftc.gov/opa/2000/06/lanelabs.htm>

¹⁴⁴ Wallace, P., "Lane Labs Agrees to Settlement but Continues its Appeal", Food Chem News, Jul 11, 2005 v47 i22 p13

The author used this case study to determine whether or not the information that Lane Lab's product Benefin prevents, treats or cures cancer is still available to Internet users. Claiming that Benefin and/or shark cartilage is a cancer remedy is prohibited by the FDA and FTC and enforced by the action of the courts. For the prohibition policy tool to be considered effective, a user should not find claims of the cancer-curative properties of Benefin and shark cartilage while performing a search for cancer information.

Introduction – Lane Labs

Dubious IDMI is prevalent on the Internet as noted in the reference to Hi-Tech Pharmaceuticals providing pro-ephedra information subsequent to the FDA ruling that it was banned. Hi-Tech's executives suffered financial consequences and may face jail-time due to their provision of prohibited medical information. While the Hi-Tech case involved medical information, it was not specific to the topic of interest, cancer. As the subject matter of interest for this work is specific to cancer, the author selected another case study for in-depth analysis.

Lane Labs was selected as a case study as an outlier example of one of the cases wherein the full enforcement capabilities of US regulatory agencies were employed. The author considered this case to be one of the infrequent examples when a cancer IDMI purveyor was thoroughly reviewed, pursued, and ultimately banned from providing information

considered to be outside the guidelines of regulatory policy. This is not the case in a vast number of the other IDMI providers available on the Internet today. A JAMA study by Morris and Avorn published in 2003 identified 443 websites providing oral supplement products of which 81% made one or more claims that their products treated, prevented, diagnosed, or cured specific diseases¹⁴⁵. Following is an example of one such claim:

- Ginseng – It is potentially beneficial for AIDS, radiotherapy, and chemotherapy patients, as it reduces the side effects of toxic drugs by increasing red and white blood cell counts. Dang Shen [product name] is given for breast cancer, asthma, diabetes, heart palpitations, memory or appetite loss and insomnia¹⁴⁶.

Claims such as that noted above and the others on 81% of the sites identified by Morris and Avorn are in direct violation of FDA policy. Furthermore, in more than half the sites identified in this study, the required standard FDA disclaimer was omitted. This is not the case for the Lane Labs website. As of the writing of this article, their site does not make any claims contrary to FDA guidelines and they do include the standard FDA disclaimer on the areas of their site wherein they are selling supplements.

Lane Labs – USA, Inc. Company Profile

¹⁴⁵ Morris, C., Avorn, J., “Internet Marketing of Herbal Products”, JAMA Sep 2003;290(11) pp 1505-9.

¹⁴⁶ Ibid.

Lane Labs – USA, Inc. is a privately held company headquartered in Allendale, New Jersey. The company was founded in 1994 and is run by Andrew Lane with less than one hundred employees in total. The company provides natural supplements, topicals, pharmaceuticals, and testing kits. Lane Labs states their mission as follows: “Our collective mission is simple: to identify and produce advanced natural compounds whose efficacy is supported by rigorous science.” – provided by Andrew Lane via LaneLabs.com.¹⁴⁷

Background

History and recent findings regarding the use of shark cartilage

The study and use of cartilage as a treatment for cancer has been ongoing for over 30 years.¹⁴⁸ In the early days of the research, there was a belief that sharks did not develop cancer. This led to the thought that there was some property of their cartilage that may treat cancer. It has since been discovered, that although rare, malignant tumors have been found in sharks thus dispelling the myth that sharks do not get cancer.

The early studies of cartilage focused on extracts from cows. During the 1960s, reports indicated that bovine cartilage decreased inflammation. In the 1970s it was first reported

¹⁴⁷ Lane Labs, “LaneLabs Mission Statement”, 2006, Nov 2006, <http://www.lanelabs.com/aboutUs/missionStatement.asp>

¹⁴⁸ National Cancer Institute, “Cartilage, Bovine and Shark”, Nov 2006, <http://www.cancer.gov/cancertopics/pdq/cam/cartilage/Patient>

that bovine cartilage contains something that blocks the formation of new blood vessels. This led to the conclusion that if new blood vessel growth (angiogenesis) was inhibited, cancerous tumors would stop growing and possibly shrink. In the late 1970s and early 1980s, researchers devised laboratory and animal studies to test bovine cartilage as a treatment for cancer. These studies included few clinical trials.

During the trials of the late 1970s and early 1980s, interest grew in shark cartilage over bovine cartilage as it was believed that whatever property was preventing angiogenesis might be more active in shark cartilage. Additionally, belonging to the class *Condrichthyes* or cartilaginous fishes, a shark's skeleton is mostly cartilage and hence much easier to harvest than bovine cartilage. In the early 1980s the first study was published in "Science" suggesting that shark cartilage contains an angiogenesis inhibitor.

In 1983 "Science" published a study by Lee and Langer indicated that shark cartilage inhibited tumor growth in the eyes of rabbits through inhibition of angiogenesis.¹⁴⁹

Biochemist and entrepreneur I. William Lane, Ph.D. began investigating the use of a pharmaceutical grade preparation of shark cartilage as a cure for cancer. Lane received a patent for the process by which he manufactures shark cartilage and began creating studies to prove his form of shark cartilage would be effective in cancer treatments. His study first published in 1991 suggested that his product stopped the growth of

¹⁴⁹ Lee, A., Langer, R., "Shark Cartilage Contains Inhibitors of Tumor Angiogenesis." Science. 1983:221 p 1185-1187.

subcutaneously introduced melanomas in mice.¹⁵⁰ Lane conducted subsequent clinical trials in Mexico and Cuba. He concluded that both studies successfully showed that his preparation of shark cartilage was effective in treating cancer. Lane stated, “In my opinion, the major activity of shark cartilage in inhibiting tumor growth is based on four proteins found in the strand-like fibers in shark fin or shark cartilage. These angiogenic-inhibiting proteins, working synergistically, when *properly processed* [emphasis added] and administered, appear to stop and reverse tumor growth.”¹⁵¹

CBS Television’s “60 Minutes” brought shark cartilage to the public’s attention in February 1993 with the airing of a program highlighting Dr. Lane’s Cuban study.¹⁵² During this television show, cancer patients enrolled in Lane’s study were shown exercising and reporting that they felt better after having been provided several weeks’ treatment of Lane’s shark cartilage preparations. The show further went on to discuss Lane’s book, *Sharks Don’t Get Cancer*. This exposure to the general public created a large demand for shark cartilage as a cancer treatment.

Subsequent to the rise in popularity of the use of shark cartilage as a cancer treatment, the National Cancer Institute had officials review Lane’s study. They concluded that the data

¹⁵⁰ Lane I.W., “Shark Cartilage: Its Potential Medical Applications.” J. Advan Med 1991:4 pp 263-271

¹⁵¹ Villaire, M., “From Idea to Trials: The Story Behind Lane’s Shark Cartilage.” Alt Ther in Health and Med 1995:11 vol 1 issue 6.

¹⁵² Hendricks, M., “Predators Promise.” Johns Hopkins Magazine Jun 2000, Nov 2006
<http://www.jhu.edu/~jhumag/0600web/shark.html>

from the Cuban study were, “incomplete and unimpressive”.¹⁵³ In addition, Lane himself acknowledged that the data in his Mexican and Cuban studies “wasn’t peer review quality.”¹⁵⁴ It is somewhat surprising that the agreement by the author that his work amounts to little more than junk science (by Milloy’s aforementioned standards) might lead to additional work. However, Lane’s work led to more than a dozen clinical trials to investigate the possibility that shark cartilage may prove to be a cancer treatment. So far, the results of four of these studies have been published in science journals.

None of the aforementioned studies, including one funded by Lane Labs and conducted by the National Cancer Institute have shown that there is a therapeutic value to the ingestion of shark cartilage.¹⁵⁵ In the opinion of noted biochemist Saul Green, “If shark proteins could be absorbed intact into the body, they would generate fatal allergic reactions.”¹⁵⁶ In addition to Green’s statement, Dr. Charles L. Loprinzi, a cancer researcher at the Mayo Clinic in Rochester MN published results of his placebo-controlled trial of shark cartilage in the July 2005 journal *Cancer* noted, “When we set out to do this as a placebo-controlled evaluation I would have loved to carry the banner of a positive study. After the study’s disappointing results, we’re not planning to look

¹⁵³ Matthews, J., “Media Feeds Frenzy Over Shark Cartilage as Cancer Treatment.” *J of the Nat Can Instit* 1993:85 pp 1190-1191.

¹⁵⁴ Villaire, M., “From Idea to Trials: The Story Behind Lane’s Shark Cartilage.” *Alt Ther in Health and Med* 1995:11 vol 1 issue 6.

¹⁵⁵ Barrett, S., “Government Action Curbs Shark Cartilage Claims”, *Quackwatch*, Jul 2004, Nov 2006, <http://www.quackwatch.org/04ConsumerEducation/News/shark.html>

¹⁵⁶ Green, S., “Shark Cartilage for Cancer.” *Sci Rvw of Alt Med* 2003:7(1) PP 21-25.

further at it, and I wouldn't recommend anyone look further at the product we looked at.”¹⁵⁷

Operation Cure.All

Operation Cure.All is a multi-national campaign that includes the efforts of government institutions, policy makers, and health professionals. The FTC released a statement in June 2000 outlining a case wherein they were beginning to make progress through Operation Cure.all in their consumer education campaign that targeted false, misleading or unsubstantiated IDMI. As part of Operation Cure.all the FTC alleged that two companies engaged in a common practice to deceive consumers that their shark cartilage based products, BeneFin and SkinAnswer were curatives for cancer. In addition, the FTC alleged that the companies falsely promoted clinical trials that supposedly provided results that BeneFin and SkinAnswer were efficacious in preventing, treating, or curing cancer. Lane Labs, Inc., was one of the two companies named in the settlement. Lane Labs would be prohibited from making unsubstantiated health claims about its dietary supplements and incurred a \$1,000,000.00 judgment against the company and its president Andrew Lane. The other company, Cartilage Consultants, was charged with helping to promote the products through third-party publications supplying consumers

¹⁵⁷ Finkelstein, J.B., “Sharks Do Get Cancer: Few Surprises in Cartilage Research.” J of Nat Can Instit 2005: v97(21) Nov 2 pp 1562-3.

with the information of how to use the products manufactured by Lane Labs in order to treat cancer.

US vs. Lane Labs, Inc.

Lane Labs, Inc., run by president Andrew Lane and Cartilage Consultants run by Andrew Lane's father I. William Lane were first notified that they were promoting their products in violation of FDA regulations in 1997. FDA issued a warning letter to Lane Labs on June 13, 1997. According to the warning letter:

At a recent medical conference, Lane Labs distributed promotional materials, including reprinted articles and a promotional brochure, at its booth in the commercial exhibit hall. These materials make numerous claims of safety and effectiveness, and thereby promote an unapproved drug. Promotion of an unapproved drug is in violation of the Act [FFDCA]. Accordingly, Lane Labs should immediately cease all activities that promote its investigational drug, BeneFin.¹⁵⁸

Though in receipt of the warning letter, Lane Labs continued to promote through mass mailings, Internet sites and employee statements and sell BeneFin. In December 1999, working as a partner of Operation Cure.all, FDA filed for a permanent injunction against the company, asking the court to legally mandate that it stop selling Benefin. The FDA made this request due to the company's demonstrated unwillingness to comply with the FFDCA.

¹⁵⁸ US FDA, "Benefin MACMIS #5465", Jun 1997, Sep 2006
<http://www.fda.gov/cder/warn/june97/5465.pdf>

After a lengthy legal battle, on July 9, 2004, U.S. District Judge William G. Bassler permanently prohibited Lane Labs-USA Inc. and its president, Andrew J. Lane, from distributing drug products. Judge Bassler's decision resulted from the conclusion that the shark cartilage based products that Lane Labs was selling to consumers, were being marketed as drugs and not as dietary supplements under the DSHEA. The products, BeneFin and Skin Answer were being marketed as treatments for cancer without FDA approval. Lane would be allowed to market the products once they received approval for marketing by the FDA or distributed under an Investigational New Drug application for purposes of conducting a clinical trial. In addition to enjoining the distribution of the products, Bassler also ordered the defendants to refund \$8 million in product cost to all purchasers of the products since Sept. 22, 1999 and destroy any stock of the products in its inventory. Lane stated that it would appeal the decision.

Dr. Lester M. Crawford, Acting FDA Commissioner referred to the New Jersey Court's decision by stating, "Today's action by Judge Bassler sends a strong signal that the promotion and sale of unapproved drug products, especially for the treatment of cancer and other serious diseases, will not be tolerated,"¹⁵⁹.

¹⁵⁹ FDA Consumer, "Company ordered to halt sales of unapproved drugs, reimburse buyers." Sept-Oct 2004 v38 i5 p5(1)

Undermining Deterrence Theory

Commissioner Orson Swindle agreed in part and dissented in part to the judgment made against Lane Labs. The conditions of the \$1 million judgment allow that Lane Labs would be granted the opportunity to use \$450,000.00 of the judgment to fund a National Cancer Institute clinical trial. The purpose of the clinical trial would be to determine whether or not shark cartilage is an effective cancer treatment. Swindle's opinion agreed with Clarke's argument that the deterrent effect of a prohibition policy is successful only when the offender experiences the pain dispensed through enforcement.

Swindle believed this to be imprudent on the part of the court. He argued that to allow Lane Labs to profit from its deception, i.e. claiming that BeneFin was effective in preventing, treating, and curing cancer, was not in line with the spirit of the case. Lane Labs did not conduct clinical trials of its product prior to distributing them to the public. Lane illegally promoted the product per the FTC Policy Statement Regarding Advertising Substantiation¹⁶⁰ and subsequently sold it at a profit to consumers. Swindle argued that Lane should have been forced to pay for a clinical trial prior to releasing BeneFin and not allowed to use the fruits of its illegal sale to pay for a study after being caught. Swindle argued that the full \$1 million should have been paid by Lane into a fund for consumer redress. If Lane wished to conduct a clinical trial, the company should have done so in addition to the \$1 million judgment. Swindle noted that by allowing a company to pay for

¹⁶⁰ Thompson Medical Co., Inc., (reprint) 104 F.T.C. 648, 839 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986)

clinical trials after illegally advertising and generating profits that it creates an incentive for advertisers to go ahead with marketing that violates FTC regulations. The Lane Case sets the precedent that manufacturers can generate substantial profits while making unsubstantiated claims knowing that if they are caught and prosecuted, they may have the option of paying for the study that should have been done prior to marketing their product with profits from the sale of the product.

Swindle noted that the consumer redress provision was not the proper vehicle for the government to use to fund cancer research. While he agreed that cancer research is in the public interest, a judgment against a company for its illegal actions is not the proper forum from which to draw the monies. The company profited from an illegal act and was allowed to use the funds to conduct a study that should have been conducted prior to the promotion of the product. The judgment partially undermines the pain that the offender should suffer under general deterrence theory. However, the \$8 million Lane Labs was directed to pay back to consumers enforced the public recognition of pain dispensation to other would-be wrongdoers.

