

Internet Healthcare Coalition  
Collaborating with the FDA  
Initiative: Inspections--Internet

Presented by:  
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Internet  
Healthcare  
Coalition

[www.ihealthcoalition.org](http://www.ihealthcoalition.org)  
Quality Health Information on the 'Net

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The Internet Healthcare Coalition ([www.ihealthcoalition.org](http://www.ihealthcoalition.org)) is an international, non-profit, non-partisan organization dedicated to identifying and promoting credible health information and resources on the Internet. The Coalition's membership of over 500 individuals represents constituents in every sector of the Internet healthcare space worldwide, including consumers, providers of Internet health information, government representatives, medical libraries, academic institutions and other accredited educational providers, special-interest societies, patient advocacy and support groups and manufacturers of regulated drugs and medical devices. The Coalition is focused on educating healthcare consumers and professionals about the evolving issues relating to the quality of Internet health information.

As part of its ongoing educational campaign, the Coalition has developed "Tips For Health Consumers: Finding Quality Health Information on the Internet" (see <http://www.ihealthcoalition.org/content/tips.html>) as well as an eHealth Code of Ethics (see <http://www.ihealthcoalition.org/ethics/ethics.html>). Our tips have appeared in major national newspapers like the Wall Street Journal ("Calling on Doctors in Cyberspace (Bring Your Own Magazines)," Marilyn Chase, August 23, 1999), in books like *The Complete Idiot's Guide to Online Medical Resources* (Joan Price, QUE, 2000), and have been featured in an Eckerd Every Day public service announcement.

The Coalition would like to collaborate with the FDA in its effort to monitor the sale of drugs over the Internet in the following ways:

- Develop "Tips For Health Consumers: Purchasing Drugs and Medical Supplies on the Internet," which would be patterned after our Tips for finding quality health information on the Net and would also be based upon our eHealth Code of Ethics and produced in collaboration with the FDA.
- Work with the FDA through our official liaison -- Melissa Moncavage (or another designated liaison) -- to coordinate educational campaigns. For example, every year the Coalition hosts the conference "Quality Health Information on the 'Net'" and this year's theme is "Establishing Trust, Ensuring Privacy, Enabling E-Commerce." We can have a session devoted to prescription drug sites and invite an FDA speaker to present.
- Develop a portion of our web site that will allow consumers and Coalition members to report sites suspected of selling drugs or medical supplies illegally or

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**Mediconsult, Inc.**

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FDA Stakeholders Meeting \* Duke University \* April 12, 2000

RE: INITIATIVE #1: Safety review for new products--Safety Assurance in Clinical Trials The volume of clinical trials has grown dramatically over the past decade, due to expanding development of new medical products. In addition, clinical trials are more often performed at multiple study sites, including multi-country studies. Extensive oversight by FDA is not feasible in an era of significantly scaled-back field staffing. FDA sees a growing need to collaborate with outside organizations in managing the research, compliance and educational aspects of clinical investigations--particularly those sponsored by academia, industry, other government agencies and other private institutions/corporations.

Mediconsult is the leading Internet provider of healthcare solutions, interactive tools, and online clinical discussions for physicians and patients. Founded in 1996, the company's mission is to improve patient outcomes through information and tools that educate doctors, empower patients and build on the doctor/patient relationship. Mediconsult has the first and most active community of online physicians--with 214,000 authenticated US physicians registered on its Physicians' Online ([www.pol.net](http://www.pol.net)) service. Its physician and patient sites consistently lead the online health industry in 'stickiness'--each month, doctors and patients spend over two million hours on Mediconsult sites. The company's business model is based on working with pharmaceutical companies to deliver integrated online marketing solutions that leverage their deep clinical expertise.

Mediconsult has the ability to recruit patients for phase III and phase IV clinical trials AND to help clinicians followup with these patients via the Internet. We propose that Mediconsult use the Internet and it's network of physician and patient sites to aggressively monitor post-launch data from both patients and treating clinicians on side-effect and safety issues. This will allow the gathering of immediate, robust safety information on all aspects of drug use, including drug-drug interactions, non-standard dosing associated risks and previously unidentified side-effects. In turn, it is essential that the FDA recognize the legitimacy of pharma companies sponsoring post-marketing paid research to physicians that includes a substantial enough number of physicians to capture a broad swath of the actual clinical use of medication.



