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ISSUE BRIEF

Physician Connectivity: Electronic Prescribing

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A discussion and demonstration featuring

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Physician Connectivity

Physician connectivity—the electronic linking of physicians with online resources such as clinical databases and sophisticated formulary systems—is allowing growing numbers of physicians to prescribe online via a handheld computer complete with formulary information as well as patient data and drug information. Advocates of this technology point out that it will yield fewer medication errors as well as increased formulary compliance. Others, however, are not as enthusiastic, citing general concerns about online prescribing and purchasing.

On-line pharmacies are not only reshaping the way pharmaceuticals are prescribed, dispensed, and distributed, but are also having a profound effect on the parties involved: patients, doctors, pharmacists, bricks-and-mortar drugstores, pharmacy benefit managers, and entrepreneurs. As is the case in all sectors of the digital economy, prescribing in cyberspace poses challenging policy questions. As regulators tread gingerly, balancing First Amendment rights with consumer protection and weighing ethical and safety issues against patient empowerment and convenience, questions of jurisdiction and responsibility have become entangled, resulting in regulatory limbo.

Many different types of prescriptions are written, representing several distinctions which need to be individually assessed in determining appropriate regulatory policy. The American Medical Association (AMA) articulated these in its June 23, 1999, resolution opposing Internet prescribing. As reported in the July 19, 1999, issue of *Millin's Health Fraud Monitor*, background materials prepared for the AMA's House of Delegates carefully distinguished between

> legitimate telemedicine as opposed to mail order pharmacy with a little electronic form perused by a physician to give it legitimacy. There also were distinctions for physicians ordering refills for patients and physicians taking action over the Internet when the physicians know the patients and have their medical records available when prescribing. Simply transmitting prescriptions to pharmacies via the Internet was also distinguished.[1]

Not surprisingly, Wall Street has also taken an interest in these online companies, and their relationship to pharmaceutical prices, company margins, pharmaceutical benefit trends, and managed care profitability.

> A new player has emerged to challenge the dominant position enjoyed by the community-based pharmacy.

> Online .com drug stores are healthcare destinations for commerce and content. . . . The market is still sorting out how to value these companies. For example, companies like Drugstore.com trade at 398 times trailing revenue, while a real estate–based Walgreen trades at 1.4 times revenue. It is clear that, in the long term, these virtual companies will be valued upon their contractual relationships. It is also clear that without *front-end electronic connectivity to the prescribing physician* (emphasis added), the .com pharmacies cannot deliver their promised increased efficiencies to the marketplace.[2]

This Forum session will focus on physician connectivity within the broader milieu of online prescribing. Specifically, discussions will highlight the use of information technology in managing pharmacy risk. To show how the actual process works, one of the speakers will demonstrate the use of electronic handheld wireless technology. The audience will also learn how physician connectivity is being used in the military. In addition, speakers will address issues of e-commerce as well as its intended and unintended consequences and its effect on various stakeholders as traditional relationships are redefined.

PRESCRIBING ONLINE

"Physicians should never again write a prescription. Given the explosion of scientific information and

advances in computer technology, prescribing medications on a blank piece of paper will soon seem as antiquated as ordering tinctures of botanicals in Latin."[3]

Gordon Schiff and Donald Rucker used the above quote to open an April 1998 article in the *Journal of the American Medical Association* extolling the virtues of computerized prescribing. The authors wrote about the positive impact computerized prescribing could have on

- Drug selection.

- Patient role in pharmacotherapy risk-benefit decision making.

- Screening for interactions (drug-drug, drug-laboratory, drug-disease).

- Linkages between laboratory and pharmacy.

- Dosing calculations and scheduling.

- Coordination between team members, particularly concerning patient education.

- Monitoring and documenting adverse effects.

- Postmarketing surveillance of therapy outcomes.

The authors conceded, however, that "development of this tool has been impeded by a number of conceptual, implementation, and policy barriers." The almost two years since their article was published have seen great advances in technology and the use of the Internet. Computerized prescribing, where the physician enters orders into pharmacy computers is evolving into today's more ergonomically acceptable handheld wireless electronic prescription pad.

While some experts are concerned about the potential marketing and commercial exploitation of online prescribing, advocates cheer its potential to improve the quality of health care, decrease costs, manage risk better, and increase efficiency.

Improving Quality and Enhancing Efficiency

The Institute of Medicine's (IOM's) Committee on Quality of Health Care in America released its report on medical errors and patient safety on November 29, 1999. The report, which emphasized the widespread nature of medical errors, including medication errors and adverse drug reactions, stated that "having physicians enter and transmit medication orders online (computerized physician order entry) is a powerful method of preventing medication errors due to misrepresentation of hand-written orders." In addition to

eliminating errors stemming from illegible handwriting on paper prescriptions, physician connectivity products can supply the prescribing physician with several key pieces of patient-specific data, including the patient's history and drug interaction warnings, enabling doctors to closely monitor compliance and dosing regimens.