Methods

This section of the work aimed to determine the effectiveness of the prohibition policy tool for IDMI. In the case study of Lane Labs, the study investigated whether or not

there is information present on the Internet regarding their product, Benefin, and its prevention, treatment or curative properties. If the prohibition policy tool were effective, one would not expect to find the information about Benefin or the use of shark cartilage as a cancer remedy through a typical Internet search process.

The method used to determine the presence or absence of this information was outlined in the preceding methods section and is based on the work done by the Pew Internet and American Life Project. Using the three most commonly employed search engines, Google, Yahoo!, and MSN, the five most commonly entered search terms for cancer were entered into these engines. The top ten results were then gathered for each of these search terms from each search engine. This resulted in a list of 150 pages.

Within the 150 pages, there were 49 duplicate pages. The duplicate pages were removed from the master data set yielding 101 unique pages in the “cleaned” data set. Each of these 101 URLs was opened and the resulting page searched for information that should not be available if the prohibition tool was effective. The following terms were searched within each page using the search feature (find (on this page)) ctrl+F of Microsoft’s Internet Explorer version 6.0.2800.1106 and also using the search feature of the unique page if that option was available:

- “Benefin”
- “Lane Labs”
- “Shark Cartilage”

If the terms were found then the corresponding material was reviewed to determine if the information provided was promoting a preventative, treatment, or cure for cancer. If information were provided that informed the user regarding a cancer cure the page would be considered a positive for providing prohibited information. If no information was found through the above mentioned search methodology, the page was considered a negative.

Results

The goal of the analysis in this case study was to use it as a tool to allow the author to discern the effectiveness of prohibition as a policy tool for IDMI. It is known from the background section of this chapter that Lane Labs was ultimately barred from providing the information to the general public that their product is a cancer cure.

The search of each of the 101 unique pages using IE's search tool resulted in zero hits for the search terms; Benefin, Lane Labs, and shark cartilage. None of these terms was listed on the page that resulted from a search of the Internet using the three most commonly used search engines.

In order to assess the search feature that 33 of the sites incorporated into the page, it was necessary to identify repetitive Second Level Domains (SLD). The SLD is the identifier

immediately to the left of the Top Level Domain (TLD). The TLD is the three character generic name typically .com, .gov, .edu, .org, or a two character country code, such as .au for Australia. Immediately to the left of the TLD is the SLD. In www.google.com for example, google is the SLD. In the case of the cleaned master data set, there were 62 instances of repetitive SLDs. The following URLs in **Table 6.1** provide an example:

Table 6.1. Example of Multiple Second Level Domains in Search Results

URL

http://www.cancer.org/docroot/cric/content/cric_2_4_1x_what_is_adult_chronic_leukemia_62.asp

http://www.cancer.org/docroot/cric/content/cric_2_4_1x_what_is_adult_acute_leukemia_57.asp?sitearea=cric

http://www.cancer.org/docroot/cric/content/cric_2_4_1x_what_is_lung_cancer_26.asp

Each of these URLs links to a unique page. However, the TLD and SLD in each case are the same, www.cancer.org. Hence, for the purposes of the site-supported search, only one of the URLs was used for collection of data points. The other two were tested to make sure the results returned were identical.

Some of the pages on the cleaned master data set contained search engines built into the site. As the search feature of the unique page is linked directly to the SLD of the site, duplicate SLDs were tested to ensure that the searches provided identical results between the unique pages. Duplicate SLD search engines, in all cases, provided identical results regardless of the sub-domains of the unique results page from the master data list.

There were a total of 39 unique SLDs in the cleaned master data set. The list of these 39 URLs is included in **Appendix 6.A** at the end of this work. Of the 39 unique SLDs, 33 had a built-in site-supported search feature. The search criteria, Benefin, Lane Labs, and

shark cartilage were entered into these 33 site-supported search engines. There were multiple hits for all of the search terms among the pages providing a search feature.

Table 6.2 below provides the number of hits for the search terms.

Table 6.2. Site-supported Search Engine Results for Prohibition Search Criteria

Search Term	Number of Hits
Benefin	8
“Lane Labs”	8
“Shark Cartilage”	21

A search of each unique SLD URL using the site-supported search feature for the prohibition specific search terms, Benefin, Lane Labs, and shark cartilage resulted in a total of 37 hits as noted above. However, a review of each of these hits revealed the information provided did not promote the use of Benefin or shark cartilage as a preventative, treatment, or cure for cancer. In almost all cases, the search results for Lane Labs and Benefin provided information about and/or links to the FTC site that provides information about the ruling against Lane Labs outlined in the background section of this chapter. Searches for Benefin and shark cartilage provided information about its use but cautioned that there is no scientific study that shows any efficacy against cancer. For example, a search on www.breastcancer.org for “shark cartilage” provided the following:

Shark Cartilage

Also known as: SC, carticin, Cartilade, BeneFin

Potential uses: There are claims that shark cartilage kills cancer cells, boosts the immune system, and prevents new blood vessels from growing to nourish a cancer.

Usual dose: The forms available contain different amounts of shark cartilage. Daily doses vary from 500 milligrams to 2 grams per day.

Are there any risks? Side effects include nausea, vomiting, diarrhea, gas, and constipation.

What does the research show? No clinical studies show that shark cartilage has any affect on breast cancer or any other cancer.¹⁶¹

None of the search results from the 33 unique SLDs with site-supported search engines provided the type of information that was prohibited in the Lane Labs case.

Discussion

As mentioned previously in this work, the use of prohibition as a policy tool is the most powerful form of regulation available to US regulatory agencies. It is also the most costly. This is because it requires oversight of the regulated community. For IDMI that would mean policing the Internet. In order to provide adequate regulatory oversight, the agency charged with Internet oversight would have to monitor the activities of all of the relevant IDMI providers. Although it is difficult to track due to proprietary information of the major search engines, estimates are that in February 2007, there were over 29 billion distinct web pages¹⁶². If only a fraction of those 29 billion pages contain medical information, it would be an incredible challenge to monitor them and also keep up with changing Uniform Resource Locators as companies abandon certain web addresses in

¹⁶¹ Breastcancer.org, “Shark Cartilage”, Jul 2007, Sep 2007

http://www.breastcancer.org/tips/nutrition/supplements/known_suppl/cartilage.jsp

¹⁶² This estimate is based on the work done by Netcraft. In April 2005, Yahoo! was the final search engine to release the number of pages it had indexed in its databases. At that time, Yahoo! indexed 19.2 billion pages. Also at that time, Netcraft conducted a study that indicated there were over 70 million unique sites. For the Feb 2007 individual page count, the author presumed approximately 270 pages per site and used Netcraft’s assessment of almost 109 million unique sites to arrive at the distinct page count.

favor of others. While there have been many calls in the medical community¹⁶³ for IDMI regulation, the expense involved in policing this community on a large scale has so far been cost prohibitive. Perhaps future technological breakthroughs using advanced automated web spiders will provide the oversight necessary to rapidly identify and contact purveyors of questionable IDMI.

This case study of the use of the prohibition policy tool against Lane Labs shows that it was effective in preventing the dissemination of the prohibited information via the most commonly used search engines for the most commonly searched cancer terms.

Government intervention and enforcement of a prohibitory regulatory policy by a multi-national cooperative proved effective in this case study.

This work identified 101 unique pages offering information regarding the most highly queried information about cancer. None of these pages immediately provided information regarding Lane Labs or the use of Benefin or shark cartilage as a prevention, treatment or cure for cancer. As this study was not conducted prior to the court's decision to prohibit Lane Labs from providing this information, there can be no direct measurement of the ruling. However, the assessment can be made that the information is not present now via the most common channels that a user might search and discover it.

¹⁶³ Drazen, J.M., "Inappropriate Advertising of Dietary Supplements", N Engl J Med, 2003;348 pp 777-8.

In addition, when taking the additional steps of reviewing the site-sponsored search engines, information about Benefin, Lane Labs, and shark cartilage was identified. Though present, none of it provided the type of information prohibited by the court's decision in US vs. Lane Labs. There were no claims that Benefin or shark cartilage cures cancer and the information about the company provided the regulatory agency's actions.

As the author conducted the analysis on the master data set, it became clear that a further review of the unique pages was warranted. By identifying the 39 unique SLDs in the master data set, the author was able to perform the thorough analysis of each of the sites. Each site-sponsored search engine often returned multiple hits for each of the three additional search criteria; Benefin, Lane Labs, and shark cartilage. This led to the author's review of anywhere from 1 to 23 results for each search term, the average being 8 results. This led to a review of 39 unique SLDs x 3 search terms x 8 results per term = 936 resulting pages to review to determine if the prohibited information was provided. This exhaustive review led to 0 pieces of prohibited information. The following example is illustrative of this process on the www.cancer.org site.

The home page of www.cancer.org has a search engine available for the user. The term "shark cartilage" was entered into this search engine as shown in **Figure 6.1**.

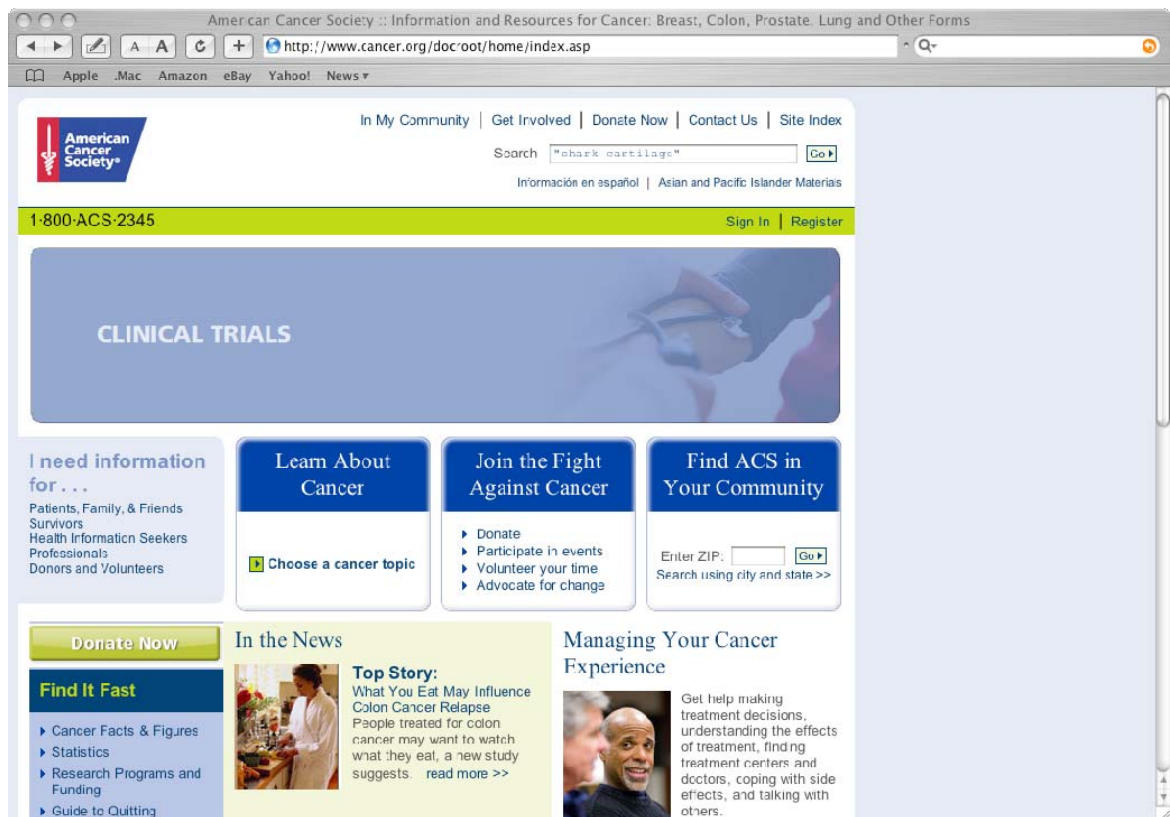


Figure 6.1. American Cancer Society Home Page Illustrating the Site's Search Feature

The search returned seven results for the term as shown in **Figure 6.2**.

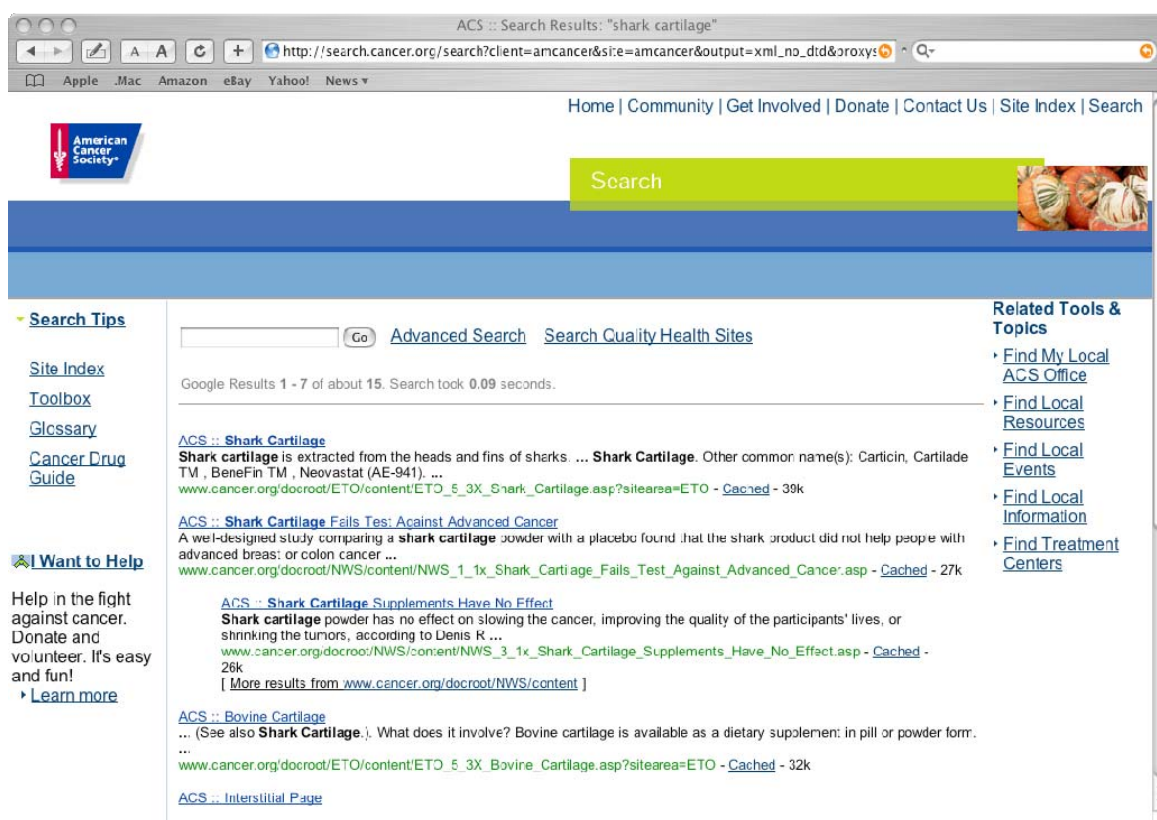


Figure 6.2. ACS Search Results for “Shark Cartilage”

Each of these seven links was opened to determine the type of information provided through the site’s search engine. **Figure 6.3** displays the first link provided information about shark cartilage, how it is used, and informed the user there is no data that shows it is effective in treating cancer.

