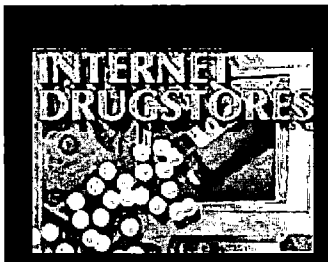
Online NewsHour

NewsHour with Jim Lehrer Transcript

ONLINE FOCUS

CONTROLLING INTERNET Rx

December 28, 1999



After this background report, Susan Dentzer discusses buying prescription drugs over the Internet and the proposed White House regulations with Gwen Ifill.

The Health Unit is a partnership with the Henry J. Kaiser Family Foundation.

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NewsHour Links

Focus: Internet Rx

Dec. 28, 1999: Update: Internet Rx Regulations

Dec. 27, 1999: Taxing E-Commerce

Nov. 17, 1999: Background on the InternetRx issue

Small Pharmacies: In on the Act.

Nov. 17, 1999: RealAudio extended excerpts with: Ron Klink, Carla Stovall and Eric Thom.

Browse the NewsHour's coverage of health.

PHARMACIST: Just a half a teaspoon, twice daily.

SUSAN DENTZER: Getting a prescription filled at your local pharmacy usually looks a lot like this...

PHARMACIST: And who's the doctor?

SUSAN DENTZER: ...but increasingly, it's apt to look more like this.

SUSAN DENTZER: First there was e-mail, then budding e-commerce -- and now, there's e-pharmacy. Just this year alone, dozens of major pharmacy sites have sprung up on the Internet, with names like Drugstore.com, Soma.com and PlanetRx. They're trying to prove to consumers that getting a prescription filled on-line is more convenient than waiting in line at the local drugstore.

Outside Links

White House

Federal Drug Administration

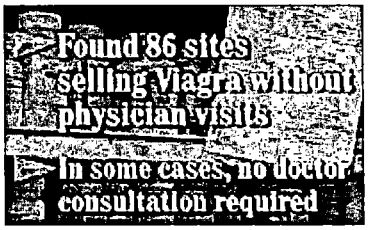
FDA testimony on e-pharmacies

National Association of Boards of Pharmacy

A new type of pharmacy

TOM PIGGOTT: I saw it as an exciting opportunity to create essentially a new type of pharmacy.

SUSAN DENTZER: Just under a year ago, thirty-one year-old Tom Piggott founded a Seattle-based Internet pharmacy site. Now owned by drugstore giant CVS, it's called CVS.com. The site affords consumers Internet access to the same products they can get in CVs pharmacies across the U.S.. Consumers simply call up the site, answer questions about their medical history, then enter their prescription and physician's name and phone number.



TOM PIGGOTT: After it is submitted, the pharmacists at CVS.com will verify the information that you have entered, contact your physician if it is a new prescription.

CVS.COM OPERATOR: Let me follow up with the doctor and I need to find out who called this prescription in today.

SUSAN DENTZER: At the customer's behest, the prescription order is then routed to one of two places -- either the customer's local CVs retail pharmacy, or to CVS.com's own state-of-the-art dispensing facility in Ohio. The order then can be packed and shipped from the warehouse directly to the customer. E-pharmacy is still just a fraction of overall pharmacy sales. But it's expected to grab an increasing share of the drugstore business. That's, in part, because the convenience of ordering medications over the Net can be a real plus for consumers. Dr. Jane Henney is commissioner of the federal Food and Drug Administration.

DR. JANE HENNEY: Ordering over the Internet for your refill or your prescription drug that you need I think is very beneficial, particularly for people who have difficulty getting to the drugstore, people who are disabled, who are home-bound, who are elderly, who live in rural communities.

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DR. JANE HENNEY, Food and Drug Administration

Filling false prescriptions

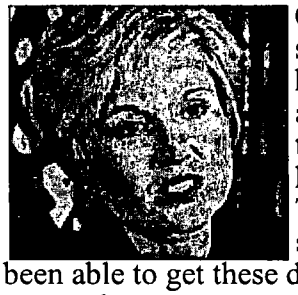
SUSAN DENTZER: But for all the benefits, Henney and other experts say there's also a serious, and even dangerous, downside. Buying already-prescribed drugs over the Internet doesn't appear to pose any safety problems. But health officials are concerned that drugs are also being prescribed over the Internet. Sometimes, legitimate physicians affiliated with the sites are doing the prescribing -- but sometimes not. A recent report published in the New England Journal of Medicine highlighted the problem. Researchers at the University of Pennsylvania Medical School examined 4000 Internet sites. They found 86 that were selling the well-known impotence drug Viagra without requiring a visit to a physician or, in many instances, even a perfunctory on-line medical evaluation. Congressman Ron Klink, a Pennsylvania Democrat, is alarmed.

We've talked to people where family pets, or people who had died 20 years ago were given prescriptions for various drugs. And they didn't lie about the information. When it said, 'What's your status?' well, family pet. Sex, neutered. And yet they were able to get Viagra.

REP. RON KLINK, (D-PA)

REP. RON KLINK: We've talked to people where family pets, or people who had died 20 years ago were given prescriptions for various drugs. And they didn't lie about the information. When it said, 'What's your status?', well, family pet. Sex, neutered. And yet they were able to get Viagra.

SUSAN DENTZER: Phony prescriptions for pets are one thing, says Klink, but the risks to humans are obviously far greater -- and growing. One reason is a rising number of foreign drug-selling sites, many of which operate out of places like Southeast Asia or Mexico. The sites are selling drugs illegally into the US, violating a number of federal and state laws in the process. State officials are also concerned. In Kansas, the attorney general, Carla Stovall, is cracking down on sites that are selling prescription drugs unlawfully to Kansas citizens -- almost always from outside the state's borders. So far, her office has sued six sites for violating state consumer-protection laws and licensing requirements. One of those sites, called Confimed.com, had sold Viagra without a prescription to the 16-year-old son of an employee in Stovall's office.



