Good morning, Mr. Chairman, and members of the committee. I am Lisa Robin, Vice President of Leadership, Government Relations and Policy of the Federation of State Medical Boards of the United States. The Federation is a non-profit organization comprised of 70 medical licensing and disciplinary boards of the United States and its territories. As such, the Federation is positioned as a leader in medical regulation and an authoritative source of research, policy development, education, and information. The Federation’s primary mission is to improve the quality, safety, and integrity of health care by promoting high standards for physician licensure and practice and assisting state medical boards in protecting the public. As a collective voice for state medical boards, the Federation monitors state and federal legislative initiatives, works collaboratively with federal and state regulatory agencies, and offers legislative assistance to and on behalf of our member medical boards.

II. Model Guidelines and Key Concerns

The Internet has had a profound impact on society, including the practice of medicine and pharmacy, and offers opportunities for improving the delivery of health care. The appropriate application of this technology can enhance medical care by facilitating communication with physicians and other health care providers, refilling prescriptions, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information and clarifying medical advice. However, the practice of medicine, including prescribing and dispensing medications, via the Internet has created complex regulatory challenges for state medical boards in protecting the public.

The Federation of State Medical Boards has been actively involved as a national leader on the use of telecommunications and the Internet in the practice of medicine for a number of years. In 1996, the Federation published A Model Act to Regulate the Practice of Medicine Across State Lines. In 2000, it published guidelines for Internet prescribing.
In 2002, it published *Model Guidelines for the Appropriate Use of the Internet in Medical Practice*, one of the first national standards established for Internet medical practice.

Those guidelines, which the Federation recommends be adopted by state medical boards, emphasize the key interest of the Federation with respect to Internet pharmacies and the use of the Internet in the practice of medicine: *An appropriate relationship between the patient and the physician must exist before a prescription is written and medication dispensed.* Failure to have an appropriate physician-patient relationship poses serious health risks including: (1) adverse drug reactions and/or interactions, (2) misdiagnosis or delay in diagnosis, (3) failure to identify complicating conditions, and (4) misuse, abuse and diversion of prescription medications, including controlled substances.

III. National Clearinghouse on Internet Prescribing

In addition to issuing the model guidelines, the Federation has aggressively sought to identify Internet pharmacies that are dispensing drugs on the basis of prescriptions written by health care providers whose relationship with the patient does not appear to meet minimal standards. In September 2000, the Federation established the National Clearinghouse on Internet Prescribing, to collect and disseminate information on “rogue” Internet sites offering prescribing and dispensing services for prescription drugs to consumers.

The Clearinghouse is uniquely qualified to coordinate information between regulatory and enforcement entities because of its formal relationship with all state medical boards in the U.S. and its territories and its well established lines of communication with state and federal regulatory agencies, including the Department of Justice, the Drug Enforcement Agency, the Food and Drug Administration, and the Federal Trade Commission, as well as the National Association of Boards of Pharmacists, the National Association of Drug Diversion Investigators, and the National Association of Attorneys General, representatives of the pharmaceutical industry, and the media.

To date, approximately 14 physicians have been the subjects of disciplinary sanctions based on Clearinghouse supplied information. The Clearinghouse has supplied information for more than 150 cases on the federal level and more than 300 cases on the state level. Additionally, information regarding Internet prescribing has been shared with the Medical Council of New Zealand and the Ministry of Health in Germany.

IV. State Regulation

The Federation strongly supports state-based regulation of the practice of medicine. With regard to Internet prescribing, state medical boards have the authority to discipline licensed physicians prescribing and dispensing medications inappropriately. Thirty-nine (39) boards have already taken actions against licensees, twenty-six (26) states have adopted rules/policies, and fourteen (14) states have introduced legislation to clarify this authority. In addition, state medical boards are communicating among themselves
regarding physicians licensed in more than one state. These cooperative efforts have been effective in closing several Internet sites and causing a number of physicians to cease their affiliation with questionable operations.

V. Federal Legislation – Internet Pharmacy Consumer Protection Act

The Federation has also supported the development of federal legislation to protect patients ordering prescriptions over the Internet. H.R. 3880, the Internet Pharmacy Consumer Protection Act, and its companion bill, S.2464, which are currently before Congress, would provide significant protection for consumers who use the Internet to obtain pharmaceuticals.

H.R. 3880 addresses three issues crucial to the protection of patients ordering prescriptions over the Internet. First, patients should know with whom they are dealing. The bill requires an Internet pharmacy to disclose the name and location of the pharmacy that is dispensing the drug as well as the name and licensing information of the physician providing the medical consultation on which the prescription is based. If a physician wrote a prescription on the basis of an online questionnaire without having any preexisting relationship with the patient, then almost without exception, a state would find that such physician had violated practice standards. Therefore, disclosure will not only be beneficial to patients but will allow state medical boards to identify individuals against whom they can take disciplinary action.

Second, state attorneys general are not able to enjoin the operations of an Internet pharmacy that affect citizens in their particular states if that pharmacy is operated out of another state. Many of our member boards believe that a number of Internet sites that dispense drugs in an inappropriate manner could be shut down if the attorneys general had nationwide injunctive powers as well as the ability to pursue other civil remedies including damages, restitution or other compensation across state lines. The bill authorizes those injunctive powers.

Third, while state medical boards have the authority to discipline physicians who are prescribing and dispensing drugs over the Internet inappropriately, the boards cannot take action against operators of Internet sites that dispense drugs. While state medical boards believe that the law and regulations governing the physicians in their state are clear as to what constitutes an appropriate physician-patient relationship for purposes of writing a prescription, some courts and prosecutors believed that certain state laws and regulations were ambiguous in this regard and thus failed to pursue certain legal actions. H.R. 3880 addresses this ambiguity with language which strikes a reasonable balance in requiring and defining an appropriate physician-patient relationship for the narrow purpose of regulating Internet pharmacies, while recognizing the exclusive role of state medical boards in defining that relationship under other circumstances.

VI. Model Guidelines on Physician-Patient Electronic Communication
In its Model Guidelines for the Appropriate Use of the Internet in Medical Practice, the Federation addresses physician use of electronic communications and the Internet in the delivery of patient care. Portions of the guidelines are excerpted below: Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings. Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care. A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise.

Patient-physician electronic mail should be maintained with written policies and procedures addressing (1) privacy, (2) health-care personnel who will process messages, (3) hours of operation, (4) types of transactions that will be permitted electronically, (5) required patient information to be included in the communication, (6) archival and retrieval, and (7) quality oversight mechanisms.

Sufficient security measures must be in place and documented to assure confidentiality and integrity of patient-identifiable information. All patient-related electronic communications, including patient-physician e-mail, prescriptions, lab results, evaluations and consultations should be stored and filed in the patient’s medical record.

Turnaround time should be established for patient-physician e-mail. E-mail systems should be configured to include an automatic reply to acknowledge message delivery and that messages have been read. Patients should be encouraged to confirm that they have received and read messages.

VII. Conclusion

In conclusion, the Internet offers tremendous opportunities for improving the delivery of health care. However, it is the position of the Federation that use of the Internet in providing medical services, including prescribing and dispensing medications, should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship. Thank you for the opportunity to testify today. I will be glad to answer any questions.