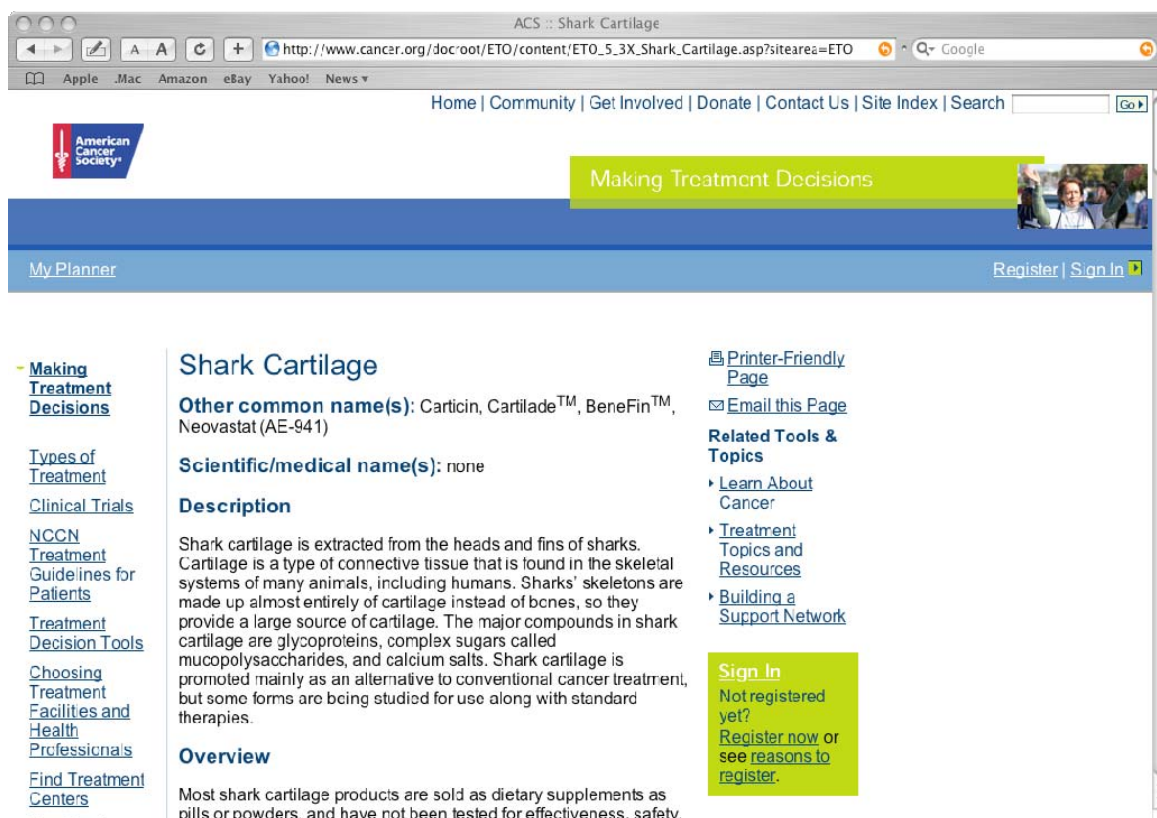


Figure 6.3. One Page of Information Resulting From the ACS Search for “Shark Cartilage”

It is important that the information prohibited by the court ruling is not available and the employment of the prohibition policy tool is effective in this situation. Many subsequent

studies have indicated that the information was flawed at best including some reports suggesting that it was in fact, “a distortion of science... propaganda 101”¹⁶⁴. This is representative of the type of pseudoscience addressed earlier in this work.

There is also an argument in some alternative therapy circles that cancer patients that have tried everything else without success realize some psychological benefit from the hope that shark cartilage might work for them even though there is no scientific evidence of a physiological benefit.¹⁶⁵

Even though Lane Labs and Cartilage Consultants were banned from providing information about shark cartilage on their sites by the 2004 court decision it is still available on the Internet. One has to simply search for alternative cancer treatments, shark cartilage or a host of other non-traditional therapies and the user is bound to come across the information claiming that shark cartilage is a prevention, treatment and cure for cancer. Due to the fact that not all sites on the Internet are frequently updated or well documented, users may find articles relating to the curative properties of shark cartilage and think of these as recent reports. If users were to apply Lundberg’s five criteria to assess the information they find, they may have a better sense of its credibility.

¹⁶⁴ Hendricks, M., “Predators Promise.” Johns Hopkins Magazine Jun 2000, Nov 2006
<http://www.jhu.edu/~jhumag/0600web/shark.html>

¹⁶⁵ Edzard, E., Cassileth B.R., “The Prevalence of Complementary/Alternative Medicine in Cancer: A Systematic Review.” Cancer 2000;83(4) pp 777-782.

Unfortunately, the website may provide most if not all of the authorship, institution, attribution, financing, and timing criteria.

The author quickly found an example of such an article titled, “Shark Cartilage and Cancer, Revisited: A Follow-Up Interview”.¹⁶⁶ Although this is an undated interview, it appears current with William Lane describing the cancer-curative properties of shark cartilage. It is little wonder that the shark cartilage supplement industry remains a multi-million dollar industry to this day.

From the author’s work on this case study, it appears that the prohibitory regulatory and enforcement mechanisms in place for IDMI may be effective. However, as this study was limited to the top three search engines employed by Internet users and looked at the top 50 results, it is possible that the prohibited information about Benefin and shark cartilage as a cancer-curative is available. A user may immediately find this information in the top results of a different search engine or through an exhaustive search of the millions of hits returned by any search engine. Nonetheless, for this study, the prohibition tool appears effective. This was the result of government intervention and enforcement of regulatory policies. It did not fulfill Kassirer’s concerns that the regulatory policy would become oppressive to the degree to be unconstitutional. Lane Labs and Cartilage Consultants do not provide information about the curative properties of shark cartilage on their sites anymore. Indeed, as this study demonstrated references to

¹⁶⁶ Passwater, R.A., “Shark Cartilage and Cancer, Revisited: A follow-up interview”, Health World Online, Dec 2006, <http://www.healthy.net/scr/interview.asp?Id=182>

such curative properties are not found on the top 50 search results of the three most widely used search engines.

VII. Information Provision Policy Tool

The hypothesis tested for the information provision portion of this work was whether or not information gathered by users searching for cancer information online would follow current regulatory guidelines. Prior to commencing the research, the author believed that information gathered using the specific terms outlined in the methods section would be within regulatory criteria. As noted in the IDMI Oversight and Providers chapter, there are a number of government institutions that monitor what health information can and cannot be provided to consumers. The regulatory criteria for information provision can be viewed from two perspectives. First, information provision can be seen as the duty of the government to combat poor or misleading data by provide high quality information to the consumer. The author calls this aspect of information provision the “functional form”. The second point of view is to understand information provision under the regulatory constraints of the governmental regulatory institutions. These institutions dictate what can and cannot be claimed by information providers on their websites and/or their products. The author calls this aspect of information provision the “regulatory form”. In short, functional information provision highlights the government’s duty to provide high quality information while regulatory information provision focuses on ensuring the kind of data provided is within regulatory guidelines.

Beyond specific governmental regulations the practices of non-regulatory institutions go further by ensuring that the health information provided not only meets regulatory guidelines but is also of very high quality. These institutions monitor the quality of online health information provided by their own sites as well as partner sites. Therefore, governmental regulation working in concert with an organization's quest to provide high quality information gives the consumer the best data possible to make informed health decisions. It is important that there is government regulation overseeing what information a site can provide to users, particularly for sites lacking a robust desire to provide the best information possible. However, a number of sites in this study go much farther than what governmental regulations require ensuring their users are given the best cancer information available. The following sections outline the functional and regulatory aspects of information provision as well as the practices of institutions that go beyond meeting the minimum requirements.

Government Intervention in Information Provision

Regulation using information provision for consumers should take place when there is informational market failure occurring or information asymmetry. In traditional microeconomic theory, both consumers and sellers have perfect information available to them¹⁶⁷. Consumers know about all offerings and have the necessary detailed information about the offerings to make a sound judgment regarding purchases. Sellers

¹⁶⁷ Mansfield, E., "Microeconomics", Norton, New York, Sec. ed., 1975.

have perfect information about their customer's needs and wants and provide their goods in accordance with this knowledge. When this traditional microeconomic theory does not hold true, there exists an informational market failure. As this theory rarely holds true, it can be argued that there is always a need for government intervention in the form of both functional and regulatory information provision.

There is an informational asymmetry for IDMI. As noted in the preceding chapter, a user seeking information on alternative cancer therapies is likely to run across numerous claims about cancer cures. As the providers making cancer curative claims are, in fact, present on the Internet, there exists the proof that an informational market failure exists in this environment. This work aimed to determine if a user would encounter the bogus cancer curative information while conducting a search on the five specific types of cancer of interest. If a user immediately identified questionable information about cancer, the tool would be considered ineffective. In other words, regulatory information provision would be considered ineffectual as data is available to consumers that is outside of the regulatory agency guidelines. Alternately, if little or no dubious cancer claims were present, information provision would be considered effective as quality information could be viewed as more prevalent with respect to this study's specific search criteria. In this instance, it may be correct to conclude that functional information provision is functioning well as the government's duty to provide accurate and high quality data is superceding any of the poor or misleading information available online.

Functional and regulatory information provision are the least intrusive forms of government regulation available to help correct the informational market failure. It is also not as costly as the prohibitory form of regulation that consumes a great deal of agency resources. There are three main benefits to the information provision policy tool:

- Consumers have a better selection of information,
- Quality of goods (information in this case) improves, and
- Reduction in prices

Better selection of information arises from the consumer's having better knowledge of what is available in the marketplace via functional information provision. Armed with more complete information, consumers may make better decisions as to the value of a specific good and/or all of the competing goods. The goods with respect to cancer information may include such aspects as surgery versus radiation versus chemotherapy versus other forms of medical management. It also includes preventative measures such as proper diet, "good" fats versus "bad" fats, and use of supplements. Quality and price for some of these goods improves based on competition among sellers. As functional information provision increases more data is made available about goods in the marketplace, consumers demand better products and alter their choices to purchase the best goods based on their increased knowledge. Similarly, consumers may opt for the better price among comparable goods resulting in competitive price reductions. With high quality information about cancer preventatives and treatments available to users they can use this to avoid lesser supplement-type products and/or make informed decisions regarding the course of cancer treatment. Consequently consumers may be protected

from harm with the advancement and provision of knowledge about cancer causes and preventatives.

One assumption inherent to the actualization of these benefits is that the information provided is credible and easily identified by users. To combat the wealth of cancer curative claims on the Internet, credible institutions providing quality IDMI must be quickly identified by users to provide a counter opinion and offer scientifically based data. In this assumption, functional information provision works in concert with regulatory information provision to provide the high quality data while keeping the misleading data to a minimum. The user might then enjoy the three aforementioned main benefits of the information provision policy tool.

The Nutrition Labeling and Education Act

The Nutrition Labeling and Education Act (NLEA) of 1990 highlights the importance of the governmental change in focus from regulatory information provision to functional information provision. Prior to the NLEA debate was not focused on whether the FDA should allow marketers to provide qualified health information about their products but whether or not the FTC should ban these claims. The passage of the Act thereby shifted the perspective of qualified health claims from one focused on regulatory information provision and prevention of bad data to functional information provision and the government's obligation to provide consumers high quality data.

The NLEA increased functional information provision by encouraging business to provide consumers additional and high quality data as opposed to simply banning information outright. In essence, the Act requires that food manufacturers petition the FDA prior to making any claims regarding their products. The FDA requires stringent scientific proof that these claims are accurate using sound methods and agreed upon by experts. Prior to 1984, health claims were not permitted on food labels. In 1984 Kellogg began promoting information that a high fiber diet might reduce the risk of cancer. This claim was in line with the long-standing recommendations of the National Cancer Institute. The effect of this advertising and the subsequent increase in competing high fiber products increased high-fiber cereal sales by \$280 million¹⁶⁸. This example of functional information provision is focused on businesses as opposed to the duty of the government to provide the data. However, it is similar to the duty of the government to provide high quality information as the claims made by the manufacturers are reviewed under the strict guidelines of the FDA. This can be viewed as distinct from the regulatory information provision actions of the FDA where this institution can block the provision of certain types of information as opposed to encouraging businesses to provide accurate, high quality data to the consumer.

¹⁶⁸ Beales, J.H., "Remarks of J. Howard Beales Before the Food and Drug Law Institute Conference on Qualified Health Claims", Washington DC, Jan 2004, Jan 2007
<http://www.ftc.gov/speeches/beales/040114foodanddruglawinstitute.pdf>

Protection of Information Provision (aka commercial speech) by the Supreme Court

The use of functional information provision is an attempt to regulate Internet content by providing a wealth of good information to counteract the bad. The attempt at remedying the information asymmetry is necessary as the Supreme Court protects some types of commercial information on the Internet. The provision of information about a commercial product, commonly known as commercial speech now enjoys some limited protection under the 1st Amendment. This was not always the case. A 1948 Court case afforded no protection to commercial speech. It stated that the Constitution does not impart a restraint on the government's regulation of "purely commercial advertising"¹⁶⁹. This case was later overturned and provisions were enacted that limited regulation of commercial speech. As a consequence, regulatory information provision comes into play when data is provided to consumers that is potentially harmful. Currently, the FTC is able to regulate commercial speech that it deems deceptive.

The 1976 Supreme Court case, Virginia Board of Pharmacy v. Virginia Citizens Consumer Council stated that "the free flow of commercial information" is imperative so the decision-making capabilities of consumers are "intelligent and well-informed"¹⁷⁰. This can be seen as the Court's recognition of the benefits of functional information provision. The Virginia Board case decision also held that commercial speech is not

¹⁶⁹ Valentine v. Chrestensen, 316 U.S. 52, 54, 86 L. Ed. 1262, 62 S. Ct. 920 (1942)

¹⁷⁰ Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 765 (1976).

wholly outside of the protection of the 1st Amendment. However, in the 1980 case, Central Hudson Gas & Elec Corp v. Pub Serv Comm’n, the Court clarified its position by stating that false or misleading information enjoys no protection from the 1st Amendment due to its potential to hamper consumers ability to make informed purchasing decisions. The Hudson case brought regulatory information provision back to the forefront. This landmark decision overturned the 1948 case and set guidelines for state restrictions on commercial speech. Any action must “directly advance” state interests and is limited to the minimum necessary to ensure that interest is served¹⁷¹. This has become known as the Central Hudson Test.