Advocates of physician connectivity also point to the greater efficiencies such online information can provide physicians and pharmacists. For example:

> Reliance on the telephone to conduct health care transactions is part of the inefficiency estimated to cost the industry as much as $280 billion a year. In round numbers, of the 30 billion health care transactions per year, more than 90 percent are conducted by phone, fax, or mail. At the moment, prescription writing takes up an incredible amount of time. A typical primary care doctor writes as many as 30 prescriptions daily and handles an equal number of renewals. Renewals, usually triggered by a call from the pharmacist, are particularly time-consuming. After the patient's chart is pulled, at a cost of $5 to $7, the doctor must review the prescription, consider new medical conditions that may have arisen, check the patient's formulary and drug history, and screen for potential adverse reactions. A nurse then calls the pharmacy back. Studies of doctors' offices by Merck-Medco found that nurses on average spend 80 percent of their time handling prescriptions. For doctors, the average is 30 minutes. More than half of the clinical calls to doctors concern pharmacy issues.[4]

Physician connectivity would cut the time spent on these issues dramatically. And, by enabling physicians to send prescriptions directly to the retail pharmacy or the mail order facility, physician connectivity promises to further improve quality and enhance efficiency.

Decreasing Costs and Managing Risk

The improved efficiencies to doctors and pharmacists and throughout the entire drug distribution system is likely to lead to a restructuring in the marketplace. It will be some time before all these interrelated factors "shake out" but advocates of physician connectivity predict these system efficiencies will translate into overall cost savings, along with reductions in the number of liability suits as quality improves and medication errors are reduced.

American consumers spend over $100 billion a year on prescription medications. As more practice groups go at risk, managing drug costs will be critical for their survival. At the December 1999 National Congress on the Future of Pharmaceuticals in Medical Care, David J. Gibson, M.D., president of RxPhysician.com, indicated

that practice groups making mistakes on their per-member-per-month contracted budgets are financially doomed and will fail. Also important is getting the trend line right. According to Gibson, "a group cannot manage risk without a point-of-decision-making information system," that is, physician connectivity. At its core, physician connectivity is a variation on the online prescribing theme.

REGULATORY RESPONSIBILITY HERE AND ABROAD

As traditional pharmacy "morphs" into online pharmacy, the existing regulatory apparatus is ill-equipped to deal with the complex emerging issues that cross state, national, and international boundaries. It is this issue that concerns many experts.

Domestic Sites

In the United States, non-over-the-counter medications require a prescription written by a physician. The medication must be approved by the Food and Drug Administration (FDA), the physician must be licensed by a state medical board, and the pharmacy and its pharmacists dispensing the medication must be licensed by state pharmaceutical boards. Online pharmacies have distorted this process. For example, in most states, a physician's prescribing of medications for patients outside the state where the physician is licensed (which often is the case with online pharmacies) constitutes the unlicensed practice of medicine.

In some cases, physicians employed by Internet sites (cyberdoctors) write prescriptions for "patients" they have never met or examined, a practice the American Medical Association has proclaimed unethical—although, as the AMA points out, the practice is not illegal. Not all online pharmacies employ cyberdocs or violate licensing laws, however. Sites such as CVS.com (which purchased Soma.com) and others do not use cyberdocs; rather, prescriptions are verified by patients' doctors over the telephone. Also, many sites are or are in the process of becoming licensed in every state in which they ship.

Still, the number of online pharmacy sites is growing and many are arguably on shaky ground when it comes to sound safety, ethical, and legal practices. A recent court case, *Missouri v. Stallknecht*, highlights some of these concerns. In this case, a Missouri judge issued an injunction against the online Texas-based pharmacy, Pillbox.com, owned by Bill Stallknecht, blocking the site's unlawful sale of prescription-only drugs to Missourians over the Internet. Missouri Attorney General Jeremiah "Jay" Nixon alleged that "the defendants violated state medical and merchandising laws by selling prescription drugs to consumers without a license and on the basis of information provided solely in on-line consultations."[5] Illinois and Kansas have filed similar lawsuits.

Federal Authority

States are not alone in their efforts to combat unsound practices. The Federal Trade Commission is concerned with consumer protection, rooting out fraud and misinformation as well as shouldering responsibility for the advertising of nonprescription drug products. The FDA oversees drug quality and the advertising of prescription drugs, while the Drug Enforcement Administration regulates controlled substances. The Department of Justice enforces civil consumer protection statutes as well as criminal provisions. Lastly, the U.S. Customs Service and the U.S. Postal Service enforce regulations and laws governing the importation and domestic mailing of pharmaceutical products.