CARLA STOVALL: What he said was that he wasn't able to have sex and that was sufficient apparently because, even though his age was 16, they sent him the drug and he received it. There is no reason to think that someone younger couldn't have been able to get these drugs too. I think it is a tremendous concern.

SUSAN DENTZER: Last June, Stovall sued Confimed, including its founder, a physician, Dr. Howard Levine. Levine would not appear on camera, so we interviewed Confimed's senior vice president, Eric Thom; at the website's small office in Seattle; he told us Confimed had seriously erred in selling Viagra to the 16 year-old.

ERIC THOM: It was a mistake. We acknowledge that mistake and we respect Kansas's jurisdiction.

SUSAN DENTZER: So what was it, the doctor just didn't notice that he was sixteen?

ERIC THOM: He didn't see it. He literally didn't see it. He made a mistake.

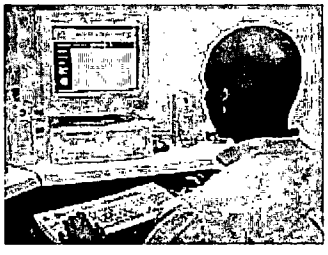
Ensuring your health

SUSAN DENTZER: Thom says Confimed has since taken steps to make sure such errors don't recur. And in reality, he says, about one in five patients who try to get Viagra from Confimed are turned down. Stovall was still concerned.

CARLA STOVALL: We don't let people today write their own prescription and walk into a pharmacy on Main Street and get that prescription filled. You have to go through your physician. And because we have Internet and it makes things more accessible doesn't mean that those rules should change, and that I should be able to write my own prescription, basically, for a drug that I want to have that my own physician won't give to me.

SUSAN DENTZER: FDA Commissioner Henney agrees.

DR. JANE HENNEY: You're putting your own health, which is really fragile, at risk and that's the issue here.



SUSAN DENTZER: Earlier this year, federal agencies formed a working group to look further into illegal activity by Internet sites and to try to enforce all applicable state and federal laws. Now, the Clinton administration is proposing to ratchet up federal regulation over the sites. It proposes to increase the FDA's investigative powers and drastically raise the financial penalties for making on-line drug sales

without valid prescriptions.

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CONTROLLING INTERNET Rx

December 28, 1999

The White House proposes tighter controls over Internet sites that sell prescription drugs. Following a background report, Susan Dentzer discusses the proposed regulations with Gwen Ifill.

The Health Unit is a partnership with the Henry J. Kaiser Family Foundation.

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National Association of Boards of Pharmacy

GWEN IFILL: For more on today's proposal, I'm joined now by Susan Dentzer. So, Susan, it was only inevitable that the federal government was going to have to get involved in this. Exactly what would the announcement that was made today accomplish?

Protecting the consumer

SUSAN DENTZER: In effect, Gwen, what the President is proposing to do is two things-- arm consumers to police the Internet better themselves and to raise the level of armament in the hands of the federal government. As far as consumers go, in effect, what would happen is that the federal government would create a new seal of approval that would be on every web site that was complying with existing state and federal statutes in the realm of drug prescriptions so that as a consumer you would be able to know that you were dealing with a site that was legitimate. In effect what they would do is build on an existing form of seal of approval that's been put together by a group of state pharmacy licensing boards called the VIPPS, the Verified Internet Practice Pharmacy Site. Essentially what the government will do is simply take over that seal of approval and in effect this site would become the federal - in effect the VIPPS seal of approval would be the federal seal of approval. So consumers would know it was a legitimate site. Then in addition to that, the government is proposing that the FDA, the Food and Drug Administration, be granted an additional $10 million in fiscal 2001 to step up its own policing efforts and in particular to acquire new personnel, up to 100 individuals, who would be charged with overseeing illegal sites. That's up from about 10 at present. So it's a dramatic increase. And in addition they'd also be able to access some new

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SUSAN DENTZER, NewsHour Health Correspondent

Pharmacy | addition they'd also be able to access some new technology. Finally, of course, is what we discussed earlier in the piece which is new financial penalties. At this point, according to the federal statute, at best if a site is violating federal law when it comes to drug prescribing, the most the government can do is stock it with a $1,000 penalty. This would increase the penalties to half a million dollars per violation.

Tougher penalties

GWEN IFILL: But in 50 states there are rules which are being violated everyday now. How would a federal seal of approval make a difference?

SUSAN DENTZER: It would essentially just put consumers on notice that if they were not dealing... Or dealing with a site that did not have the seal of approval, the likelihood was very high that they were dealing with a site that is not in compliance with the law. The states do have these existing licensing requirements, as you point out. The problem is now that as you have Internet commerce taking place between and among states, it's very hard for the state authorities to police that and to enforce that as in the case of in our piece when we had violations of consumers obtaining drugs in Kansas. Usually those sites were not in Kansas, it was difficult for the state attorney general to crack down.

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SUSAN DENTZER, NewsHour Health Correspondent

GWEN IFILL: You were talking about the horror stories, the 16-year-old who were able to get Viagra, other people who were able to get prescriptions sight unseen basically by a doctor -- how exactly would this stop that or is this just a way of putting people on notice?