In 1993 a Supreme Court opinion provided a summary of the general principles that underlie the protection of commercial speech:

The commercial market place, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment.¹⁷²

While government agencies are free to pursue their respective regulatory approaches through such extreme measures as prohibition of information, the rulings of the Court during the later part of the 20th century show a preference for less intrusive regulation. Instead of upholding agency bans on information provision, the Court has shown a propensity for increasing information flow in the marketplace and regulatory remedies

¹⁷¹ Central Hudson Gas & Electric Corp. v. Public Service Commission Of New York, No. 79-565, Supreme Court Of The United States, 447 U.S. 557; 100 S. Ct. 2343; (1980)

¹⁷² Edenfield v. Fane, 123 L. Ed. 2d 543, 113 S. Ct. 1792, 1798 (1993)

that follow this ideology. Once again, as with the Virginia case, functional information provision became the favored policy tool instead of regulatory information provision.

Beyond Governmental Regulation of Information Provision

There exist many regulatory standards for sites providing medical information via the Internet. Regulatory and functional information provision guidelines are enacted and enforced by the FDA and FTC to monitor cancer curative claims and oversee the promotion of cancer treatments respectively. However, there seem to exist criteria for functional information provision beyond what the regulatory agencies require. This work identified 150 sites providing cancer information via the Internet. The majority of that information is of very high quality, much more so than a user might find if sites simply followed the regulatory information provision standards of the monitoring agencies.

Most of the IDMI sites in this study provide criteria on their websites regarding how the information provided is created, reviewed, and ultimately disseminated to users. To gather more insight into the reasons for the functional provision of higher quality information than the governmental regulations require, the author contacted five specific providers. Initial discussions with an expert in the field of medical information provision suggested that this may be due to a community of online health information providers that; visit each other's sites, have open discussions about how to build, maintain, and improve their sites, adopt industry standards and best practices thereby creating high

quality information provision sites¹⁷³. Such actions are beyond the scope of the requirements of the regulatory agencies.

Information Provider Site Development

Multiple IDMI content providers were individually contacted through telephone and email requests for additional information not specifically delineated on their websites. Subsequent contacts were attempted from October 2007 through May 2008. Through the follow up contacts, the author intended to discover how the site's managers develop their information and how they ensure high quality information for their sites. The provision of quality medical information by each of the providers is generally addressed on the respective site, as noted in the preceding chapter regarding the specific provider. One universal goal by all five of the respondents was search engine optimization. This is a process to improve the volume of traffic to a site through the higher placement in the results of search engines. Typically, the higher a site ranks on a search result, the more users that will visit the site.

Cancer.org and Cancer.gov

The author was able to gain additional specific information from The American Cancer Society (ACS) and The National Cancer Institute (NCI) through personal

¹⁷³ Harris, L, Personal Communication, Apr 2008

communications. As noted in the “Cancer.org” and “Cancer.gov” sections, the ACS and NIC goals are to provide the public and medical professionals the latest cancer resources. According to the author’s interviews with the ACS and NCI representatives, they accomplish this through the following means. The organizations have teams of medical professionals that constantly review any new literature on the subject of cancer and any tangentially relevant medical areas. Based on the reviews, material for the site is updated and/or created as necessary. The modified and/or newly created material is circulated through a peer review process to ensure it meets high quality standards as set forth by each organization. A team of editorial professionals also constantly monitoring the new and modified information and keeps close watch on the site itself to ensure the quality of the information provided to users. The NCI specifically noted that they are, “Looking at more ways to add more structure to some of our review processes”¹⁷⁴. Through these processes these organizations employ a number of steps to ensure that their sites provide users with high quality medical information about cancer.

In order for users to find the results of the ACS and NCI efforts, their sites must be highly ranked in search results when a user seeks cancer information online. The organizations do this through a practice known as search engine optimization best practices. The practice involves multiple steps and includes:

- Consistent use of their domain name, cancer.org,

¹⁷⁴ National Cancer Institute, Personal Communication, Feb 2008.

- Use of the appropriate meta tags,
- Use of appropriate linking to other sites generating higher traffic and subsequent higher listing ranks in certain search engines,
- Understanding of the different search engine algorithms,
- Use of a site map containing the appropriate key words for search engine spiders to identify, and
- Use of site coding and structure to allow for optimum search engine indexing.

In addition to search engine optimization best practices, the ACS also drives users to their site through marketing campaigns. The ACS attempts to increase user traffic during promotional periods such as, Great Americans, National Breast Cancer Awareness Month, and Access to Health Care. The NCI focuses additional effort at bringing targeted users to their site through providing NCI research funding opportunities and current research programs. These efforts are directed more specifically to cancer researchers as opposed to the general public. Through these steps the ACS and NCI enable users to find their sites and subsequently take advantage of the high quality information they provide.

Richard Manrow – National Cancer Institute¹⁷⁵

¹⁷⁵ Manrow, R, Personal Communication, May 2008

The author conducted an interview with Dr. Richard Manrow of the National Cancer Institute to gain additional specific insight into the development and maintenance of information on cancer.gov. Manrow is the Chief of International Cancer Research Databank Branch, Office of Cancer Information Products and Systems at the NCI. As noted earlier, he emphasized that search engine optimization is of great importance to making sure that the NCI's information is available and provided to users. Apart from getting the information to users, the quality of the information is driven in part by the NCI's status as the gold standard for cancer information. Manrow believes the information provided by cancer.org is state of the art as it covers 580 cancer information summaries and is developed and reviewed by six editorial boards consisting of experts in all areas of cancer research. The aim of the site is, "to be all things to all people" including public information provision, grant availability, NCI mission updates, strategic planning, and clinical trials. The information is constantly being reviewed for accuracy and quality. Manrow's office is responsible for any new content provided on cancer.gov.

NCI's ability to provide cancer information to the public began in earnest with the National Cancer Act of 1971. This act and subsequent legislation for practitioners allowed for the development of information and educational programs for the general public. Specifically regarding cancer.gov, the E-Government Act of 2002 provided additional resources for and spotlighted Internet information. For NCI this meant a shift from cancer.gov being a mostly administrative site to a public information warehouse. Because of their status as the gold standard for cancer information, the information

needed to be “bullet-proof”. NCI worked and continues to work with over 100 different sites that provide cancer information. While the National Cancer and E-Government Acts provided some resources, they do not have the capability to host all of the cancer information they deem necessary to provide to the public. Consequently, cancer.gov acts as an overseeing body and makes recommendations to their partner sites in an effort to provide the highest quality information possible. There is an ongoing effort to integrate and consolidate all of this information into one repository. Manrow notes that this would make the required gap analysis to determine overlapping, contradictory or missing information much easier to conduct. At this point, additional resources are necessary to complete this action.

The NCI monitors its quality by both internal mechanisms as well as by external processes. The American Customer Satisfaction Index (ACSI), E-Government Satisfaction Index provides the main external oversight. This survey uses methodology developed by the University of Michigan and scientifically quantifies the elements that drive online customer satisfaction. The NCI uses the quarterly report by the ACSI to track customer satisfaction and ensure they are meeting their needs. Manrow stated the NCI, “wants to do the best job possible in meeting our customer’s needs”. The independent review of the ACSI survey provides the NCI the feedback they need to meet those needs. The NCI consistently ranks in the top ten of e-government sites.

Sandra Williams Hilfiker – Office of Disease Prevention and Health Promotion, Healthfinder.gov¹⁷⁶

Sandra Hilfiker is a Public Health Advisor with the Office of Disease Prevention and Health Promotion, Office of Public Health and Science, at the US Department of Health and Human Services. The author spoke with Hilfiker regarding her experience in running a portal site, healthfinder.gov that provides medical information to the public. She echoed many of the same thoughts that Manrow provided such as search engine optimization and the use of ACSI surveys to monitor user satisfaction. Hilfiker provided additional thoughts regarding the types of information content that is allowed to link to .gov sites. She noted that healthfinder.gov has over 5000 resources from over 1600 organizations. In essence, although Hilfiker runs a .gov site, she manages links and content review from many institutions including .edu and .org sites. Due to the commercial nature of .com sites, healthfinder.gov does not link to them. Sites must provide trusted consumer resources and cannot sell any products or have commercial advertising. This is to keep commercial sites and advertisements from having the appearance of government approval and/or support.

The review process for healthfinder.gov content as well as linked content is, “extremely rigorous”. There are steering committees for content provision from government, nonprofit, and educational institutions. Multiple subject matter experts review

¹⁷⁶ Hilfiker, S.W., Personal Communication, May 2008

information for quality, accuracy, relevancy and usability regardless of origin. Even information that is currently posted on other .gov sites but not yet linked to healthfinder is stringently reviewed before it is linked. One unique aspect of healthfinder.gov that Hilfiker noted that the author did not find with other sites is the willingness to work with Wikipedia. As noted in Chapter Four, Wikipedia has a somewhat tenuous reputation in the academic world. However, Hilfiker noted that users are going to build pages on Wikipedia about health topics of interest to the community. They have taken the step to therefore actively monitor subjects of interest to healthfinder.gov and attempt to make sure that information displayed on Wikipedia is accurate. She said that, so far, the Wikipedia pages they are actively monitoring are providing useful information and they have yet had a need to make major changes to any listing. In addition, Wikipedia actually drives users to the healthfinder portal thereby generating increased traffic.

Similar to cancer.gov, healthfinder.gov is resource limited and Hilfiker sometimes finds the amount of information they need to review is “overwhelming”. She notes that it is easy for pieces of information to become out of date and there is a constant effort to remain at the forefront of the Internet information overload. In addition, healthfinder makes efforts to refrain from overwhelming users with too much information. There is a “significant” effort to provide the most relevant information in a concise format as opposed to publishing every paper, article, or recommendation available. Due to this effort, there are sometimes inconsistencies between the offices and agencies with regard to which piece of information provides cutting edge information.

Costs of Information Provision

The costs of functional and regulatory information provision can be viewed from different perspectives. There is the cost for the seller to comply with the regulation, the cost of the government to enforce the regulation and any collateral costs due to unintended side effects. The cost of functional information provision to the seller may include the printing costs if label information is required, time-costs associated with information approval due to minor changes in the good requiring a label change, and costs associated with the record keeping and/or conducting studies to validate certain claims made about the good. Regulatory information provision and the government enforcement costs can be quite variable. The FDA takes a selection approach to enforcement responding to consumer complaints about goods and selective marketing of certain goods in their purview. On the other end of the spectrum, USDA requires sellers to seek approval for each label change regarding the goods under their authority. The costs of unintended side effects are difficult to tally. They depend on how the information provision regulation is promulgated. For example, for functional information provision, if the seller is required to provide additional information about competing goods in a certain type of message provided to consumers, that seller may decide not to provide that particular type of multi-product ad and instead provide a single product ad not mentioning the competition. The unintended cost for functional information provision here is that there is less information available to the consumer since the seller has decided against providing competitor information due to the extra cost associated with multi-product ads.

Beyond the costs of producing the information, there are other costs to consider for providers of questionable IDMI. These may range from low to very high. A virtual-only based organization may provide information on its site in order to promote a cancer therapy. From the functional information provision perspective, the cost associated is the writing of the information and costs associated to host the site. From the regulatory information provision perspective, should a site be contacted by an enforcement agency that they are violating certain regulations, the work-around is to shut down the site and open it again under a different URL. These expenses are negligible when compared with the costs that a pharmaceutical company might face should they face investigation and punishment. Under regulatory information provision, a traditional brick and mortar company providing questionable IDMI may face very high costs such as that incurred by Hi-Tech Pharmaceuticals. Hi-Tech's executives are facing very high fines and possible jail time for the provision of information and products that were banned from use by the FDA.

Effectiveness of Functional Information Provision

There is debate in the literature regarding the effectiveness of functional information provision as a regulatory tool. Many studies have investigated the use of functional information provision campaigns and attempted to analyze the outcomes. There is not a great deal of quantitative data that shows that information provision provides consumers

the necessary resources to surmount the imperfect knowledge they may have about a good. In order for a functional information provision campaign to be effective, consumers must have access to the information, understand it, and employ it in their decision making process. If information is provided yet consumers are not aware of it, do not understand it, or do not incorporate it into their selections of goods, the campaign cannot be effective. A user that identifies the use of shark cartilage as a cancer cure based on an Internet search would need to have immediate access to information that provided the scientific data countering this claim in order for a functional information provision campaign to be effective. Alternately, if the user enters search criteria that do not return questionable IDMI regarding bogus cancer cures, the user would not need an informational campaign. In the instance that the user finds questionable information, a functional information campaign might counteract any harm by the provision of high quality data. In the instance that a consumer did not find questionable data, it might be believed that regulatory information provision is working to keep this data from reaching the consumer.

Adler and Pittle published a study in 1984 regarding the efficacy of educational campaigns¹⁷⁷. They determined that there was little evidence that functional information provision effectively changes consumer behavior. Consumers gain little new knowledge

¹⁷⁷ Adler, R. Pittle, D., "Cajolery or Command: Are Education Campaigns an Adequate Substitute for Regulation?", Yale J on Reg, 1984 v1, pp 159-194.

via the campaign and rarely modify their actions in response to the new information provided.

However, there are published studies that indicate a positive response by consumers to a functional informational campaign. Viscusi and O'Connor conducted a study published in 1984 that demonstrated that consumers made aware of the risks associated with chemical labeling did in fact change their behavior so as to lower their risk¹⁷⁸.

Consequently, the information provided about the hazards of using certain chemicals in certain ways led to a modification of consumer behavior thereby lowering consumer risk. A follow up study by Viscusi, Magat, and Huber in 1986 on the actions of household consumers to the use of certain combinations of chemicals again demonstrated a change in behavior based on functional information provision. The authors note that as they have showed a positive result in their information provision studies that prior educational campaigns may have been ineffective due to the low level of informational content of these campaigns¹⁷⁹. These are two examples of functional information provision attempting to correct the informational market failure leading to a change in consumer behavior consistent with the presence of perfect information.

¹⁷⁸ Viscusi, W.K., O'Connor C., "Adaptive Responses to Chemical Labeling: Are Workers Bayesian Decision Makers?", *Amer Econ Rev*, 1984 v74, pp 942-956.

¹⁷⁹ Viscusi, W.K., Magat, W.A., Huber, J., "Informational Regulation of Consumer Health Risks: An Empirical Evaluation of Hazard Warnings", *RAND J Econ*, 1986 v17:3, pp351-365.

Should this work identify multiple bogus cancer curative claims using the identified search criteria, further study might look at the effect of a functional informational provision campaign to counter the questionable IDMI. It would be valuable to know if the information provided by credible institutions had a positive effect on a user's utilization of such products as shark cartilage.

Methods

This section of the work aimed to determine the effectiveness of regulatory and functional information provision. Initial research indicated that there is still information on the Internet which makes claims about cancer preventatives, treatments, and cures and is therefore not in line with US regulatory guidelines (see below in study discussion for example site and claim). Consequently, initial research indicated that regulatory information provision was ineffective. The preceding background section provided a review of regulatory agency (FDA and FTC) documents and investigated proposed and enacted policy recommendations regarding regulatory provision of information. The 1981 Howard Beales, Richard Craswell and Steven C. Salop of the FTC work investigated the functional provision of information to consumers so they might be protected against unsafe information provided in the market. A review followed of the subsequent articles on this policy followed and how information is provided to consumers and their reactions to that information.