As a result of congressional prodding, these agencies are in the process of sorting out which agency should take the lead responsibility for online prescribing activities. A March 25, 1999, letter on the subject of Internet pharmaceutical sales, cosigned by Reps. Henry A. Waxman (D-Calif.), John D. Dingell (D-Mich.), Ron Klink (D-Pa.), and Sherrod Brown (D-Ohio), posed several questions to the FDA as Commerce Committee Democrats pushed to clarify which agency should take the lead. The following were the six questions asked of the FDA:

- What agency or department (at either the state or federal level) does FDA believe is the primary regulator of Internet pharmacies? For this question, please also identify and describe the roles of the other state/federal agencies that may make up this structure.

- What specific activities or functions does FDA believe it is responsible for with regard to regulating Internet pharmacies? Please describe both the precise activities now conducted by FDA, and the number of full-time equivalents (FTEs) dedicated to all identified efforts. Does FDA believe it has enough resources to conduct the activities it presently feels are under its jurisdiction in this regard? If not, what additional resources does FDA require?

- Does FDA believe that existing laws and regulations, or the present state/federal regulatory structure adequately regulate online pharmacy operations? If not, what are the discrepancies, and what changes, if any, does FDA believe must be made?

- Please describe FDA's knowledge regarding the differences between existing online pharmacies. For example, some reports suggest that most online pharmacies only fill prescriptions. Other reports, however, have suggested that some actually provide for a doctor consultation (for example, a quick questionnaire is submitted over the Internet, it is reviewed, and then the prescription is approved and sent directly to the patient without a doctor ever seeing the patient). How prevalent is this latter operation? Do any trends appear in comparing one form of online pharmacy with another?

- What is FDA's understanding of how these firms deal with issues such as medical records, privacy/protection, the selling of controlled substances, or drug interactions? How serious are these issues and what shortcomings, if any, do online pharmacies have with regard to these issues? Does FDA have any knowledge of how online pharmacies prevent unqualified persons from receiving prescriptions? Are online pharmacies more susceptible to fraud or deception? If so, please explain how.

- Finally, what quality issues does FDA believe relate to the methods used to ship online pharmaceutical products, and does FDA believe it has jurisdiction in this area?

The FDA responded to the questions of Waxman and his colleagues with a letter dated May 7, 1999, and signed by Melinda K. Plaisier, interim associate commissioner for legislative affairs, with copies sent to Reps. Thomas J. Bliley Jr. (R-Va.), Michael Bilirakis (R-Fla.), and Fred Upton (R-Mich.). (The FDA's Web site, at http://www.fda.gov, addresses many of the issues raised in Waxman's letter.)

Foreign Sites

A June 18, 1999, *FDA Week* article, "House Panel Asks Feds to Clarify Roles on Regulating Internet Rx," reported:

> While the committee as a whole is looking into the matter, congressional sources say a rift is developing between Democrats and Republicans because the Republicans are more protective of the states' jurisdiction over pharmacies. But Democrats stress that the problems posed by foreign sites are beyond the states' ability to regulate on their own and need federal intervention.

While all indications point to the eventual monitoring of domestic drug Web sites for safe, ethical, and legal practices, non-U.S. sites pose a monumental problem from a regulatory and enforcement perspective. Robert Pear reported in a January 9, 2000, *New York Times* article that "the number of packages with prescription drugs seized by the U.S. Customs Service totaled 9,725 in 1999, 4.5 times as many as in 1998." Experts acknowledge that this is only the tip of the iceberg. In addition to violating import laws, many of the products seized have been found to have been misbranded, non-FDA approved, and of substandard quality. Successfully remedying the safety, ethical and legal challenges will require the cooperation of a wide range of authorities, organizations, and regulatory agencies, as well as the pharmaceutical and pharmacy industries themselves.

But the road ahead will not be smooth. Pear makes the point in his January 9 article that

> regulation of offshore Internet sites is tricky for the Clinton administration because Vice President Al Gore and other Democrats continually berate drug companies for charging higher prices in the United States than in other countries, and one of the main reasons consumers buy online from foreign pharmacies is to get lower prices.