SUSAN DENTZER: It's a way of putting people on notice and essentially beefing up existing ability to enforce the law. If a site knows that the most it can incur now is maybe a $5,000 penalty from the state, maybe at best $1,000 penalty from the federal government, there's obvious incentive given the market out there to keep doing what you're doing illegally. If, in fact, the penalties are going to be much larger, in fact, consumers are going to be put on notice that they ought not to be dealing with you unless you have that seal of approval. It will be a lot tougher for the illegal sites to operate.

GWEN IFILL: What's to stop an illegal site from simply moving its operations offshore to the Bahamas or someplace and continuing to sell and not be subject to U.S. law?

SUSAN DENTZER: Nothing is stopping the sites from doing that and, indeed, the FDA is well aware that that could be one unintended consequence of increasing regulation here in the U.S.. The fact remains, though, that there are plenty of sites operating offshore as it is now and one of the great problems with the regulations that are being proposed now that they would do virtually nothing to deal with the growing problem of offshore prescribing. In fact, the FDA is now looking at other means to deal with that which may involve more screening of shipments of illegal drugs into the US -- it may involve more partnering with foreign regulatory agencies to try to prosecute sites that are prescribing illegally, but that's a big problem and it is, indeed, one that might grow bigger as a consequence of this but it's going to be big no matter what happens.

Regulating e-pharmacies

GWEN IFILL: Is there any concern in the Internet industry that this constitutes an unwarranted federal intrusion into free marketing?

SUSAN DENTZER: There hasn't been much comment to that effect yet mainly because people recognize that the federal government has, for more than 50 years, had a very strong role in drug policy, in pharmaceutical drug policy. We decided again more than 50 years ago that drugs had a lot of benefits to them but they also had a lot of risks, that they needed to be certified by the federal government, that there needed to be safety and effectiveness testing before they were brought out and, in fact, that once drugs were prescribed they had to be prescribed by physicians who were licensed in individual states and also sold through licensed pharmacies in individual states. What people are saying now is if these rogue sites continue to operate, you might as well throw that entire federal and state regulatory apparatus in the junk pile because if it can't prevent drugs from being sold illegally and even if some cases unapproved drugs from being sold illegally to people, again, we might not as well have had this marvelous regulatory system that has been created over the last five decades that has worked fairly well in the past.

The issue here is sites that are not playing by the existing rules, they're not playing by the rules that we've already got in place and the Internet gives them an ability to do that in a much more convenient-- for them-- way and that's really what all of this initiative is targeted at.

SUSAN DENTZER, NewsHour Health Correspondent

GWEN IFILL: You just touched on three things that make e-pharmacy shopping so much different from other kinds of Internet shopping and that's that there's a confidentiality concern, a licensing concern, and a liability concern for people who are actually selling these drugs. Is this a slippery slope that we've entered on to, this sort of being able to get prescription medication online?

SUSAN DENTZER: I think it's a boon when it's done illegally as Commissioner Henney pointed out in our taped piece for people who are disabled, who live in rural areas, to be able to go on line, get a legitimate prescription filled and delivered to your door in the space of a day is a fantastic benefit and is probably going to increase overall health of many Americans. The issue here is sites that are not playing by the existing rules, they're not playing by the rules that we've already got in place and the Internet gives them an ability to do that in a much more convenient-- for them-- way and that's really what all of this initiative is targeted at.

GWEN IFILL: And the Internet makes it much more difficult to enforce in any kind of realistic way as well.

SUSAN DENTZER: Absolutely right.

GWEN IFILL: Susan Dentzer, thank you very much.

SUSAN DENTZER: Thanks, Gwen.

December 20, 1999

FDA Opens Advice Web Page

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

Filed at 3:33 p.m. EST

By The Associated Press

WASHINGTON (AP) -- Want to buy prescription drugs or other medical products over the Internet? The government opened a consumer-advice Web page Monday to help patients ensure they're buying from legitimate stores instead of dangerous quacks.

The new Food and Drug Administration service also includes instructions for Americans to report any suspicious Internet sites, and urges that they especially alert FDA quickly if they suffer a serious side effect or injury from a product bought online.

Those anonymous consumer reports will trigger investigations of problem online drugstores and, if necessary, warnings to the public -- part of what FDA pharmacist Tom McGinnis called a ``much more aggressive'' effort to police Internet medicine.

The Internet ``has opened up many new options for consumers to purchase products more conveniently,'' said Dr. Jane Henney, FDA commissioner. ``However, the Internet has also provided unscrupulous individuals with immense new opportunities'' to harm vulnerable patients.

It can be difficult to tell the difference between legitimate online drugstores and those that sell illegal products -- some outright dangerous, others a waste of money, the FDA warned.

For example, the FDA recently uncovered illegal at-home AIDS tests sold over the Internet that didn't work, meaning people who used the tests may think they are healthy when they are not.

The FDA also warns about a 53-year-old Chicago man who died after taking the impotence pill Viagra he ordered over the Internet, instead of seeing a doctor who could have advised him that he had heart disease risks that make taking Viagra dangerous.

And just two weeks ago, the FDA warned consumers not to be misled by Internet claims that shark cartilage cures cancer.

The FDA isn't the only agency cracking down. States are beginning to shut down online pharmacies that illegally sell drugs without a valid prescription or properly licensed professionals. Michigan just last week ordered 10 online pharmacies to stop selling or face legal action.

But it is so easy to create new medical Web sites that policing them is difficult, so the FDA site -- http://www.fda.gov -- advises consumers to protect themselves. Among the warnings:

--If you purchase medicine from an illegal Web site, you could get a dangerous counterfeit or contaminated product.

--The National Association of Boards of Pharmacy is certifying legitimate online pharmacies. Before ordering from one, check www.nabp.net to see if its Web site is listed.