The information provision section model is similar in nature to the model used for the analysis conducted on the prohibition policy tool for the analysis of the Lane Labs case study. A search was conducted on the Internet using the same three search engines as the prohibition work to determine availability of information. Again, the search will be based on the prior work done by the Pew Internet and American Life Project.

This study attempted to discover if a significant amount of information on the Internet provides information regarding cancer in line with regulatory guidelines. It is known that as yet there is no cure for cancer with the three most common forms of treatment being surgery, chemotherapy and radiation therapy. For information provision to be an effective policy tool, the expected results of a search of information on the Internet would be expected to be in line with the guidelines of the FDA and FTC. Any claims made regarding treatment options regarding cancers should be qualified health claims and fall under FDA guidelines for drugs or supplements under the 1994 DSHEA.

As in the prohibition chapter, this work used the master data set created in January 2007 [see **Appendix A**] by entering the most commonly searched cancer terms into the three most commonly used search engines. The 101 unique pages that resulted were termed the “cleaned” data set. As in the prohibition chapter, each of these unique pages was visited. Unlike the prohibition work however, this search aimed to determine the extent that the information available conformed to regulatory guidelines.

The 101 pages were classified as “yes” or “no” as to the URL’s provision of information regarding providing a cancer treatment and following the guidelines of US regulatory agencies. The author reviewed each unique URL and assessed the information contained on the page to determine if the information provided offered the user promises of a treatment, prevention or cure for cancer that was outside of agency guidelines. As noted in the Literature Review chapter, this would be information such as:

- THIS IS NOT A TREATMENT FOR CANCER: IT IS A CURE!... It takes 5 days to kill the parasites that cause intestinal cancer. The cancer is then killed...
- Herb Veil 8 has been used in the successful removal of carcinoma, adenocarcinoma, and melanoma.
- This formula is a “power house” and has been used on (and restored to health), cancer of the spine, arthritis, and polio, and has helped rebuild torn cartilage and sinews, fractures, etc. etc...¹⁸⁰

The author collected any potentially misleading information to be tabulated and analyzed further.

As an additional method to the visual review of each page, a search was conducted using the search feature of Microsoft Internet Explorer version 6.0.2800.1106. Each of the 101 unique pages was searched for the following three terms:

¹⁸⁰ Beales, H., “Health Fraud and the Elderly: A Continuing Epidemic”, Prepared Statement of the FTC Before the US Senate Special Committee on Aging, Washington DC Sep 2001.

- “Cancer prevention”
- “Cancer treatment”
- “Cancer cure”

The search terms were highlighted on the page through IE’s character recognition system and the surrounding information was reviewed.

The results were compared statistically to determine if the information provision policy tool was effective. Through this work, the author intended to determine if there was a preponderance of sites that did not break the guidelines of US regulatory agencies by making unverifiable claims to cure cancer.

Results

Each of the 101 unique pages was different in length depending on the information being provided. Some contained a great deal of information and others contained an index or a web site introduction. Using the “print preview” search feature of IE, each site was cataloged as to the number of “pages” within each unique URL. The “print preview” feature of IE formats a website for printing standard 8.5 x 11 pages. The largest amount of information was on the Wikipedia sites with one containing twenty “pages” of information for prostate cancer. Fourteen of the unique URLs contained only one page of information.

Overall, the author reviewed 388 “pages” from the 101 unique URLs for information outside of agency guidelines. On average there were approximately four “pages” of information per unique URL.

Of the 101 unique URLs, over 50% have a Top Level Domain (TLD) of .org. The .org TLD is used by associations and non-profit organizations and its usage is monitored by ICANN. The next largest group of TLDs in this data set was for the commercial sites, .com, at 27.5%. The remaining TLDs in the data set were .gov at 12.5%, .edu at 5%, and .net at 2.5%.

Zero instances of information were provided on any of these unique URLs or within the 388 pages reviewed that would be construed as counter to agency guidelines. Since zero instances of information were identified, an additional data set containing the pieces of information counter to agency guidelines was not created.

Using the IE search feature on each of the 101 unique URLs identified many instances within the 388 pages of the search terms; “cancer prevention”, “cancer treatment” and “cancer cure”. However, the surrounding information did not provide information or make cancer prevention, treatment, or cures that went against agency guidelines. The use of the IE search feature was a backup to the visual review conducted. It was conducted to

provide additional assurance that the visual review provided adequate coverage regarding the type of information provided in the 101 unique URLs.

Discussion

Mentioned in the background portion of this chapter is a section related to the costs involved in an information provision policy tool. The three aspects of the costs are; to the information provider, to an agency to oversee information compliance, and unintended side effects. While this work did not intend to quantify the costs for the provision of information regarding cancer via the Internet, some observations can be made. As described in the results, all of these pages provided information in compliance with agency and DSHEA guidelines. All of the .com sites had links to (presumably paying) advertisers. The advertisers may or may not have anything to do with the search criteria that found the URL in the first place. For example, at the time of the compilation of the data set, <http://breastcancer.care2.com/> had two major banner advertisements for a mortgage company and a printer company. These banner advertisements had nothing to do with the breast cancer information that was provided on this site. By contrast, .org, .gov, .edu, and .net had no advertising on their URLs. This being the case, any money provided by selling advertising space on the .com sites could presumably offset any costs to the information provider. The other TLDs would not generate this revenue through the provision of information on their sites. However, the other TLDs undoubtedly find

support via other means whether through taxes, tuition, fundraising, donations, or the like.

It might be argued then that the .coms are consequently incentivized to provide information to a user that is inline with agency guidelines. In order for a site to garner the advertising fees for banner space, it needs to have a large number of users visit the site. If the .com was to provide information that was against agency guidelines, an agency may decide to investigate the site that may result in an eventual shut down. Even bad press regarding the site's provision of harmful information may drive users to seek their medical information elsewhere. Either would clearly disrupt the revenue generation capabilities through advertising.

The other main TLDs in the data set, .org, and .gov account for a combined 64.5% of the sites, a clear majority. The costs for providing the information from these sites are through fundraising and donations, and taxes respectively. These sites are incentivized to provide agency-approved information through their charters. They have no commercial goal in their efforts and exist with the purpose to provide the most accurate information available based on the current knowledge of the topic area searched. Indeed, the interviews that the author conducted with the representatives of health information provision sites provided a clear sense that there is a strong desire to maintain very high quality of information. Specifically, Dr. Manrow is clearly proud of the status that NCI has as the gold standard in providing cancer information to the public. They go well

beyond what the regulatory standards require to ensure that their customers are getting the best possible data. Additionally, search engine optimization is a priority for these providers. Although this study did not specifically identify information outside of regulatory guidelines it is encouraging that sites providing high quality cancer information are striving for increased user traffic. They are actively working to bring users to their sites and subsequently provide consumers with the best information available. This may allow a higher degree of efficacy for information provision as a regulatory tool because these sites would combat any low quality cancer information with high quality data.

The results of this section indicate that the information provision policy tool is working. The 101 unique URLs under investigation all provided information that follows the guidelines of regulatory agencies. In fact, they provided higher quality than a user might expect if sites only followed the regulatory guidelines.

VIII. Certification Policy Tool

McLellen described the search for IDMI as, “trying to get information from the internet is like drinking from a fire hose [and] you don't even know what the source of the water is.”¹⁸¹ In an effort to help users determine the quality of the IDMI they find, many organizations have created methods as an aid to their search. The use of the certification policy tool is one such effort. It is aimed to provide guidelines for IDMI providers and subsequently the type of information provided on a site. This assists consumers through a somewhat less invasive policy by helping to insure higher quality IDMI.¹⁸²

Third Party Certification Systems

As noted earlier, there is a call for the credentialing of IDMI in order to help ensure the high quality of the information. The credentialing is important as Weisbord et al. note as medical misinformation may be a grave matter when applied by an unwitting user¹⁸³.

One manner of credentialing sites purveying IDMI is through the application of 3rd party

¹⁸¹ McLellen, F., "Like Hunger, Like Thirst: Patients, Journals and the Internet", Lancet 1998; 352 (suppl II): 39-43S.

¹⁸² As noted earlier in the work, the prohibition policy tool is the most restrictive while information provision is the least of the three modes analyzed.

¹⁸³ Weisbord, S.D., Soule, J.B., Kimmel, P.L., "Brief Report: Poison On Line – Acute Renal Failure Caused By Oil of Wormwood Purchased Through the Internet", N Eng J Med, 1997;337:p825.

certification systems. Of the many certification systems currently available, one is a leader in the field, the Geneva based not-for-profit NGO known as Health On the Net Foundation (HON). There are many other organizations that provide certification for IDMI in addition to HON. They include but are not limited to the American Medical Association, DISCERN Internet Health Care Coalition, Hi-Ethics, URAC and MedCERTAIN. These organizations create guidelines for IDMI with some that review sites using exacting standards. Although there are many certification systems listed, not all are active and some are very difficult to find on any IDMI sites. Only the most prevalent certification systems currently employed by IDMI sites are reviewed below.

Health On the Net Foundation

As described in the IDMI Oversight and Providers Chapter of this work, Health On the Net's mission is to provide guidance to Internet users about the validity of the information they gather online. HON is a Swiss non-profit organization that sets forth standards and provides a set of criteria regarding the content of medical information sites. Should the sites meet and remain in compliance with the criteria, they are then authorized to use the HONcode certificate.

The goal of the HONcode is to bolster the quality of IDMI. The voluntary nature of submitting a site for approval and subsequently abiding by the HONcode is dependent upon the site's compliance. Though HON reserves the right to ask any site to remove the

HONcode logo at any time, it would normally only do so in the case of fraudulent usage. This has occurred at least on one occasion as pointed out in a study released by Eysenbach in 2000. Eysenbach noted that the site www.selfhealthsolutions.com featured the HONcode logo in 1999¹⁸⁴. The Eysenbach study noted that the site had “dubious content” that did not conform to the criteria as outlined above and yet was able to display the logo as if the information had received the approval of HON. Eysenbach’s 2000 article immediately received a response from the executive director of HON, Timothy Nater. In the rebuttal letter, Nater points out that HON knew of the use of their logo on the site in question and asked that it be removed¹⁸⁵. The HONcode logo was removed by Jul 1999. Eysenbach responded to Nater noting that on the HON site itself it is stated:

The HONcode is not an award system, nor does it intend to rate the quality of the information provided by a Web site. It only defines a set of rules to:

- hold Web site developers to basic ethical standards in the presentation of information;
- help make sure readers always know the source and the purpose of the data they are reading.¹⁸⁶

Eysenbach notes that there is confusion in the popular and peer-reviewed literature about what HON actually does. He believes that this confusion then translates into users becoming complacent about the quality of information due to the placement of a logo on

¹⁸⁴ Eysenbach, G., “Towards Ethical Guidelines for E-Health: JMIR Theme Issue on eHealth Ethics”, J Med Internet Res, 2000;2(1) e7 www.jmir.org/2000/1/e7

¹⁸⁵ Nater, T., Boyer, C., Eysenbach, G., “Debate About Evaluation and Monitoring of Sites Carrying the HON-Logo”, J Med Internet Res, 2000;2(2) e13 www.jmir.org/2000/2/e13

¹⁸⁶ Health on the Net Foundation, “Introduction”, <http://www.hon.ch/HONcode/> Jan 2007, Feb 2007,

a site. Eysenbach questions, “If HON does not rate quality, on what grounds are quackery sites such as the one show in the editorial’s illustration [www.selfhealthsolutions.com] asked to remove the HON-logo?”¹⁸⁷”

Internet Healthcare Coalition

The Internet Healthcare Coalition (IHC) was founded in 1997 and incorporated in Washington D.C.¹⁸⁸ The IHC is an international non-profit organization funded by user fees, grants, and donations whose mission is to improve the quality of health information on the Internet. The principles outlined by the IHC code are intended to protect users from harmful information, create an ethical medium for dissemination, and help promote fairness and collaboration among Internet stakeholders. The process by which the code works is through volunteer participation by the site to maintain its content in such a manner as to remain in compliance with the stated code. Since there are no external reviews to determine if the site is in fact in compliance, the onus is on the user to determine if the honor code is maintained. This requires an informed, interested, caring, and knowledgeable user community to investigate the sites that claim to have and be in compliance with a stated honor code.

¹⁸⁷ Nater, T., Boyer, C., Eysenbach, G., “Debate About Evaluation and Monitoring of Sites Carrying the HON-Logo”, J Med Internet Res, 2000;2(2) e13 www.jmir.org/2000/2/e13

¹⁸⁸ National Health Information Center, “Health Information Resource Database: Internet Healthcare Coalition”, <http://www.health.gov/NHIC/NHICScripts/Entry.cfm?HRCCode=HR3211> Sep 2005, Feb 2007.

The IHC's membership includes almost every sector of IDMI including; consumers, commercial entities, libraries, health professionals, special interest groups, government officials and manufacturers¹⁸⁹. In late 1999 the IHC responded to the request of the medical community by commencing its ongoing eHealth Ethics Initiative. Currently, one of the IHC's functions is to provide a forum for interaction and discussion with the goal of developing a set of principles for IDMI websites.

The IHC works with many government agencies including the US FDA and FTC. These affiliations strive to bring about better medical information online and combat the prevalence of misleading and potentially harmful IDMI. Working with the FTC, the IHC formed an Internet Health Fraud Resources Working Group that coordinates an international health fraud database through an Internet website. The database links authorities that have jurisdiction over the identified health fraud information identified by the working group. By utilizing the site, a consumer or healthcare professional can provide the group with the identifying information about online health fraud. That information can then be acted upon, locally, or globally by the appropriate authorities. This action may include the removal of any and/or all certifications the site displays that may mislead consumers to believe the site's information to be credible.

¹⁸⁹ Mack, J., "The Internet Healthcare Coalition", J Med Internet Res, 2000:2(1) e3
www.jmir.org/2000/1/e3

Non-content Review Certifications

Upon opening a URL regarding IDMI a user may be confronted by certifications and logos somewhere on the page that have nothing to do with medical information review.

A few of the more prevalent ones are TRUSTe, ICRA, and USA.gov (changed from FirstGov in Jan 2007).



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Although official looking logos, these have nothing to do with oversight or monitoring the medical information on the site. TRUSTe is a nonprofit organization that is concerned with the privacy of its clients. It is fairly common on IDMI websites as it relates directly with the protection of sensitive personal health information. However, it does so from a privacy perspective and does not monitor the content of the information to determine whether or not it meets any set criteria for quality. The Internet Content Rating Association (ICRA) is a nonprofit international organization that promotes self

¹⁹⁰ TRUSTe, <http://www.truste.org/> 2007, Feb 2007.

¹⁹¹ Internet Content Rating Association, <http://www.icra.org/> 2007, Feb 2007

¹⁹² USA.gov, "Linking To USA.gov", http://www.usa.gov/About/FirstGov_Logos.shtml Feb 2007

regulation as the primary measure for creating a safer Internet. A site provider fills out a questionnaire and based on the responses ICRA labels the site so that filtering programs can either allow or disallow access depending on the criteria on the user's filter. The ICRA states that it "does not rate Internet content – the content providers do that, using the ICRA labeling system. ICRA makes no value judgment about sites."¹⁹³ USA.gov encourages webmasters to link to www.usa.gov by pasting the USA.gov logo on their sites. USA.gov states that the provision of the USA.gov logo on a site, "is to be used only as a marker to the USA.gov home page and not as a form of endorsement or approval from USA.gov, the Office of Citizen Services and Communications or the US General Services Administration."¹⁹⁴ Though not studied in this work, there is some potential that the inclusion of these credentials on a site may lead users to assume the site is certified when that is not the case. This would be an interesting area for future research.