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- Develop a portion of our web site that will allow consumers and Coalition members to report sites suspected of selling drugs or medical supplies illegally or unethically on the Internet (or provide a gateway to an FDA site with the same function).
- Keep our members informed about FDA actions in this area via our email newsletter.



www.ihealthcoalition.org

**FOR IMMEDIATE RELEASE**

For More Information Contact:

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**e-Health Ethics Summit Offers World  
International Code of Ethics For The Health Internet**

*--Public Comment and Review Process To Begin Immediately--*

**WASHINGTON, D.C., February 18, 2000** – The first draft of the Internet Healthcare Coalition endorsed “International e-Health Code of Ethics” was unveiled today and can be fully accessed with additional notes and definitions via the Coalition’s Web site at: <http://www.ihealthcoalition.org/community/ethics.html>.

This draft Code represents both the insights and reflections of the e-Health Ethics Summit which convened in Washington, D.C. 31 January – 2 February 2000. The draft in its present form has not yet been formally endorsed by the e-Health Ethics Summit. Formal endorsement will take place after an eight-week period of public comment and consultation. Following this period, the draft will be revised for final publication on or about 15 May 2000.

“Never before have we witnessed such broad consensus on such an important topic,” said e-Health Ethics Summit Co-Chair Helga Rippen, MD, PhD, MPH.

“Through a democratic process we have offered the world a truly international, living Code of e-Health Ethics,” said e-Health Ethics Summit Co-Chair Ahmad Risk, MD.

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“Continued review and public consultation will only make it stronger and more widely accepted.”

The e-Health Ethics Summit Steering Group oversaw the work of The Hastings Center, an independent, non-profit research institute that addresses ethical issues in medicine and the life sciences, which has reviewed, organized and edited the minutes of the working Summit to develop the current draft Code. While developing the draft, both the Steering Group and The Hastings Center preserved the original language of the working Summit.

This draft Code was created with the input from all key Internet Health constituencies including consumers and patients, healthcare professionals, ethicists, dot-com entities, academicians, special-interest societies, manufacturers of regulated drugs and medical devices, governmental agencies, and international representatives.

### **The International e-Health Code of Ethics:**

#### ***Vision Statement:***

The Internet is changing how people receive health information and health care. All who use the Internet for health-related purposes must join together to create an environment of trusted relationships to assure high quality information and services, protect privacy, and enhance the value of the Internet for both consumers and providers of health information, products, and services. The goal of the "e-Health Code of Ethics" is to ensure that all people worldwide can confidently, and without risk, realize the full benefits of the Internet to improve their health.

#### ***Introduction:***

Health information has the potential both to improve health and to do harm. All people who use the Internet for health-related purposes must be able to trust that the sites they visit adhere to the highest ethical standards and that the information provided is credible.

Because health and health care are critically important to people, the organizations and individuals that provide health information on the Internet have special, strong obligations to be trustworthy, provide high quality content, protect users' privacy, and adhere to standards of best practices for online commerce and online professional services in health care.

## ***Guiding Principles***

### **1. Candor & Trustworthiness**

#### ***Guiding Principle:***

Organizations and individuals providing health information, products, or services on the Internet have an obligation to candidly disclose

- (A) Those factors that could influence content
- (B) The potential risks of providing personal information on the Internet

### **2. Quality**

#### ***Guiding Principle:***

Organizations and individuals offering health information, products, or services on the Internet have an obligation to

- (A) Provide high quality information, products, or services
- (B) Provide means for users to evaluate the quality of health information

### **3. Informed Consent, Privacy & Confidentiality**

#### ***Guiding Principle:***

Organizations and individuals providing health information, products, or services on the Internet have an obligation to

- (A) Safeguard users' privacy
- (B) Obtain users' informed consent when gathering personal information

### **4. Best Commercial Practices**

#### ***Guiding Principle:***

Organizations and individuals who sponsor, promote, or sell health information, products, or services on the Internet have an obligation to

- Disclose any information a reasonable person would believe might influence his or her decision to purchase or use products or services
- Be truthful and not deceptive
- Engage in responsible business relationships and affiliations
- Guarantee editorial independence
- Disclose the site's privacy policy and terms of use

## **5. Best Practices for Provision of Health Care on the Internet by Health Care Professionals**

### ***Guiding Principle:***

Health care professionals and organizations who provide health information, products, or services on the Internet have an obligation to

- (A) Adhere to the highest standards of professional practice
- (B) Help patients to understand how the Internet affects the relationship between professional and patient while adapting the highest professional standards to the evolving interactions made possible by the Internet

Comments about the Code are welcome via the Internet Coalition's Web site, <http://www.ihealthcoalition.org/community/draft.html>.