--Don't buy from sites that sell prescription drugs without a real prescription from a physician you know. Health experts say those online questionnaires some Web sites use as ``virtual prescriptions'' don't count, and can let patients get drugs too risky for their condition. Legitimate online pharmacies will get a verified prescription from your doctor.

--Don't buy from sites that sell drugs not approved by FDA, that have no access to a registered pharmacist to answer questions about your medicine, or do not provide a U.S. address and phone number to contact if there's a problem.

--Don't buy from foreign Web sites because it usually is illegal for them to import their drugs, the risks may be greater from countries with less oversight of drug manufacturing, and ``there is very little the U.S. government can do if you get ripped off.''

--Beware of sites that advertise a new cure for serious diseases like cancer or AIDS, a quick cure-all for a wide range of ailments, or personal stories claiming amazing results.

December 29, 1999

Web Pharmacies Mull Regulations

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

Filed at 6:37 a.m. EST

By The Associated Press

NEW YORK (AP) -- Online drug companies are withholding a formal endorsement of President Clinton's plan to regulate their high-flying industry, but concede they could gain from the strategy.

Clinton on Tuesday proposed giving the Food and Drug Administration new powers to review and certify drug-dispensing Web sites. Violators would face half-million dollar fines for each infraction.

The proposal would mark the first federal foray to regulate businesses on the Internet, said Washington, D.C., health care attorney Keith Korenchuck.

``This is extremely significant'' he said, because it is a tacit acknowledgment by the White House that current state-by-state rules can't keep up with the rapidly growing cyberspace health industry.

While executives said they are worried that Clinton's proposal might duplicate state regulations, they said it could curb rogue Web sites which illegally sell drugs without a prescription. Such sites, in addition to posing a health risk to consumers, take away business from established Internet drugstores.

``Clearly anything that gives greater credence and trust to legitimate online pharmacies is for the good,'' said Dr. Matthew Naythons, a vice president for South San Francisco, Calif.-based PlanetRx.com.

PlanetRx.com is one of four major online drugstores that have started selling over the Internet in the last two years. The others are Merck-Medco Managed Care, Drugstore.com and CVS.com. These companies all require patients to have a prescription before they fill any orders.

Though the industry is projected to have about $44 million in sales this year, revenues are expected to reach nearly $1 billion by 2003, according to Jupiter Communications. That still would be less than 1 percent of the total retail prescription drug market.

The established players, which are affiliated with major brick-and-mortar drug stores, pharmaceutical chains or pharmacy-benefits managers, have had to compete with hundreds of small operators that often fill prescriptions without requiring a patient to see a doctor.

Men too embarrassed to ask a doctor to prescribe Viagra to treat their impotence or Propecia to treat their hair loss have flocked to these rogue sites.

Critics worry no one is making sure consumers are protected.

The regulation of drug sales is largely the province of state government, which license doctors and pharmacists. But critics say state efforts have lagged, in part because Internet companies operate in multiple states.

The federal plan would require online pharmacies to get FDA certification that they are legally operating or face sanctions; impose fines of $500,000 for each time a site sold a prescription drug to someone without a valid prescription and give the FDA new power to subpoena the records of online sites while investigating these operators.

The White House also plans a public education campaign to advise consumers how to order drugs safely over the Internet.

Analysts stress even if the proposal is approved by Congress, it may not be able to curb Web sites based outside the United States.

``We are always worried that rogue sites would get in the way of consumers getting the benefits of online pharmacies," said Peter Neupert, chief executive officer of Bellevue, Wash.-based Drugstore.com. He said he wants to see more details of Clinton's plan, particularly how it would give added powers to subpoena information from the businesses.

But he said he's all for a federal education campaign to teach consumers how to buy drugs online.

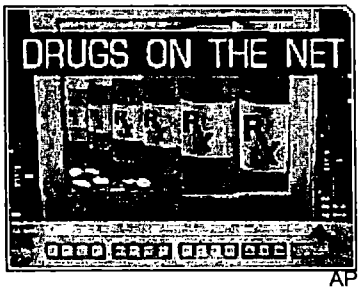
Such an effort might explain how some companies, including the four largest online drug stores, are certified by the National Association of Boards of Pharmacy, he said. That group reviews online drug stores to make sure companies confirm the receipt of a prescription and make sure the correct drug is dispensed, among other duties.

In the end, such a voluntary effort might suit the industry better than new federal requirements, Neupert said.

HEALTH CBS

Crackdown On Web Drugstores

WASHINGTON
Tuesday, December 28,1999 - 08:53 PM ET



AP

(CBS) Online drugstores offer convenience and, sometimes, lower prices than the corner pharmacy. But some also offer prescription drugs without prescriptions. That had the White House calling Tuesday for new Food and Drug Administration regulations.

It should be said from the start, reports **CBS News' Elizabeth Kaledin**, that the majority of Internet drugstore companies *are* legitimate. They are places where people like Hugh Snyder can get his heart medication without leaving the house.

"They called the doctor," says Snyder. **"They got the prescription and three days later I got the medicine."**

But in the unregulated world of e-commerce, the FDA has encountered a bitter pill: drugstores distributing prescription drugs without doctors or pharmacists on board.

"We do see an increasing number of sites that are now available that are selling either unapproved drugs or prescription drugs without a prescription," says the FDA's Dr. Jane Henney.

So for the first time, the federal government is cracking down, threatening investigations and harsh fines of up to a half-million dollars. Online drugstores will also require an FDA seal of approval so consumers will know which sites are safe.

In a written statement, President Clinton said there are rogue pharmacies on the Web that ignore federal and state laws by selling medications illegally.