MedCERTAIN Certification system

There have been attempts at implementing other certification systems. So far, these have met with limited success. The primary example of a proposed comprehensive third party certification system that actively monitored site content was MedCERTAIN. This initiative was launched in 2000 and was an international project funded in part by the

¹⁹³ Internet Content Rating Association, "Labelled with ICRA", 2006, <http://www.icra.org/sitelabel/> Dec 2006.

¹⁹⁴ USA.gov, "Linking To USA.gov", http://www.usa.gov/About/FirstGov_Logos.shtml Feb 2007

European Union's Internet Action Plan (IAP). The EU's IAP committee states the following aim:

The action plan is a European Commission proposal for a number of initiatives from 1 January 1999 to 31 December 2002 with a total budget of 25 million Euro. The initiatives, created in close cooperation with industry, Member States and users, include a network of hot-lines, support for self-regulation, developing technical measures and awareness initiatives. The aim of the Action Plan is to ensure implementation of the various initiatives on how to deal with undesirable content on the Internet. It is designed to support non-regulatory initiatives for promoting safer use of the Internet.¹⁹⁵

The goal of MedCERTAIN was to decentralize the content review of IDMI sites. These sites were to be reviewed globally by experts in their respective fields. If the expert consensus revealed the IDMI site provided quality medical information then it would be granted a seal that established it as a reviewed site. The seals would be dynamic and require a site to remain in compliance or the seal would be removed. Monitoring of the site would take place through a filtering mechanism intended to identify and alert the appropriate authorities at MedCERTAIN should a site provide questionable content. This active monitoring of a site through this unique filtering mechanism aimed to "provide a trustmark system which allows citizens to place greater confidence in networked information... and identifies standards for interoperability of rating and description services (such as libraries or national health portals) and fosters a worldwide collaboration to guide consumers to high-quality information on the web."¹⁹⁶ While a

¹⁹⁵ European Union Internet Action Plan Committee, "A Multiannual Community Action Plan On Promoting Safer Use Of The Internet By Combating Illegal And Harmful Content On Global Networks", http://www.qlinks.net/comdocs/Work_Programme.html Mar 1999, Feb 2007.

¹⁹⁶ Eysenbach, G., Yihune, G., Lampe, K., Cross, P., Brickley, D., "Quality Management, Certification and Rating of Health Information on the Net with MedCERTAIN: Using a medPICS/RDF/XML Metadata

noble effort that generated a large amount of interest in the online health community, MedCERTAIN is no longer a working project and its overall results were deemed questionable¹⁹⁷.

Methods

This section aimed to determine the effectiveness of the certification policy tool. Initial research indicated that many sites providing information about cancer did not display any type of third party certification system. The previous two studies on prohibition and information provision investigated the type of information being provided on the sites. This part of the work identified which, if any, systems of certification were present on these sites. The percent of sites containing a certification system and the types of systems was recorded for analysis.

Similar to the methods for the prohibition and information provision policy tools, the criteria selected to investigate the certification study were based on the presence or absence of certification information on a selected set of Internet sites. In the prohibition study the author searched for the presence of banned information. The information

Structure for Implementing eHealth Ethics and Creating Trust Globally”, J Med Internet Res, 2000;2(suppl2) e1

¹⁹⁷ Burkell, J., “Health Information Seals of Approval: What Do They Signify?”, Information, Community and Society, Dec 2004;7(4) pp 491-509.

provision section study sought to identify whether the information purveyed followed the guidelines of the regulatory agencies overseeing IDMI. This study aimed to discern if the sites provide the information that they are certified and if so what type of certification.

As in the prohibition and information provision chapters, this chapter used the master data set created in January 2007 [see **Appendix A**] by entering in the most commonly searched cancer terms into the three most commonly used search engines. Each of the 101 unique pages identified in the clean data set was visited to determine the presence or absence of a certification label. All certification labels on a given site were recorded. The labels were tabulated and researched to determine what if any health related criteria they required a site to follow for inclusion on a site. For certification to be an effective policy tool, the expected results of an Internet search on a cancer-relevant topic would provide a preponderance of sites containing certifications.

The 101 pages were initially classified as yes or no as to their provision of a certification label on the URL from the cleaned master data set. Those pages containing certification labels were noted and the labels on those sites were recorded. All labels on a site that provided some type of certification were recorded regardless if the label had to do with the review of health information or not.

The results were compared statistically to determine if the certification policy tool was effective. If there was a preponderance of sites that provide certifications this policy tool may prove effective.

Results

As expected, not all of the URLs provided a certification logo on the site. 50 of the 101 sites provided some type of certification label. This is 49.5% of the sites. The other 51 sites (50.5%) did not provide any type of certification logo and therefore did not warrant any additional review for this phase of the work. Following are the top five logos that were displayed on the sites reviewed.



The HONcode logo was present on 31% of the sites containing a certification.



The Better Business Bureau logo was present on 21% of the sites.



The USA.gov logo was present on 16% of the sites



The Department of Health and Human Services logo was on 13% of the sites.



The National Institutes of Health logo was on 11% of the sites.

The following logos were present on less than 5% of the sites reviewed.



HONcode and USA.gov have been discussed in the background portion of this chapter. The other three logos identified as being most prevalent in the results, Better Business Bureau, Department of Health and Human Services, and National Institutes of Health were opened to determine what if any content review or certification assurance they provide to the user.

- Better Business Bureau – This is a monitoring system for charitable organizations that states as its purpose, “This confirms that an evaluation of informational materials provided by [name of website] to the BBB Wise Giving Alliance shows that the organization meets all of the Standards for Charity Accountability in effect at the time of the review.”¹⁹⁸
- The Department of Health and Human Services – This logo is simply a link to the DHHS homepage at www.hhs.gov
- The National Institutes of Health – This logo is simply a link to the NIH homepage at www.nih.gov

The five most prevalent logos covered a total of 92% or 46 of the 50 sites reviewed.

Only one, HONcode, of the five most prevalent logos that appear to be certification logos

¹⁹⁸ Better Business Bureau, “BBB Wise Giving Alliance”, <http://www.give.org/seal.asp?ID=1413312005> Feb 2007.

on the IDMI sites studied is relevant to health information. The other four do not provide any criteria whatsoever for the type of information provided on the site that their logo is displayed.

The remaining four logos that were identified on the reviewed sites were each found on less than 5% of the overall 50 sites that had logos. Their presence in such low numbers was determined to be low enough as to not warrant further analysis as in this small of an occurrence; the certification system would have minimal impact on the overall data set.

Discussion

The certification logo most prevalent was HONcode at 31%. This was also the only certification logo present on a majority of the sites that had anything to do with certification of health information via the Internet. The remaining certification logos identified in this work did not have anything to do with site content review with one exception. The NHS logo



is a health information certification system based in Scotland that has as its aim to, “Help patients and the public identify quality assured, evidence-based health information.”¹⁹⁹

However, it was only present on one of the pages reviewed (<1%) and consequently did not make a significant difference as to its impact on the quality of IDMI provided on the 101 pages.

In the prohibition and information provision chapters, the content of all of these 101 pages was thoroughly reviewed. None of the sites provided information that was out of line with agency guidelines or prohibited by other regulatory actions. These analyses suggest that the 101 pages in the master data set would presumably all pass the criteria of HON, IHC, or any other certification system. However, less than 50% had any time of certification logo whatsoever and only 31%, or 31 sites had a certification logo that was health content related. From another perspective, 69% or 70 of the sites identified as providing quality health information did not demonstrate any of the most commonly currently employed health information certification system. A clear majority of the IDMI sites that most users would find using the three most common search engines and the five most commonly searched cancer terms would not provide the user with a certification logo on the site that is being called for in the healthcare community.

Even with the over decade long request of a multitude of experts including many peer-reviewed studies, along with the various attempts at their creation, a third party

¹⁹⁹ NHS, “NHS Direct Information Partners”, <http://www.nhsdirect.nhs.uk/articles/article.aspx?articleId=1161> Dec 2006, Feb 2007.

certification system remains elusive. To date, no one certification system has been universally adopted and many remain in effect with varying degrees of success. The results of this study indicate that even though a common certification system is not yet established for IDMI, the presence or absence of a certification logo does not necessarily mean the content of the site is good or bad. All of the sites reviewed in this work appear to provide good quality medical information with less than a third of them showing a certification logo applicable to health information content.

IX. Conclusion

This work aimed to answer the question of whether or not three currently used policy tools provide effective regulation of Internet disseminated medical information. The author examined the prohibition, information provision, and certification tools. The empirical analysis of data sets gathered on each of the tools allowed each hypothesis to be tested to determine the individual policy tool's effectiveness.

Results Summary

The author hypothesized that the prohibition policy tool would be effective in preventing the dissemination of information banned by regulatory agencies. The prohibition analysis was conducted as a case study to provide an in-depth study of a single case where the full power of the regulatory agencies and courts were employed to prevent the dissemination of a specific company's information. Prohibition proved to be an effective tool as no instance of Lane Lab's making cancer curative claims for their product, Benefin, was identified in the data set.

The information provision hypothesis stated that the tool would be effective in providing information in line with regulatory agency guidelines. One benefit this tool is to provide

a wealth of information that is beneficial to a consumer in an attempt to combat the prevalence of harmful medical information. The tool proved to be effective as no instance of harmful medical information was found anywhere in the data set. An exhaustive search of the 388 pages of information gathered in the data set provided only information inline with agency guidelines. Consequently, the author determined that information provision is effective in balancing the information asymmetry of medical Internet information.

It was hypothesized that the certification tool would not be prevalent on enough sites in order to be effective. Another aspect of certification is that there would not be a single certification system in place but rather a mixture of many systems. Consequently, users would not feel assurance that a certification informs them that the site is credible.

Furthermore, there would be no branch recognition for a single system such as a consumer might have for the Better Business Bureau. Certification was not present on a majority of the sites in the data set. Over 50% of the sites had no certification whatsoever. Of the sites that had certification, 31% had the HONcode certification.

Only one other health information certification was present on just one of the sites.

Therefore, certification is not presently employed in enough cases for users to recognize a benefit of this tool. However, when it is used, HONcode is the most prevalent and a clear leader in providing certification for medical information sites.

Discussion of Results

For these specific search criteria on the subject area of cancer, each of the policy tools provides a unique level of effectiveness for IDMI consumer protection. Prohibition and Information Provision both showed high levels of effectiveness in accomplishing their respective purposes and are effective as stand-alone tools. No instance of banned information was found regarding Benefin. That is the best result that a prohibition regulation can offer. Information provision is adequately combating the information asymmetry through the provision of credible information to users. All of the information provided in a detailed analysis of the data set was in line with regulatory agency guidelines. In contrast, the certification system is not yet adopted by enough sites to be effectively used as a stand-alone policy tool. All the information reviewed would be eligible for HONcode certification according to HON guidelines though it is not used by a majority of the sites identified in this work. The author found that two of the three policy tools are effectively providing consumer protection for specific searches of medical information on the Internet.

The results of this work indicate that the prohibition and information provision policy tools are effectively providing consumer protection within the limited confines of the defined criteria. Additional work should continue to better define the effectiveness of these tools when applied to other subject areas with different sets of criteria. This subsequent work may well identify the need to increase the regulatory reach of these tools due to their inability to provide effective consumer protection on other subjects.

Should such a result be identified an increase in monitoring and enforcement may be required for an effective prohibitory tool. Regulators would need to provide constant vigilance to prevent the dissemination of prohibited information. Similarly, an increase in credible information provided to consumers would be required to combat the wealth of harmful information should such a result be found. Policymakers would need an accurate estimate of the level of harmful information in order to assess the need for provision of credible information. Both activities would require a great deal of resources to monitor the billions of pages of Internet information.

The certification tool may provide a mechanism to assist regulators in the difficult work of monitoring the Internet. This work found that the certification tool is not yet adopted by enough sites to be considered effectively providing consumer protection. Should the adoption rate of the certification tool increase, it would provide a method for regulators to make an accurate assessment of the number of pages of credible information. This would aid in determining how many sites are assisting in the provision of information thereby helping to alleviate the information asymmetry. Additionally, with a higher certification adoption rate, Internet monitors might focus on those sites providing medical information (identified through their key words and meta-tags) that do not display certifications. Providers of harmful medical information would be ineligible for a certificate from an organization such as HON and consequently be more readily identifiable by monitors. A higher certification adoption rate by IDMI providers would be beneficial to both consumers and regulators.

“Type of Cancer” vs. “Cancer Cure”

This study looked at cancer as the topic of interest for the reasons provided in the introductory chapter in the section “Selection of Cancer as IDMI Subject Area”. In brief, cancer is highly prevalent in our society and many users turn to the Internet to learn more about the disease. This work aimed to discover whether banned information about cancer was present, if the information provided followed appropriate guidelines, and if certification systems were prevalent enough to assure users of credible information. In order to accomplish this, the five most searched cancers were used as a basis in the three top search engines to provide the data set. The five most searched cancers at the time of the study were, breast, lung, leukemia, prostate and colon. The data set is comprised of information about these particular types of cancer. This is an important distinction for this work. The author sought information on the “type of cancer” as opposed to “cancer cures”. The results might have been very different if the focus was on cures as opposed to types.

A search on Google in February 2008, for “cancer cure” provided a link as the 4th result to www.1cure4cancer.com that makes the following claim:

Cure or Prevent Cancer naturally
with Vitamin B17 ~ Amygdalin
Laetrile ~ Apricot seeds!²⁰⁰

²⁰⁰ www.1cure4cancer.com accessed Feb 2008

This is the type of result that would have changed the conclusion of this work. However, because of the search for “type” as opposed to “cure” the results did not provide such data points. Perhaps the providers of such disingenuous medical information are targeting only certain segments of the Internet search market through the key words and meta-tags that capture these sites in search engines. It would be enlightening to run this study again using different sets of search terms to determine the targeted key words for harmful IDMI. Based on this quick search of one search engine with one term, it appears that additional regulation of IDMI is necessary for adequate consumer protection.

Regulatory Oversight

Multiple regulatory bodies oversee activities on the Internet. This work identified two of these agencies that specifically oversee information related to medical information, the FDA and FTC. Each agency has a role regarding Internet regulation. The FDA is responsible for monitoring companies that provide unsubstantiated claims regarding their products. The FTC is charged with consumer protection and ensuring fair competition. For a company promoting a “cancer cure” product, there may be some confusion regarding which agency has the authority to intercede. In this instance, the company’s claims would fall under the FTC’s oversight as they are making advertising claims for an over-the-counter drug that must be truthful and non-deceptive. However, due to the nature of the claim, that it is a curative for a disease, it also falls under the FDA’s rules for labeling of the drug. Consequently, the Internet informational claim may require

action on one or both of the regulatory bodies in order to effectively provide consumer protection.