Others, however, take issue with the claim that prices of pharmaceutical products purchased online are lower and point to embarrassment and convenience as the motivating forces for online purchasing:

> Although many sites advertise lower prices to consumers than otherwise available, Bloom and colleagues found that this was not the case. On average, prices for Viagra and Propecia were about 10 percent more expensive when they were obtained from a local Web site than from a local pharmacy. Of course, consumers may be willing to pay more for the convenience of an online pharmacy.[6]

Nevertheless, the Clinton administration has moved ahead with a plan to crack down on Internet pharmacy irregularities by having the FDA require Web sites to certify that they are in compliance with existing state laws and to display a seal. The White House proposal calls for $10 million for FDA to hire more personnel to regulate both domestic and foreign sites that prescribe and dispense drugs online.

In addition to the Clinton proposal, similar measures are sprouting up in the private sector. In an effort to assist consumers with determining "reputable" sites (that is, sites that have licensed pharmacists), the National Association of Boards of Pharmacy (NABP) has established a voluntary certification program called VIPPS—Verified Internet Pharmacy Practice Sites. Receiving a VIPPS seal of approval requires on-site inspection and compliance with 17 criteria, including

documentation of licensure compliance in all jurisdictions where the site conducts business. In a recent development, the FDA is considering working with the NABP to oversee pharmaceutical Web site inspections. (Details, such as the retention of FDA oversight authority and federal access to information, are still under discussion.) In a similar vein, the Federation of State Medical Boards is working with the AMA to develop a model practice act that would delineate the minimum steps necessary to generate a valid prescription, such as taking a history, conducting a physical, and providing a follow-up contact.

THE FORUM SESSION

A number of policy questions arise as experts grapple with the complexities of online prescribing and physician connectivity. Among them are the following:

- How will the traditional roles of pharmacist, physician, and patient evolve as a result of online prescribing and physician connectivity?

- What impact will online prescribing and physician connectivity have on future pharmacy benefit design?

- What role, if any, will online prescribing and physician connectivity play in research (that is, clinical trial data gathering)?

- Who will have access to patient data?

- As physician connectivity takes hold, what effect will it have on rebates? On drug prices?

- How will physician connectivity affect market share of various drug products?

- Who bears the costs associated with physician connectivity? Who realizes the savings (that is, from improved physician compliance with formularies)?

- Are prescription drugs really less expensive when purchased over the Internet, given shipping charges and, in some cases, the lack of acceptance of prescription drug insurance plans?

- How will the pharmaceutical distribution process change as a digital infrastructure is incorporated into the health care system?

- What, if any, is the future of group purchasing?

- What, if anything, can be done to protect consumers against illegal offshore sites selling and distributing prescription drugs in the United States?

- Who or what entity would be liable when someone is injured as a result of receiving an incorrect or impure online prescription or suffers some other related injury?

- What are the minimum requirements for clinical incorporation of a computer system?

This Forum session will begin with an overview of e-commerce and an update on Internet pharmacies by **Jean Paul Gagnon, Ph.D.,** director of health policy for Aventis Pharmaceuticals (the new life sciences company resulting from the merger of Hoechst Marion Roussel and Rhone-Poulenc Rorer). **David J. Gibson, M.D.,** president of RxPhysician.com, will discuss the use of information technology to manage pharmacy risk. Dr. Gibson will provide a demonstration of the cutting-edge technology being piloted in many physician practices today. **Helene Levens-Lipton, Ph.D.,** a professor at the Schools of Pharmacy and Medicine at the University of California at San Francisco, will address the issue of patient-provider relationships, examining the intended and unintended consequences of online prescribing. Physician connectivity is not a new phenomenon in the military. **Harold M. Koenig, M.D.,** a retired surgeon general of the navy, will highlight the lessons learned regarding the use of online prescribing and physician connectivity in military medicine. Wrapping up the session will be comments from a representative of the pharmacy industry.

ENDNOTES

1. "AMA Opposes Internet Prescribing, As Do AGs in Kansas and Missouri," *Millin's Health Fraud Monitor,* July 19, 1999, 5.

2. David J. Gibson, "Innovation in Pharmaceutical Distribution: Wholesale, Retail, Mail Order and Internet," paper presented at the National Congress on the Future of Pharmaceuticals in Medical Care, December 8-10, 1999.

3. Gordon D. Schiff and Donald Rucker, "Computerized Prescribing: Building the Electronic Infrastructure for Better Medication Usage," *Journal of the American Medical Association*, 279, no. 13 (April 1, 1998), 1024.

4. Michael Menduno, "apothecary.now," *Hospitals and Health Networks*, July 1999, 35-36.

5. "Cyberpharmacies Zapped by State Regs—Legal Update," *Business and Health,* December 1999, 12.

6. Katrina Armstrong and Bernard S. Bloom, "Sale of Prescription Drugs over the Internet," *LDI Issue Brief,* 5, no. 3 (November/December 1999).