"Rogue operators pose a threat to the health of

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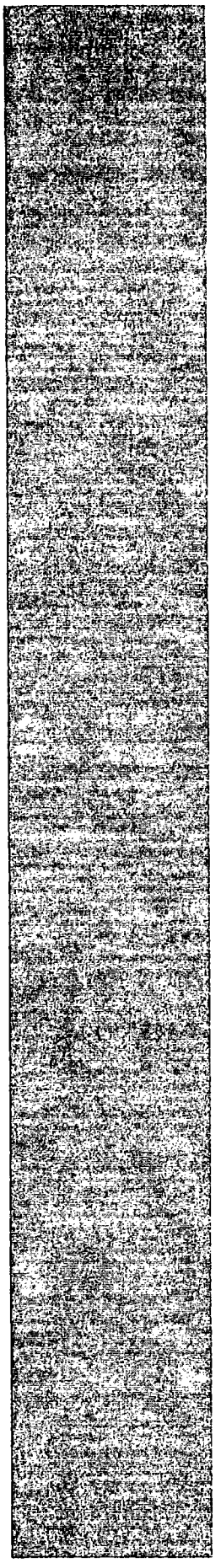
Video
CBS News Correspondent Elizabeth Kaledin Reports

the transcript from last night is not up yet — we isolate quotes from the News story that ran last night.

Americans," Mr. Clinton said. **"Today we are unveiling a proposal that sends a signal that we have zero tolerance for prescription drug Internet sites that ignore federal and state laws and harm patient safety and health."**



The rise in rogue drug sites has been fueled by a need for privacy: among the biggest sellers are Viagra for impotence, Propetia for baldness and a variety of drugs for obesity.

"Consumers are either embarrassed to use a traditional system or find a traditional system inconvenient,"says Carmen Catizone, executive director of the National Association of Boards of Pharmacies.

Pharmacy organizations have been trying to police themselves, but say it's getting harder and harder without any regulation.

"If we can't stop these activities, pretty much the door will be open for anyone to order from anywhere in the world any medication they want."

So far, 12 Web sites have been shut down and 200 are being investigated. For now, the safest sites for getting prescriptions filled may still be the local drugstore.
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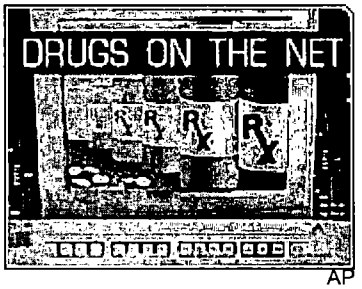

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the transcript from last night is not up yet — here are quotes from the News story that ran last night.

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The rise in rogue drug sites has been fueled by a need for privacy: among the biggest sellers are Viagra for impotence, Propetia for baldness and a variety of drugs for obesity.

"Consumers are either embarrassed to use a traditional system or find a traditional system inconvenient,"says Carmen Catizone, executive director of the National Association of Boards of Pharmacies.

Pharmacy organizations have been trying to police themselves, but say it's getting harder and harder without any regulation.

"If we can't stop these activities, pretty much the door will be open for anyone to order from anywhere in the world any medication they want."

So far, 12 Web sites have been shut down and 200 are being investigated. For now, the safest sites for getting prescriptions filled may still be the local drugstore.
and, sometimes, lower prices than the corner pharmacy. But some also offer prescription drugs without prescriptions. That had the White House calling Tuesday for new Food and Drug Administration regulations.

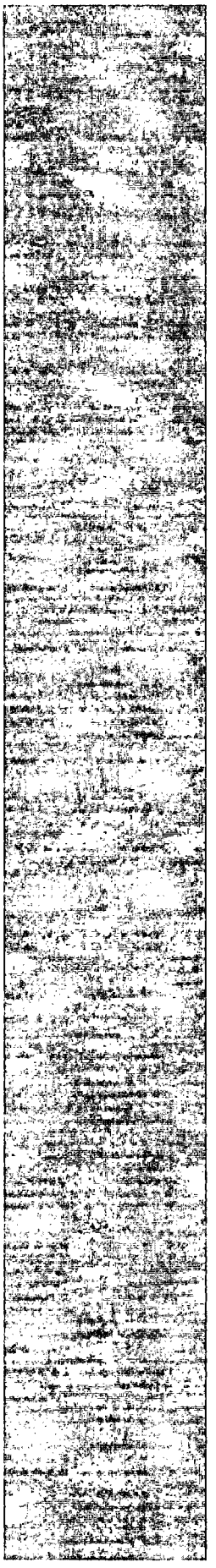
It should be said from the start, reports **CBS News' Elizabeth Kaledin**, that the majority of Internet drugstore companies *are* legitimate. They are places where people like Hugh Snyder can get his heart medication without leaving the house.

"They called the doctor," says Snyder. **"They got the prescription and three days later I got the medicine."**

But in the unregulated world of e-commerce, the FDA has encountered a bitter pill: drugstores distributing prescription drugs without doctors or pharmacists on board.

"We do see an increasing number of sites that are now available that are selling either unapproved drugs or prescription drugs without a prescription," says the FDA's Dr. Jane Henney.

So for the first time, the federal government is



cracking down, threatening investigations and harsh fines of up to a half-million dollars. Online drugstores will also require an FDA seal of approval so consumers will know which sites are safe.

In a written statement, President Clinton said there are rogue pharmacies on the Web that ignore federal and state laws by selling medications illegally.

"Rogue operators pose a threat to the health of Americans," Mr. Clinton said. **"Today we are unveiling a proposal that sends a signal that we have zero tolerance for prescription drug Internet sites that ignore federal and state laws and harm patient safety and health."**

The rise in rogue drug sites has been fueled by a need for privacy: among the biggest sellers are Viagra for impotence, Propetia for baldness and a variety of drugs for obesity.