The FDA and FTC are the two main US agencies actively overseeing medical information on the Internet. An attempt was made to coordinate the FDA and FTC Internet regulatory activities through Operation Cure.All. However, each agency acted and continues to work independently and in conjunction outside of the auspices of Operation Cure.All to provide information to consumers and prohibit harmful information provision via the Internet. An assessment of Operation Cure.All activities is at the end of this section.

The ongoing Internet regulatory activities of these two agencies can be found in their respective budgetary statements provided for fiscal year 2009. The FDA FY 2009 budget goals include a number of ways to enhance their website to, “Enhance patient and consumer protection and empower them with better information about regulated products”²⁰¹. The FDA conducted a series of focus groups to identify how to enhance consumer protection through the use of their website. They found that users were unable to satisfactorily navigate the FDA website and had significant trouble finding the information they wanted. Based on the details of these focus group sessions,

²⁰¹ US FDA, “FDA’s FY 2009 Congressional Justifications, Online Performance Appendix”, Office of Management, DHHS, Jan 2008, accessed Sep 2008, http://www.fda.gov/oc/oms/ofm/budget/2009/FDA_Online_Appendix.htm

recommendations for website improvement are included in the goals for FY2009. They include,

- “Group similar items and use labels for the groups that make sense to users,
- Provide overviews with links to more detailed information, and
- Make important information more visible: put it above the fold, reduce extraneous detail, and divide long pages into smaller "chunks" that cover one issue per page.²⁰²”

Once acted upon, it is believed that users are more likely to turn to the FDA website for critical information about serious emerging risks regarding products under the FDA regulatory purview. This in turn should help to achieve the objective of enhancing patient and consumer protection through the provision of better information.

Beyond the improvements the FDA has determined are necessary for their website, the agency continues to monitor and address complaints made about websites promoting false medical information via the Internet. A recent FDA press release noted that as of September 2008, the FDA has issued a total of 187 warning letters to companies that are attempting to sell fake cancer remedies on the Internet²⁰³. The FDA’s associate commissioner for regulatory affairs noted, “Although promotions of bogus cancer ‘cures’ have always been a problem, the Internet has provided a mechanism for them to flourish”²⁰⁴. The warning letters were primarily targeted at US companies. However, the FDA also identified international companies selling bogus cancer cures and has referred

²⁰² Ibid.

²⁰³ US FDA, “FDA Warns Individuals and Firms to Stop Selling Fake Cancer “Cures””, Jun 2008, accessed Oct 2008 <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01852.html>

²⁰⁴ Ibid.

this information to the relevant foreign governing authorities. The warning letter campaign is part of the ongoing effort that the FDA is undertaking to prevent companies from marketing bogus products to consumers. If a company fails to comply with the required actions in the warning letter, the company is subject to enforcement action that includes seizing the illegal products, injunctions, and/or criminal prosecution.

The FTC's FY 2009 Congressional Budget Justification states that the FTC, "enforces the laws that prohibit business practices that are anticompetitive, deceptive, or unfair to consumers"²⁰⁵. Specifically regarding health fraud (both Internet related and non) the FTC states they will continue to combat deceptive marketing practices particularly against products making disease prevention claims. Of the many enforcement action examples provided, four are given that are specific to online advertising targeting consumers hoping for weight loss. The bogus claims by these companies led to separate cases against each of the companies. Collectively the cases were settled by the companies wherein they surrendered cash and assets worth \$25 million²⁰⁶. In 2006 the FTC set up a teaser site for "Glucobate" a purportedly all-natural diabetes remedy. When a user clicked any link for additional information they are taken to the FTC's "Be Smart. Be Skeptical" website²⁰⁷. The FTC claims that this site has generated numerous blogs, bulletin boards and other discussions regarding how best to warn consumers about

²⁰⁵ US FTC, "Fiscal Year 2009 Congressional Budget Justification Summary", Feb 2008, accessed Sep 2008 <http://www.ftc.gov/opa/2008/02/gpra.shtm>

²⁰⁶ Ibid.

²⁰⁷ <http://www.wemarket4u.net/glucobate/>

deceptive product claims. The FTC continues to prohibit misleading information disseminated via the Internet as well as attempts to make consumers more aware and skeptical of bogus claims through efforts such as Glucobate.

An attempt was made to coordinate the activities of the FDA and FTC as well as other US and non-US based regulatory agencies through the creation of Operation Cure.All. However, it is difficult to assess how effective this collaboration has been. Multiple attempts to contact an individual willing to discuss the activities of Operation Cure.All at the FDA and the FTC went unanswered as of the completion of this work. The only response was provided after submitting an inquiry through the Operation Cure.All website at <http://www.ftc.gov/cureall/>. The request for: a contact person and number, where does funding originate, a mission statement, and a host of other questions, was answered with the following email:

*From: COMPLAINT@FTC.GOV
Subject: Response to your complaint Ref No. 11820234
Date: October 11, 2007 12:19:29 PM MDT
To: kmay3@gmu.edu*

Thank you for contacting the Federal Trade Commission. We entered the information you provided into our shared law enforcement data base. We share this data base with Federal, State and Local law enforcement agencies. Attached is your electronic response, which includes your reference number. Any enclosures can be found at www.ftc.gov under Consumer Protection and Consumer Information section.

Information from consumers like you helps Federal, State and Local authorities investigate possible illegal practices and enforce our laws. Someone from the Federal Trade Commission or another law enforcement agency may contact you if they need additional information to help them in an investigation.

Please visit the FTC's web page, www.ftc.gov, to get free information to help you avoid costly consumer problems.

There was no response to written requests to the FDA for additional information regarding Operation Cure.All. In addition, there have been no updates to the Operation Cure.All Press Room page <http://www.ftc.gov/bcp/online/edcams/cureall/press.htm> regarding the activities of the partnership since a press release posting dated October 28, 2003²⁰⁸. It would be a benefit to future researchers of IDMI should the agencies directly involved with monitoring this environment provide up to date reports on their activities. In this way, the policy tools under investigation might be better linked to the regulatory body charged with its use.

Extension of Model

This work provides a cross-sectional analysis of the state of three regulatory mechanisms currently in place for protecting consumers of IDMI. It is specific to the topic area of cancer and further restricted by the search criteria. As noted in the “Discussion of Results” in this chapter, alternate search criteria would have provided different results. In addition, a different subject area may well provide different results. The model used for this work may be adapted to provide data and subsequently provide additional data sets for subsequent analysis of other area. For example, the model may be used to investigate any other medical topic wherein consumer protection is of concern. Barrett and Jarvis note that there are many areas prone to consumer fraud.

²⁰⁸ US FTC, Operation Cure.All, “News Releases”, Oct 2003, Feb 2008
<http://www.ftc.gov/bcp/online/edcams/cureall/press.htm>

Hair analysis? The latest diet book? Megavitamins? "Stress formulas"? Cholesterol-lowering teas? Homeopathic remedies? Magnets? Nutritional "cures" for AIDS? Products that "cleanse your system"? Or shots to pep you up? Business is booming for health quacks. Their annual take is in the billions! Spot reducers, "immune boosters," water purifiers, "ergogenic aids," systems to "balance body chemistry," special diets for arthritis. Their product list is endless.²⁰⁹

Any of the subject areas noted by Barrett and Jarvis may provide further insight into the effectiveness of the policy tools.

The model may also be applied to other subject areas outside of the dispersion of medical information to determine regulatory effectiveness for consumer protection. In 1999 the US Department of Justice began a program to conduct investigations and start prosecutions against providers of deceptive and/or fraudulent Internet information. The DOJ identified the following major categories of Internet Fraud:

- Auction and retail schemes
- Business opportunity/work-at-home schemes
- Credit-card schemes
- Identity theft
- Investment schemes
- Market Manipulation schemes
- Quick divorce schemes²¹⁰

Application of the model to any of these subject areas may provide enlightening information into the currently employed regulatory mechanisms used to protect

²⁰⁹ Barrett, S., Jarvis, W.T., "How Quackery Sells", Quackwatch, Jan 2005, Feb 2008

<http://www.quackwatch.com/01QuackeryRelatedTopics/quacksell.html>

²¹⁰ US DOJ, "Internet and Telemarketing Fraud", Feb 2008, <http://www.usdoj.gov/criminal/fraud/internet/>

consumers against these types of Internet fraud. Further adaptation of the model may be required to provide this insight as the three policy tools studied for the subject area of cancer may not be appropriate for other topic areas. For example, it may be determined that of Eisner's nine tools that policymakers use to regulate market behaviors: prohibitions; licensing; price, rate, and quantity restrictions; product standards; technical production standards; performance standards; subsidies; information provision; and assigning property rights and liability²¹¹, a completely different set is needed to investigate identity theft. Alternatively, completely new policy tools may be adopted due to technological advances that may be tested using this model.

Overall, it is hoped that this work provided the reader with a better understanding of the currently regulatory practices used to monitor Internet medical information. Additional research into this specific subject area, other medically important areas, and any other Internet fraud area will provide greater insight into the nature and effectiveness of Internet regulation in the twenty-first century.

²¹¹ Eisner, M.A., E.J. Ringquist, J. Worsham, "Contemporary Regulatory Policy", Boulder CO, Lynne Rienner Publishers, 2000.

X. Comprehensive Data Set

The purpose of this section is to provide the reader with specific information as to how the data was collected. The analysis of the data specific to each of the three policy tools studied is incorporated into the empirical chapter dedicated to each of the tools.

Entering in five search terms into three search engines and collecting the top ten pages resulting from the searches produced 150 pages to review. As the search algorithms are different and proprietary for each engine, they do not return identical sets of results for the list of top ten sites provided on the results page of the search. However, there are some duplicate pages between the sites. The initial 150 pages in the master data list presented below were reviewed for duplicates. This review revealed that there were 101 unique pages returned using the three search engines. As this study was not intended to be a comparison of search engine algorithms, further comparison regarding which engine returned which page or a comparison of where duplicate pages resulted was not conducted. There was a fairly even distribution of duplicate pages among the search criteria. The search term and the number of duplicate pages are provided in **Table 10.1** below.

Table 10.1. Duplicate Search Terms for All Search Engine Page Results

Search Term	Number of Duplicate Pages
“Breast cancer”	20
“Lung cancer”	18
“Leukemia”	23
“Colon cancer”	19
“Prostate cancer”	21

Removal of the duplicate pages resulted in a “cleaned” master data list of 101 unique pages. This list is provided below as **Table A.16** in **Appendix A**.

As mentioned, the Internet is a highly chimerical environment. Preliminary work done in preparation for this study did not provide identical page results to the search conducted to produce the master data set for this project. For example, a search using Google and Yahoo! in May 2006 using the term “Breast cancer” did not return identical page results for the top ten pages as did the search conducted to create the master data list in January 2007.

Master Data List

The master data list for this work follows in **Tables A.1 – A.15** in **Appendix A**. This list was created over the course of two days. The first search was conducted using Google and began on January 20, 2007 at 10:00 eastern. The final search ended using MSN on

January 21, 2007 at 15:35 eastern. The tables below present the data in the order that it was collected over that time period. The master data list was created within the framework of capturing the data for a cross-sectional analysis as opposed to a longitudinal study. As the title line of the page and the Uniform Resource Locator (URL) are captured in the list, the author was able to go to the page to conduct the in-depth review for each of the policy tool empirical sections without having to rerun the search. Indeed, subsequent reruns using the search criteria to verify some of the URLs provided different page results in the top ten lists on January 24, 2007, just days after the master list was finished. In all cases, for the detailed studies for the prohibition, information provision, and certification policy tools, the pages were captured and were consequently available for review and study over the course of the analysis.

APPENDIX A

Table 6.A. List of 39 Unique SLDs from the Master Data List

<http://breastcancer.care2.com/>
http://www.cancer.org/docroot/cri/content/cri_2_4_1x_what_is_adult_chronic_leukemia_62.asp
http://en.wikipedia.org/wiki/Breast_cancer
<http://nihseniorhealth.gov/prostatecancer/toc.html>
<http://personalweb.sunset.net/~mansell/polyp.htm>
<http://prostatecancer.about.com/>
www.4woman.gov/faq/lung.htm
www.breastcancer.org
www.cancer.gov/cancer_information/cancer_type/leukemia
www.cancer.med.umich.edu/prostcan/prostcan.html
www.cancerbacup.org.uk/Cancertype/Breast
www.ccalliance.org
www.cdc.gov/cancer/breast
www.coloncancerfoundation.org
www.emedicinehealth.com/articles/13615-1.asp
www.feminist.org/other/bc
www.kidshealth.org/parent/medical/cancer/cancer_leukemia.html
www.komen.org
www.leukemia.org
www.leukemia-lymphoma.org
www.leukemia-research.org
www.lungcancer.org
www.lungcanceronline.org
www.lungusa.org/site/pp.asp?c=dvLUK9O0E&b=35427
www.mayoclinic.com/health/colon-cancer/DS00035
www.medicinenet.com/colon_cancer/article.htm
www.mesolink.org
www.nationalbreastcancer.org
www.nature.com/leu
www.nlm.nih.gov/medlineplus/prostatecancer.html
www.oncolink.org/types/article.cfm?c=2&s=4&ss=25&id=9534
www.oncolink.upenn.edu/types/types.cfm?c=9
www.oncologychannel.com/coloncancer
www.prostate.com
www.prostate-cancer.org

www.prostatecancerfoundation.org
www.thebreastcancersite.com
www.urologychannel.com/prostatecancer
www.ustoo.com

The following tables, as noted in the Methods Section, provide the page title line and URL search results for the engines in the order they were conducted.