### **About the Internet Healthcare Coalition**

The Internet Healthcare Coalition, a non-profit, non-partisan organization, is dedicated to identifying and promoting quality healthcare resources on the Internet. Founded in 1997 and based in Washington, D.C., the Coalition's membership represents every sector of the Internet health space, including consumers, commercial developers of health information, medical libraries, special-interest societies, and manufacturers of regulated drugs and medical devices.

The goal of the Coalition is to educate healthcare consumers and professionals about the evolving issues relating to the quality of Internet health resources and information. In October 1999, responding to calls from within the Internet health community, the Coalition launched its ongoing "eHealth Ethics Initiative" to provide a forum for the development of a universal set of ethical principles for health-related Web sites.

More information regarding the Internet Healthcare Coalition and its "eHealth Ethics Initiative" can be found on the Web at <http://www.ihealthcoalition.org>.

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## **Internet Healthcare Coalition To Host e-Health Ethics Summit**

### ***Responding to Industry-wide Call to Arms, Non-Partisan Coalition of Internet Healthcare Thought-Leaders Convene To Establish Guiding Principles***

WASHINGTON, D.C., Oct. 27, 1999 – The Internet Healthcare Coalition, a non-profit organization dedicated to quality healthcare information on the Internet, today announced it will host a high-level working summit in Washington D.C., on February 1-2, 2000, to forge a set of ethical principles for health-related Web sites. The announcement was made in response to growing demand from users of the medical Internet for reliable healthcare information, increasing media attention to this issue and a number of calls to action by industry leaders.

In the most recent example, George Lundberg, M.D., editor-in-chief of *Medscape*, said in a keynote address to the Coalition's annual meeting on Wednesday, October 13, 1999: "The essence of professionalism is self-governance. Just as the International Committee of Medical Journal Editors, founded in 1978, has set the standards for how medical journal authors and editors should behave, the leaders of the e-health information enterprise should now set common standards for ethical behavior." Lundberg, former editor-in-chief of the *Journal of the American Medical Association*, then threw down the following challenge: "I call upon the Internet Healthcare Coalition to now set international standards that can become commonly accepted."

The Coalition's "e-Health Ethics Summit" will examine topics such as advertising practices, sponsored content, privacy and disclaimers. The summit aims to develop principles through the consensus of industry, academic, government and patient leaders, and will post its work on the Internet to allow for greater participation of the Internet health community.

"Ethical conduct does not happen by accident," said Dr. Helga Rippen, chair of the Internet Healthcare Coalition. "It requires leadership, vision, and integrity. The IHC is ideally suited to lead the debate as one of the most diverse and experienced independent, international organizations involved in quality information online."

Invitees will include all the key stakeholders in the healthcare Internet space, including academic specialists in the fields of ethics and public health policy, commercial developers and providers of Internet-based health-related education and information services, medical libraries and database providers, medical specialty and special-interest societies, and manufacturers of regulated drugs and medical devices.

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“We feel extremely confident that before the end of 2000, we will have a set of principles that can help guide the health Internet community,” said Rippen.

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**THE INTERNET HEALTHCARE COALITION HOSTS  
“QUALITY OF HEALTH INFORMATION ON THE NET ‘99”  
IN NEW YORK CITY**

***Non-Partisan Conference of Healthcare Thought Leaders Convene  
to Improve Online Information***

NEW YORK, Oct. 13, 1999 – The Internet Healthcare Coalition hosts its second annual conference, “Quality Health Information on the Net ‘99,” today at the Grand Hyatt Hotel in New York City. Entitled “Health Care Professionals and Consumers Online: Fixing the Broken Link,” the conference will address the current state of Internet health information, online patient/physician communication and the future of Internet healthcare.

Coalition conference keynote speakers include George D. Lundberg, MD, editor in chief of Medscape and former editor of the *Journal of the American Medical Association*, and Tom Ferguson, M.D., editor and publisher of *The Ferguson Report*. Panel and roundtable discussions will address the quality of healthcare information online, including targeted topics such as medical record privacy and security, pharmaceutical company marketing and online fraud.