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LEVEL 1 - 19 OF 42 STORIES

SHOW: ALL THINGS CONSIDERED (9:00 PM ET)

NPR

December 28, 1999, Tuesday

LENGTH: 651 words

HEADLINE: PRESIDENT CLINTON ANNOUNCES HE WILL ASK CONGRESS FOR NEW MONEY AND POWERS SO THE FDA CAN REVIEW AND CERTIFY PHARMACY WEB SITES

ANCHORS: NOAH ADAMS; ROBERT SIEGEL

REPORTERS: JOANNE SILBERNER

BODY:

NOAH ADAMS, host:

It's NPR's ALL THINGS CONSIDERED. I'm Noah Adams.

ROBERT SIEGEL, host:

And I'm Robert Siegel.

Today President Clinton proposed new regulations to control the sale of **drugs** over the Internet. The online **prescription drug** business has mushroomed over the last year, in part because of the sale of Viagra. The president is asking that the Food and **Drug** Administration be allowed to regulate Internet **drug** sales. NPR's Joanne Silberner reports.

JOANNE SILBERNER reporting:

Dr. Matthew Naythons is vice president of PlanetRx.com, one of the biggest Internet **prescription drug** providers. He says the service is easy to use.

Dr. MATTHEW NAYTHONS (Vice President, PlanetRx.com): The process would be, you just come back from your doctor's office, you've got a **prescription** for, let's say, Lipitor for your blood pressure. You go, you log onto PlanetRx, you open up an account...

SILBERNER: ...you fill in what other **drugs** you're taking, put down your medical history and what the doctor wrote on the **prescription** pad. If you can't

read it, it doesn't matter. Naythons says PlanetRx calls the doctor to check on every **prescription** they fill.

Dr. NAYTHONS: Once we verify your **prescription,** and we check your **prescription** against other medicines that you are taking--'cause you've told us. We run a **drug**-interaction database--we'll send it to you by mail or by overnight FedEx, if that's what you want.

SILBERNER: Food and **Drug** Administration Commissioner Jane Henney says there are potential benefits to ordering **drugs** over the Internet.

Commissioner JANE HENNEY (Food and **Drug** Administration): Access, convenience and privacy, I think, are the big three in terms of what the Internet brings to consumers and patients.

SILBERNER: That can mean a lot to someone who's homebound or in a rural area. Henney says it has the potential to save consumers money, but it's too early to tell. On PlanetRx.com today, 30 days of anti-allergy **drug** Claritin was 30 percent lower than the price cited at a chain store in Washington. 'But something is missing from the Internet,' Commissioner Henney says.

Comm. HENNEY: There has been a safety net for patients and consumers with respect to medical products that has worked well in this country for many years and it's built around the tradition of having a physician and a pharmacist involved as particularly **prescription drugs** are given.

SILBERNER: Those physicians and pharmacies are subject to state law. So are Internet sites, but Henney says prosecution is difficult because they operate across state lines. The administration hopes that federal oversight would make it easier to stop Internet sites that have no licensed pharmacist, or pay doctors to write **prescription drugs** for patients they haven't seen, or those that sell **drugs** not approved by the FDA. So the president is proposing setting up an Internet FDA approval process and creating civil penalties of up to $ 500,000 for selling **prescription drugs** when there's no **prescription.**

'In the meantime, there are things consumers can look for today,' says Carmen Catizone. He heads the National Association of Boards of Pharmacy, the state level regulators.

Mr. CARMEN CATIZONE (National Association of Boards of Pharmacy): Any site that promises or advertises you being able to obtain a **prescription drug** without a **prescription,** or without seeing a doctor, are definitely sites to avoid.

SILBERNER: The National Association of Boards of Pharmacy has a voluntary authorization process. A hundred companies have applied. Requirements include privacy guarantees, the presence of a licensed pharmacist. Only five companies, including PlanetRx, have been approved. As for federal oversight of what's been a state responsibility, 'PlanetRx,' says Matthew Naythons, 'is waiting to see the details.'

Dr. NAYTHONS: Another level of regulation, federal regulation, is probably unnecessary, but we want to do what's best for the consumer. And if it turns out that what's best for the consumer is for federal regulation, we'll wind up supporting it.

SILBERNER: The president says he'll submit his plan with the budget next year. Congress has been leery about expanding the power of the FDA, but there have been hearings on the issue and politicians are clearly interested. Joanne Silberner, NPR News, Washington.

LANGUAGE: English
LOAD-DATE: December 29, 1999

LEVEL 1 - 8 OF 42 STORIES

CNN

CNN
(1)

SHOW: CNN TODAY 13:00 pm ET

December 28, 1999; Tuesday 1:18 pm Eastern Time

Transcript # 99122803V13

TYPE: LIVE REPORT

SECTION: News; Domestic

LENGTH: 386 words

HEADLINE: President Clinton Proposes New Regulations to Protect Online Pharmaceuticals Buyers

BYLINE: Natalie Allen, Chris Black

HIGHLIGHT:
It is possible to buy just about anything on the Internet, including **prescription drugs,** but those sales are not always above- board. So, President Clinton is proposing some new federal regulations.

BODY:
THIS IS A RUSH TRANSCRIPT. THIS COPY MAY NOT BE IN ITS FINAL FORM AND MAY BE UPDATED.

NATALIE ALLEN, CNN ANCHOR: You can buy just about anything on the Internet, including **prescription drugs,** but those sales are not always above-board. So, President Clinton is proposing some new federal regulations.

CNN White House correspondent Chris Black joins us from the White House with the latest on the president's plan -- Chris.