Table A.1. Breast Cancer – Google

Google – “Breast cancer”	www.google.com
Leading Line	URL
1. BreastCancer.org - Breast Cancer Treatment Information and Pictures	www.breastcancer.org
2. The Breast Cancer Site	www.thebreastcancersite.com
3. Susan G. Komen Breast Cancer Foundation	www.komen.org
4. Breast Cancer Information from National Breast Cancer Foundation Inc	www.nationalbreastcancer.org
5. MedlinePlus: Breast Cancer	www.nlm.nih.gov/medlineplus/breastcancer.html
6. Breast cancer - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Breast_cancer
7. What You Need To Know About™ Breast Cancer - National Cancer Institute	www.cancer.gov/cancertopics/wyntk/breast
8. Breast Cancer Home Page - National Cancer Institute	www.cancer.gov/cancertopics/types/breast
9. American Cancer Society - Information and Resources for Breast	www.cancer.org

10. Breast Cancer	www.emedicinehealth.com/breast_cancer/article_em.htm
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Table A.2. Lung Cancer - Google

Google – “Lung cancer”	
Leading Line	URL
1. Welcome to Lung Cancer.org	www.lungcancer.org
2. Facts About Lung Cancer - American Lung Association site	www.lungusa.org/site/pp.asp?c=dvLUK9O0E&b=35427
3. Lung Cancer Online	www.lungcanceronline.org
4. MedlinePlus: Lung Cancer	www.nlm.nih.gov/medlineplus/lungcancer.html
5. Lung cancer information on symptoms, diagnosis, treatment, types ...	www.medicinenet.com/lung_cancer/article.htm
6. Lung Cancer Home Page - National Cancer Institute	www.cancer.gov/cancertopics/types/lung
7. What You Need To Know About™ Lung Cancer - National Cancer Institute	www.cancer.gov/cancertopics/wyntk/lung
8. Lung cancer - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Lung_cancer
9. MesoLink.org -- Your Link To Mesothelioma Information	www.mesolink.org
10. Lung Cancer	www.4woman.gov/faq/lung.htm

Table A.3. Leukemia - Google

Google- Leukemia	
Leading Line	URL
1. The Leukemia & Lymphoma Society	www.leukemia.org

2. Leukemia	www.nature.com/leu
3. Leukemia - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Leukemia
4. Leukemia Home Page - National Cancer Institute	www.cancer.gov/cancertopics/types/leukemia
5. What You Need To Know About™ Leukemia - National Cancer Institute	www.cancer.gov/cancertopics/wyntk/leukemia
6. Leukemia Causes, Diagnosis, Information, Treatments, and Symptoms ...	www.medicinenet.com/leukemia/article.htm
7. Leukemia Research Foundation, Fighting Leukemia , Lymphoma and ...	www.leukemia-research.org
8. Leukemia	www.emedicinehealth.com/leukemia/article_em.htm
9. Leukemia - Symptoms - oncologychannel	www.oncologychannel.com/leukemias/symptoms.shtml
10. Leukemia & Lymphoma Society - Disease Information - Leukemia	www.leukemia-lymphoma.org/all_page?item_id=7026

Table A.4. Colon Cancer - Google

Google – “Colon cancer”	
Leading Line	URL
1. ACS :: All About Colon and Rectum Cancer	www.cancer.org/docroot/CRI/CRI_2x.asp?sitearea=LRN&dt=10
2. MedlinePlus Medical Encyclopedia: Colon cancer	www.nlm.nih.gov/medlineplus/ency/article/000262.htm
3. MedlinePlus: Colorectal Cancer	www.nlm.nih.gov/medlineplus/colorectalcancer.html
4. Colon cancer information on causes, symptoms, tests to detect ...	www.medicinenet.com/colon_cancer/article.htm
5. Colon polyps, Colon Cancer and All the Information You Wanted ...	personalweb.sunset.net/~mansell/polyp.htm

6. Colon Cancer Alliance: Support and Information for People Affected ...	www.ccalliance.org
7. Colorectal cancer - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Colorectal_cancer
8. Colon and Rectal Cancer Home Page - National Cancer Institute	www.cancer.gov/cancertopics/types/colon-and-rectal
9. Colon Cancer Treatment - National Cancer Institute	www.cancer.gov/cancertopics/pdq/treatment/colon
10. Colon Cancer	www.emedicinehealth.com/colon_cancer/article_em.htm

Table A.5. Prostate Cancer - Google

Google – “Prostate cancer”	
Leading Line	URL
1. Prostate Cancer , Prostate Cancer Symptoms, Prostrate Cancer ...	www.prostatecancerfoundation.org
2. MedlinePlus: Prostate Cancer	www.nlm.nih.gov/medlineplus/prostatecancer.html
3. Prostate Cancer Home Page - National Cancer Institute	www.cancer.gov/cancertopics/types/prostate
4. What You Need To Know About Prostate Cancer - National Cancer ...	www.cancer.gov/cancertopics/wyntk/prostate
5. Prostate Cancer Research Institute -- Education, Awareness and ...	www.prostate-cancer.org
6. Prostate cancer - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Prostate_cancer
7. Prostate.com	www.prostate.com/
8. ACS :: All About Prostate Cancer	www.cancer.org/docroot/CRI/CRI_2x.asp?sitearea=LRN&dt=36
9. NIHSeniorHealth:	nihseniorhealth.gov/prostatecancer/toc.html

Prostate Cancer - Table of contents	
10. Us TOO International Prostate Cancer Education & Support Network	www.ustoo.com

Table A.6. Breast Cancer - Yahoo

Yahoo! – “Breast cancer”	www.yahoo.com
Leading Line	URL
1. Breast Cancer: The Basics	www.oncolink.org/types/article.cfm?c=2&s=4&ss=25&id=9534
2. All About Breast Cancer - American Cancer Society	www.cancer.org/docroot/CRI/CRI_2x.asp?sitearea=LRN&dt=5
3. Susan G. Komen Breast Cancer Foundation	www.komen.org
4. MayoClinic: Breast Self-Examination	www.mayoclinic.com/invoke.cfm?id=WO00026
5. What You Need to Know About Breast Cancer	www.cancer.gov/cancerinfo/wyntk/breast
6. BreastCancer.org	www.breastcancer.org
7. Breast Cancer - MedlinePlus	www.nlm.nih.gov/medlineplus/breastcancer.htm
8. CancerBACUP: Breast Cancer Information Centre	www.cancerbacup.org.uk/Cancertype/Breast
9. Breast Cancer Information Center	www.feminist.org/other/bc
10. Breast Cancer - eMedicine.com	www.emedicinehealth.com/articles/13615-1.asp

Table A.7. Lung Cancer - Yahoo

Yahoo! – “Lung cancer”	
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Leading Line	URL
1. What Is Lung Cancer ?	cancer.org/docroot/cric/content/cric_2_4_1x_what_is_lung_cancer_26.asp
2. It's Time to Focus on Lung Cancer	www.lungcancer.org
3. Lung Cancer - MedlinePlus	www.nlm.nih.gov/medlineplus/lungcancer.html
4. American Cancer Society	www.cancer.org
5. Lung Cancer Online	www.lungcanceronline.org
6. Lung Cancer Home Page - National Cancer Institute	www.cancer.gov/cancertopics/types/lung
7. OncoLink: Lung Cancer	www.oncolink.upenn.edu/types/types.cfm?c=9
8. Lung cancer - MayoClinic.com	www.mayoclinic.com/health/lung-cancer/DS00038
9. Lung Cancer	www.cdc.gov/cancer/lung/index.htm
10. MedicineNet: Lung Cancer	www.medicinenet.com/lung_cancer/article.htm

Table A.8. Leukemia - Yahoo

Yahoo! - Leukemia	
Leading Line	URL
1. Leukemia	www.nature.com/leu
2. The Leukemia and Lymphoma Society	www.leukemia-lymphoma.org
3. leukemia	www.medicinenet.com/leukemia/article.htm
4. leukemia & lymphoma society	www.leukemia-lymphoma.org/all_page?item_id=9346
5. Leukemia - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Leukemia

6. Childhood Cancer: Leukemia	kidshealth.org/parent/medical/cancer/cancer_leukemia.html
7. Leukemia Home Page - National Cancer Institute	www.cancer.gov/cancer_information/cancer_type/leukemia
8. leukemia	www.mayoclinic.com/health/leukemia/DS00351
9. leukemia	cancer.org/.../cri_2_4_1x_what_is_adult_chronic_leukemia_62.asp
10. what is acute lymphocytic leukemia ?	cancer.org/docroot/cri/content/...?sitearea=cri

Table A.9. Colon Cancer - Yahoo

Yahoo! – “Colon cancer”	
Leading Line	URL
1. colon cancer	www.cancer.gov/cancerinfo/pdq/treatment/colon/patient
2. colon cancer information on causes, symptoms, tests to detect ...	www.medicinenet.com/colon_cancer/article.htm
3. Colon Polyps and Colon Cancer	personalweb.sunset.net/~mansell/polyp.htm
4. National Cancer Institute: Colon and Rectal Cancer	www.cancer.gov/cancertopics/types/colon-and-rectal
5. ACS :: All About Colon and Rectum Cancer	www.cancer.org/docroot/CRI/CRI_2x.asp?sitearea=LRN&dt=10
6. OncologyChannel: Colon Cancer	www.oncologychannel.com/coloncance
7. Colorectal cancer - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Colon_cancer
8. MayoClinic: Colorectal Cancer	www.mayoclinic.com/invoke.cfm?id=DS00035
9. Colon Cancer - eMedicine.com	www.emedicinehealth.com/articles/13703-1.asp
10. colon cancer	www.cancer.org/docroot/CRI/CRI_2_1x.asp?dt=10

Table A.10. Prostate Cancer - Yahoo

Yahoo! – “Prostate cancer”	
Leading Line	URL
1. Prostate Cancer - MedlinePlus	www.nlm.nih.gov/medlineplus/prostatecancer.html
2. Prostate Cancer Home Page - National Cancer Institute	www.cancer.gov/cancer_information/cancer_type/prostate
3. Prostate Cancer Foundation	www.prostatecancerfoundation.org
4. Prostate Cancer	www.cdc.gov/cancer/prostate/index.htm
5. Prostate Cancer Research Institute (PCRI)	www.prostate-cancer.org
6. about.com: prostate cancer	prostatecancer.about.com
7. UM Comprehensive Cancer Center: Prostate Cancer	www.cancer.med.umich.edu/prostcan/prostcan.html
8. Prostate Cancer (PDF)	www.cancer.org/downloads/PRO/ProstateCancer.pdf
9. Prostate.com	www.prostate.com
10. ACS: Prostate Cancer	www.cancer.org/docroot/CRI/CRI_2x.asp?sitearea=LRN&dt=36

Table A.11. Breast Cancer - MSN

MSN – “Breast cancer”	www.msn.com
Leading Line	URL
1. BreastCancer.org - Breast Cancer Treatment Information and Pictures	www.breastcancer.org
2. Understanding Breast	www.breastcancer.org/ubc_intro.html

Cancer	
3. Breast cancer - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Breast_cancer
4. ACS :: What Is Breast Cancer ?	www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_is_breast_cancer_5.asp
5. ACS :: What Is Breast Cancer ?	www.cancer.org/docroot/CRI/content/CRI_2_2_1X_What_is_breast_cancer_5.asp?sitearea=
6. Breast Cancer Home Page - National Cancer Institute	www.cancer.gov/cancertopics/types/breast
7. Breast Cancer Information from National Breast Cancer Foundation Inc	www.nationalbreastcancer.org
8. End Breast Cancer from Care2.com and TBCF!	breastcancer.care2.com
9. MedlinePlus: Breast Cancer	www.nlm.nih.gov/medlineplus/breastcancer.html
10. Cancer - Breast Cancer	www.cdc.gov/cancer/ breast

Table A.12. Lung Cancer - MSN

MSN – “Lung cancer”	
Leading Line	URL
1. Welcome to Lung Cancer.org	www.lungcancer.org
2. Lung Cancer.org	www.lungcancer.org/patients/fs_patient_caregivers.htm
3. Lung cancer - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Lung_cancer
4. MedlinePlus: Lung Cancer	www.nlm.nih.gov/medlineplus/lungcancer.html
5. Lung Cancer	www.cdc.gov/cancer/lung
6. Lung Cancer Home Page - National Cancer Institute	www.cancer.gov/cancertopics/types/lung
7. Lung Cancer Online	www.lungcanceronline.org

8. Lung Cancer - oncologychannel	www.oncologychannel.com/lungcancer
9. Lung cancer information on symptoms, diagnosis, treatment, types of ...	www.medicinenet.com/lung_cancer/article.htm
10. Lung cancer - MayoClinic.com	www.mayoclinic.com/health/lung-cancer/ DS00038

Table A.13. Leukemia - MSN

MSN - Leukemia	
Leading Line	URL
1. Leukemia - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Leukemia
2. The Leukemia & Lymphoma Society	www.leukemia.org
3. The Leukemia & Lymphoma Society	www.leukemia.org/hm_lls
4. Leukemia	www.nature.com/leu/index.html
5. Leukemia Causes, Diagnosis, Information, Treatments, and Symptoms on ...	www.medicinenet.com/leukemia/ article.htm
6. Leukemia & Lymphoma Society - Disease Information - Leukemia	www.leukemia-lymphoma.org/all_page?item_id=7026
7. MedlinePlus Medical Encyclopedia: Leukemia	www.nlm.nih.gov/medlineplus/ency/article/ 001299.htm
8. MedlinePlus: Leukemia, Adult Acute	www.nlm.nih.gov/medlineplus/leukemiaadultacute.html
9. Leukemia Home Page - National Cancer Institute	www.cancer.gov/cancertopics/types/ leukemia
10. Childhood Cancer: Leukemia	www.kidshealth.org/parent/medical/cancer/cancer_ leukemia.html

Table A.14. Colon Cancer - MSN

MSN – “Colon cancer”	
Leading Line	URL

1. Colon cancer information on causes, symptoms, tests to detect cancer ...	www.medicinenet.com/colon_cancer/article.htm
2. ACS :: All About Colon and Rectum Cancer	www.cancer.org/docroot/CRI/CRI_2x.asp?sitearea=LRN&dt=10
3. ACS :: Learn About Cancer	www.cancer.org/docroot/lrn/lrn_0.asp
4. Colorectal cancer - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Colon_cancer
5. Colon cancer - MayoClinic.com	www.mayoclinic.com/health/colon-cancer/DS00035
6. MedlinePlus Medical Encyclopedia: Colon cancer	www.nlm.nih.gov/medlineplus/ency/article/000262.htm
7. Colon Cancer Treatment - National Cancer Institute	www.cancer.gov/cancerinfo/pdq/treatment/colon/patient
8. Colon Cancer , Colorectal Cancer - oncologychannel	www.oncologychannel.com/coloncancer
9. Colon Cancer Foundation Home	www.coloncancerfoundation.org
10. Colon Cancer Alliance: Support and Information for People Affected by ...	www.ccalliance.org

Table A.15. Prostate Cancer - MSN

MSN – “Prostate cancer”	
Leading Line	URL
1. Prostate Cancer Home Page - National Cancer Institute	www.cancer.gov/cancertopics/types/prostate
2. Prostate Cancer Treatment - National Cancer Institute	www.cancer.gov/cancertopics/pdq/treatment/prostate/patient
3. Prostate cancer - Wikipedia, the free encyclopedia	en.wikipedia.org/wiki/Prostate_cancer

4. Prostate Cancer Research Institute -- Education, Awareness and ...	www.prostate-cancer.org
5. MedlinePlus: Prostate Cancer	www.nlm.nih.gov/medlineplus/ prostatecancer.html
6. Prostate Cancer Causes, Diagnosis, Information, Symptoms, Treatment ...	www.medicinenet.com/prostate_ cancer/article.htm
7. Prostate Cancer - Urologychannel	www.urologychannel.com/prostatecancer
8. ACS :: Detailed Guide: Prostate Cancer	www.cancer.org/docroot/CRI/CRI_2_ 3x.asp?rnav=cridg&dt=36
9. Prostate.com	www.prostate.com
10. Prostate cancer - MayoClinic.com	www.mayoclinic.com/health/prostate-cancer/ DS00043

Table A.16. URLs of Cleaned Master Data List with Duplicate Sites Removed

<http://breastcancer.care2.com/>
http://www.cancer.org/docroot/cri/content/cri_2_4_1x_what_is_adult_chronic_leukemia_62.asp
http://www.cancer.org/docroot/cri/content/cri_2_4_1x_what_is_adult_acute_leukemia_57.asp?sitearea=cri
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