“This conference provides a unique forum for the healthcare community and patients alike to debate the pros and cons of the current Internet healthcare environment,” commented John Mack, president of the Internet Healthcare Coalition.

The conference brings together key thought leaders from the healthcare industry, including online healthcare representatives, professional and patient organizations and government representatives to exchange views about healthcare and the Internet. The goal of the meeting is to guide the future of physician-patient use of the Internet to improve the quality of care.

“Limiting consumer access to medical, health and drug information on the Internet is not practical,” Mack said. “Instead, we’re aiming to educate both consumers and health professionals to recognize and demand high-quality resources and information on the Internet, and therefore, improve health care.”

(more)

The conference, sponsored in part by Intel, follows Intel's Internet Health Day on October 12. Together, the two conferences are providing attendees with a comprehensive review of Internet healthcare and ways to utilize and improve the quality of these resources.

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More information regarding the Internet Healthcare Coalition can be found on the Web at <http://www.ihealthcoalition.org>.

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[www.ihealthcoalition.org](http://www.ihealthcoalition.org)

## **Internet Healthcare Coalition's Annual Conference**

**Quality Healthcare Information on the 'Net 2000:**  
*Establishing Trust, Ensuring Privacy, Enabling E-Commerce*  
October 3-4, 2000 • Las Vegas Hilton • Las Vegas, NV

### **HOLD THE DATE!**

The annual Fall meeting of the Internet Healthcare Coalition will be held concurrently with **Windows on Healthcare 2000**. This 2-day meeting will include:

- Speaker presentations
- Panel discussions
- Networking opportunities, and
- Exhibitors

Noted keynote speakers and other experts in the field of ethics, privacy, and e-commerce in the online health area will be featured. Multiple conference tracks will focus on the Coalition's eHealth Code of Ethics, health fraud on the Internet, privacy and confidentiality, health information literacy, and other topics.

### **Who Should Attend**

Approximately 600 to 800 people are expected to attend this third annual conference of the Internet Healthcare Coalition. Attendees are expected from online health and e-commerce web sites, pharmaceutical companies, hospitals, patient organizations and advocates, libraries, publishers, healthcare systems and plans, and government organizations.

### **Sponsors and Exhibitors**

Sponsorship opportunities include networking receptions, luncheons, registration materials, conference book, etc. Also, there will be a special "**e-Health.com Showcase**" with pods set up with convenient high-speed Internet connections and standard signage. This showcase will be open to 2500 **Windows on Healthcare 2000** attendees as well as IHC conference attendees. For more information, call John Mack at 215-504-4164.

### **About the Internet Healthcare Coalition**

The Internet Healthcare Coalition is an international, non-partisan and non-profit educational organization, dedicated to the development and promotion of ethical principles relevant to the fast expanding area of online, interactive healthcare communications.

### **For More Information**

Visit our web site at [www.ihealthcoalition.org](http://www.ihealthcoalition.org) or call John Mack at 215-504-4164 (FAX: 215-504-5739) or email [ihc-president@ihealthcoalition.org](mailto:ihc-president@ihealthcoalition.org).



## **The Internet Healthcare Coalition Backgrounder**

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As individuals take a larger role in managing their own healthcare, more consumers are independently seeking out health information via the Internet. Health professionals are also turning to the Internet to keep informed and interact with their patients. Given the vast amount of healthcare data available on the Internet, the Internet Healthcare Coalition was created to promote quality health resources online and to ensure that consumers and professionals are able to find reliable, trustworthy health information online.

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The Coalition consults with various government agencies, including the World Health Organization, the Food and Drug Administration and the Federal Trade Commission on broader-based efforts to promote credible healthcare information and combat health fraud online. In addition to acting as a consultant, the Coalition has taken the initiative to gather parties with a vested interest in an open forum to discuss online healthcare resources.

The Coalition holds an annual conference in October for key thought leaders in the healthcare industry and government representatives to exchange their thoughts and opinions about the problems associated with and solutions to healthcare and the Internet. In October 1999, responding to calls from within the Internet health community, the Coalition launched its ongoing "eHealth Ethics Initiative" to provide a forum for the development of a universal set of ethical principles for health-related Web sites. The Coalition can be found at [www.ihealthcoalition.org](http://www.ihealthcoalition.org).