CHRIS BLACK, CNN WHITE HOUSE CORRESPONDENT: Natalie, the Clinton administration is taking steps, today, to protect consumer who purchase consumer **drugs** and other pharmaceutical products online on the Internet.

The growth in this area has been explosive. Last January, there were 26 online Web sites that sold pharmaceutical products. Just seven months later, there were more than 400.

Officials say this service is a boon to consumers who are homebound or who live in remote rural areas, but, they say, it is largely unregulated and that

some fly-by-night operations are taking advantage of consumers by selling them contaminated **drugs**, illegal **drugs and drugs** without proper medical **prescription**.

The -- this proposal would give the Food and **Drug** Administration the authority to impose civil penalties of up to half a million dollars for each illegal **drug** sale. It would expand the FDA's subpoena authority to speed up the investigative process, and the Federal Government also plans to launch a public education campaign just after the first of the year to warn the public of the perils of buying **drugs** online.

Prescription drugs typically can only be legally purchased with a valid **prescription** and after a physical examination by a doctor. But officials say it's very easy to bypass these safeguards on the Internet, so the federal government wants to set up a system that will give consumers a way to determine which Web sites are legitimate with a sort of FDA seal of approval. They're also looking for $10 million from the Congress in order to set up a rapid-response team and to improve the FDA's computer technology so they can better police these fraudulent sites.

Chris Black, CNN, reporting live from the White House.

LANGUAGE: ENGLISH

LOAD-DATE: December 28, 1999

LEVEL 1 - 16 OF 42 STORIES

CNNFN

SHOW: TAKE IT PERSONALLY 17:30:00 pm ET

December 28, 1999; Tuesday 5:45 pm Eastern Time

Transcript # 99122804FN-108

CNN 2

TYPE: PACKAGE

SECTION: Business

LENGTH: 309 words

HEADLINE: Regulating Rx Purchases on Web, CNNfn

BYLINE: Valerie Morris, Dan Ronan

BODY:

THIS IS A RUSH TRANSCRIPT. THIS COPY MAY NOT BE IN ITS FINAL FORM AND MAY BE UPDATED.

VALERIE MORRIS, CNNfn ANCHOR, TAKE IT PERSONALLY: And stay with the general theme of computers and **drugs,** the Clinton Administration is seeking authority for the Food and **Drug** Administration to regulate cyber pharmacies. Dan Ronan has more.

(BEGIN VIDEOTAPE)

DAN RONAN, CNN CORRESPONDENT (voice-over): Now, buying **prescription drugs** on the Internet is as easy as pointing and clicking. The Clinton administration wants to crack down on illegal **drug** sales on the Web. It's seeking from Congress, sweeping Food and **Drug** Administration authority to regulate the industry.

Among the proposals: online pharmacies would need FDA certification; companies could face fines up to $500,000 for selling **drugs** without a **prescription;** and the FDA would have subpoena power to investigate on-line pharmacies.

BRIAN CLIFFORD, SUNAMERICA ASSET MANAGEMENT: I think the incumbents that have the resources and the capital to operate on the straight and narrow are going to be able to continue to do so. I think this probably more goes after

the mom and pops than the, quote, unquote, "rogue distributors" that are operating in an unregulated fashion at this point.

RONAN: The Clinton administration says the regulations are needed because of several cases where medical devices or **drugs** were sold without a **prescription.** Meanwhile, the FDA has added a section to its Web page, www.fda.gov, so consumers can see if pharmacies are legitimate. And the National Association of Boards of Pharmacy is certifying on-line **drug** stores. Their Web site is www.nabp.net.

(END VIDEOTAPE)

LANGUAGE: ENGLISH

LOAD-DATE: December 28, 1999

LEVEL 1 - 4 OF 42 STORIES

ABC NEWS

CHRIS — could not find NBC story. ABC

possible that they did not run one!

SHOW: WORLD NEWS TONIGHT (6:30 PM ET)

December 28, 1999, Tuesday

TYPE: Newscast

LENGTH: 367 words

HEADLINE: PRESIDENT CALLS FOR ONLINE **DRUG** SITE REGULATIONS

ANCHORS: PETER JENNINGS

REPORTERS: JOHN COCHRAN

BODY:

PETER JENNINGS, anchor:

In Washington today, President Clinton announced his plan for the federal government to regulate sales of **prescription drugs** on the Internet. Congress is considering at least 70 similar regulatory bills. It's an effort to bring some sort of official order to the Internet. It won't be easy. Here's ABC's John Cochran.

JOHN COCHRAN reporting:

(VO) Buying **drugs** over the Internet is a godsend for people in rural areas where there are no drugstores, and for people everywhere who want cheaper prices, but the Food and **Drug** Administration says some online firms sell **drugs** without requiring **prescriptions,** or sell **drugs** which should not be legally available.

Dr. JANE HENNEY (FDA Commissioner): We certainly have information about young girls with anorexia nervosa being able to obtain diet **drugs.**

COCHRAN: (VO) Cases, too, where Viagra has been sold to people with heart conditions, which can be dangerous. So the crackdown proposed by President Clinton today would require online pharmacies to be investigated and certified by the FDA, and impose a fine of $ 500,000 for selling a controlled **drug** without a valid **prescription.** Congress must approve, and some members worry that regulations could stifle the growth of the Internet. Others say **drugs** are a special case.

Representative JOHN DINGELL (Democrat, Michigan): Our problem is to watch out for fast-buck art--artists, slippery--slippery individuals, rogues and rascals who are more interested in making money than in protecting somebody who has a heart condition.

COCHRAN: (VO) The Internet industry argues that regulations would simply force companies to move overseas where they could still sell **drugs** to Americans.

