

**Congress of the United States**  
**Washington, DC 20515**

November 26, 2001

The Honorable Tommy G. Thompson  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

Dear Secretary Thompson:

We are writing to urge you to take action to prevent inappropriate sales of Cipro and other antibiotics over the Internet. Recently, web sites have sprung up that offer Cipro and other antibiotics for anthrax infection to an alarmed public without a doctor's prescription. Antibiotic sales by these businesses can cost as much as ten times more than the government pays and lead to unnecessary adverse reactions and antibiotic resistance.

The Food and Drug Administration (FDA) has moved to stop web sites from selling foreign drugs in the United States.<sup>1</sup> However, the agency has not taken a clear position on sites that offer domestic antibiotics illegitimately.

Many state boards of medicine and pharmacy, working with state attorneys general, have tried to take action against suspect web sites and participating physicians and pharmacists.<sup>2</sup> Unfortunately, state laws often are vague and can require that prosecutors revisit the question of whether prescribing drugs over the Internet is appropriate in each case. Another problem is that states are wary of starting an investigation of a web site that may lead to doctors and pharmacists in another state's jurisdiction.

Now, after several years in which many state pharmacy organizations expressed concerns about Federal involvement in regulating internet drug sales, states are now turning to FDA for leadership. On October 25, 2001, Dale L. Austin, Interim Chief Executive Officer of the Federation of State Medical Boards, and Carmen A. Catizone, Executive Director of the National

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<sup>1</sup>*FDA Issues Cyber-Letters to Web Sites Selling Unapproved Foreign Ciprofloxacin*, FDA Talk Paper (Nov. 1, 2001).

<sup>2</sup>See, e.g., *Officials Warn Those Ordering Prescription Drugs Online*, Florida Times-Union (Feb. 13, 2001).

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Association of Boards of Pharmacy, jointly wrote you to request urgent assistance to curtail “an immediate and significant threat to the health and security of the United States.”<sup>3</sup> According to these leaders, who represent the boards that accredit physicians and pharmacists across the country, illegal internet sales of antibiotics undermine the public health.

First of all, the web sites “clearly fail to meet an acceptable standard of patient care.”<sup>4</sup> In some cases, the sites may mail out Cipro without any prescription at all. In others, physicians who have never met, interviewed, or examined purchasers may churn out dozens of prescriptions a day. Such lax rules essentially guarantee that some patients will suffer needless adverse reactions because allergies or complicating medical conditions will not be identified. Moreover, should someone start taking Cipro for actual anthrax symptoms, the lack of a doctor’s exam might prevent him or her from receiving more intensive and potentially life-saving treatment.

Also, the indiscriminate use of antibiotics made possible by these web sites can lead to antibiotic resistance. Because Cipro is in a class of medications already used clinically for drug-resistant infections, increases in Cipro resistance could jeopardize public health. The leaders of the licensing organizations wrote you:

[T]he illegitimate and illegal distribution of medications by Internet sites substituting medical questionnaires and cyberspace consultations in lieu of a bona fide and direct patient-prescriber relationship could further endanger the health and safety of all Americans through the development of resistant strains of anthrax and other biological terrorist agents.<sup>5</sup>

Similarly, the Centers for Disease Control and Prevention (CDC) has advised that, “using antibiotics when they are not needed can lead to the development of drug-resistant forms of bacteria.”<sup>6</sup>

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<sup>3</sup>Letter from Dale L. Austin and Carmen A. Catizone to Secretary Tommy G. Thompson (Oct. 25, 2001).

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<sup>5</sup>Letter from Dale L. Austin and Carmen A. Catizone to Secretary Tommy G. Thompson (Oct. 25, 2001).

<sup>6</sup>*Children and Anthrax: A Fact Sheet for Parents*, CDC (Nov. 7, 2001).

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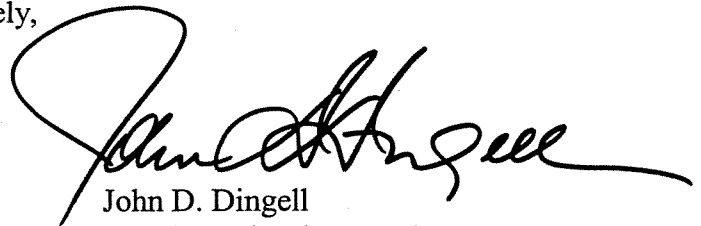
FDA's authority to take needed action to curtail these sales is found in the Food, Drug, and Cosmetic Act (FDCA). As Janet Woodcock, director of the Center for Drug Evaluation and Research has testified, "Under [FDCA], FDA has the legal authority to take action against . . . the sale or dispensing of a prescription drug without a valid prescription."<sup>7</sup> FDA should quickly clarify that a valid prescription excludes internet sales on the basis of a questionnaire without any real doctor-patient relationship. State agencies, which have the authority to enforce federal law in this area, could then work to shut down these dangerous businesses. Given the public health consequences of unnecessary antibiotic use, FDA has good cause to act expeditiously.

Without decisive action soon at the Federal level, the leaders of the Federation of State Medical Boards and National Association of Boards of Pharmacy warned, "The damage inflicted on the American public and medication distribution system [may be] so severe that it will have long lasting consequences."<sup>8</sup> We urge you to take prompt action to address this important issue.

Sincerely,



Henry A. Waxman  
Ranking Minority Member  
Committee on Government Reform



John D. Dingell  
Ranking Minority Member  
Committee on Energy and Commerce

cc: The Honorable Dan Burton, Chairman  
Committee on Government Reform

The Honorable W. J. "Billy" Tauzin, Chairman  
Committee on Energy and Commerce

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<sup>7</sup>Janet Woodcock, *Testimony before the Subcommittee on Oversight and Investigations, Committee on Commerce, U.S. House of Representatives* (July 30, 1999).

<sup>8</sup>Letter from Dale L. Austin and Carmen A. Catizone to Secretary Tommy G. Thompson (October 25, 2001).