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www.ihealthcoalition.org

## Internet Healthcare Coalition Membership Application Form

Use the form below to apply for membership. One-year membership is \$50. Organizations may be members, but each individual representing the organization as a member must fill out an application and pay \$50. Members who supply their e-mail addresses will be subscribed to the **IHC-NEWS** e-mail list through which they will receive information about Coalition events. At most, 2 or 3 e-mail messages - including our newsletter - are posted to this list each month.

If paying by check, make sure check is drawn against a U.S. bank and is payable to **Internet Healthcare Coalition**. Mail the completed form and check to **Pentz Group, 57 Macintosh Road, Levittown, PA 19056, USA**. If you are paying by MasterCard or VISA, you may FAX the completed form to **215-943-0369** or send by mail to the above address.

The Internet Healthcare Coalition is a tax-exempt organization and your donation (or membership fee) may be tax-deductible. Our EIN number is 23 292 80 85.

Name: \_\_\_\_\_  
First Name Last Name

Title: \_\_\_\_\_

Company/Organization: \_\_\_\_\_

Street Address: \_\_\_\_\_

City: \_\_\_\_\_

State/Province: \_\_\_\_\_

Country: \_\_\_\_\_ Postal Code: \_\_\_\_\_

\_\_\_\_\_  
Phone (include area code)

\_\_\_\_\_  
FAX (include area code)

E-mail Address: \_\_\_\_\_

\_\_\_\_\_  
CHECK HERE IF YOU DO NOT WANT YOUR NAME AND ADDRESS GIVEN TO SPONSORS WHO MAY SEND YOU PROMOTIONAL MATERIAL.

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\_\_\_\_\_  
Check enclosed for \$50 payable to Internet Healthcare Coalition drawn against U.S. bank.

If you prefer to pay by credit card (MasterCard or VISA), please provide the following information:

Amount \$ \_\_\_\_\_

\_\_\_\_\_  
MasterCard    \_\_\_\_\_ VISA

Card # \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Name on card: \_\_\_\_\_

Signature: \_\_\_\_\_



## Finding Quality Health Information on the Internet

### —Tips For Health Consumers—

According to a recent Harris Poll, more than 70 million people logged on to the Internet in search of healthcare information in 1999. This number is expected to grow significantly as more people gain access to the Internet.

With more than 20,000 Web sites dedicated to nearly every conceivable health subject, you must ask how reliable is the information? Since 1997, the Internet Healthcare Coalition has been working to provide clear guidance for evaluating online sources of health information – from product- or disease-related sites developed by regulated manufacturers, to peer-reviewed electronic publications, to patient support and discussion groups. The Coalition's goal is to develop well-informed Internet healthcare consumers, professionals, educators, marketers and media.

The Internet Healthcare Coalition offers the following tips in evaluating the reliability of online health information and advice:

1. Choosing an online health information resource is like choosing your doctor. You wouldn't go to just any doctor, and you may get opinions from several doctors. Therefore, you shouldn't rely on just any one Internet site for all your health needs. A good rule of thumb is to find a Web site that has a person, institution or organization in which you already have confidence. If possible, you should seek information from several sources and not rely on a single source of information.
2. Trust what you see or read on the Internet only if you can validate the source of the information. Authors and contributors should always be identified, along with their affiliations and financial interests, if any, in the content. Phone numbers, e-mail addresses or other contact information should also be provided.
3. Question Web sites that credit themselves as the sole source of information on a topic, as well as sites that disrespect other sources of knowledge.
4. Don't be fooled by a comprehensive list of links. Any Web site can link to another and this in no way implies endorsement from the either site.
5. Find out if the site is professionally managed and reviewed by an editorial board of experts to ensure that the material is both credible and reliable. Sources used to create the content should be clearly referenced and acknowledged.
6. Medical knowledge is continually evolving. Make sure that all clinical content includes the date of publication or modification.

7. Any and all sponsorship, advertising, underwriting, commercial funding arrangements or potential conflicts should be clearly stated and separated from the editorial content. A good question to ask is: Does the author or authors have anything to gain from proposing one particular point of view over another?
8. Avoid any online physician who proposes to diagnose or treat you without a proper physical examination and consultation regarding your medical history.
9. Read the Web site's privacy statement and make certain that any personal medical or other information you supply will be kept absolutely confidential.
10. Most importantly, use your common sense! Shop around, always get more than one opinion, be suspicious of miracle cures, and always read the fine print.

***Internet Healthcare Coalition***

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