Mr. JEFFREY EISENACH (The Progress and Freedom Foundation): And the impact of that would be to drive all that economic energy offshore, away from the United States and into other nations.

COCHRAN: Cyberspace firms account for 40 percent of America's economic growth. The debate over whether and how much to regulate them is just beginning. Many in Congress are content to leave them alone, including those which sell **drugs**. John Cochran, ABC News, the White House.

LANGUAGE: English

LOAD-DATE: December 29, 1999

THE WALL STREET JOURNAL INTERACTIVE EDITION
FROM THE ARCHIVES

CNBC.com

December 29, 1999

FDA's Plan to Curb Drugstores On Web Is Stung by Criticism

By CHRIS ADAMS
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON -- Some pharmacy groups bristled at the Clinton administration's plans to clamp down on rogue Internet pharmacies, fearing another layer of regulation could create unnecessary hassles.

"States are already looking at these Internet sites, and they have a long history of regulating pharmacies," said Susan Winckler, a policy director for the American Pharmaceutical Association. "The FDA doesn't have that history, and it really has no experience in that area... . I don't know that the FDA jumping in and regulating will bring any benefit. It will just confuse the situation."

Drug Makers Decry Dispensing on Web but Don't Block It (Nov. 29)

Further, federal regulation of Internet pharmacies could eventually lead to similar regulation of mail-order pharmacies, which essentially provide the same services, some industry groups said. That would make getting the plan through Congress even more difficult, they said. Other industry groups, however, were reserving judgment on the plan.

The White House's proposal Tuesday seeks to address the new breed of pharmacies operating on the Internet -- many of which offer to deliver pills to patients even without valid prescriptions. While some of the sites are offshoots of major drugstore chains and others are already well-known consumer brands, a good number are fly-by-night operations based overseas and expert at evading detection.

FDA Commissioner Jane Henney says while the states have done a

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Corrections

commendable job dealing with pharmacy regulation, it hasn't been enough, and what is needed is a "federal system of credentials" for Internet pharmacies.

U.S. Food and Drug Administration
www.fda.gov

National Association Of Boards of Pharmacy
www.nabp.net

She added the explosive growth of Internet pharmacies -- and the multistate nature of their operations -- has outrun state investigators' abilities to keep up. "Enforcement has to be stronger if we are to provide people the same level of protection and safeguards that exist in the traditional pharmacy system," she said.

But the proposal could face problems from suggestions that it takes away power from the states, which have traditionally regulated pharmacies. If the new FDA approval process merely piggybacks on the relatively new -- and still voluntary -- state-certification process, "then everybody's happy," said Carmen Catizone, executive director of the National Association of Boards of Pharmacy. But if it duplicates that state role, he added, "then we have a major problem."

The size of the Internet pharmacy market is difficult to gauge. The pharmacy boards association said it has tracked down 260 online providers, many of whom are then linked to more than one Web site. Of those 260, about 85 have applied for voluntary certification from the pharmacy boards group, and five of those have been granted what is recognized as the industry's seal of approval.

Drugs on the Web

The White House/Food and Drug Administration proposal for online pharmacies would:

- Require federal government approval of online pharmacies
- Strengthen penalties for selling **prescription drugs** without a valid prescription
- Grant FDA subpoena power to conduct investigations
- Boost staff and computer resources to investigate online pharmacies
- Conduct public awareness campaigns about safe ways to buy drugs online

As for the other 175, "The fact is, there are a number of sites that are practicing illegally and need to be shut down," Mr. Catizone said.

The White House proposal would: require that online pharmacies seek FDA approval before they begin operations; strengthen the penalties for selling **prescription drugs** without a prescription; and spend $10 million in fiscal 2001 to boost the resources dedicated to ferreting out illegal Internet sites.

While online pharmacists and trade groups said they supported the administration's desire to crack down on illegal Web sites --

particularly those operating offshore -- some said the proposal seemed like too little, too late.

"Ten million dollars seems like a rather modest sum, to be frank with you," said William Zellmer, deputy executive vice president of the American Society of Health-System Pharmacists.

"I think [the illegal operators] will continue to do the things they do to avoid the law," said Peter Neupert, chief executive of drugstore.com Inc. "However, I do think it creates a bigger risk for them."

Shares in online drugstores tumbled on the prospect of increased federal oversight. At 4 p.m. in Nasdaq Stock Market trading, Drugstore.com fell $3.5625 to $32.4375, or 10%, and PlanetRx.com Inc. slipped 25 cents to $14.5625.

Write to Chris Adams at chris.adams@wsj.com

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U.S. FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER
OFFICE OF POLICY

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Transmission Record

DATE: December 21, 1999

Number of Pages Including Cover Sheet:

Message:

FDA
TALK PAPER

Food and Drug Administration
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, MD 20857

FDA Talk Papers are prepared by the Press Office to guide FDA personnel in responding with consistency and accuracy to questions from the public on subjects of current interest. Talk Papers are subject to change as more information becomes available.

T99-56
December 10, 1999

Print Media: 301-827-6242
Broadcast Media: 301-827-3434
Consumer Media: 888-INFOFDA

FDA TAKES ACTION AGAINST FIRM MARKETING UNAPPROVED DRUGS

The Food and Drug Administration today stepped up its efforts to protect the public against unproven claims for unapproved drugs by seeking a permanent injunction against the marketing of three unapproved drug products being illegally promoted as treatments for cancer and other diseases by a New Jersey corporation and its top officer.

The products, called BeneFin, SkinAnswer and MGN-3, are promoted and sold by Lane Labs-USA, Inc., in Allendale. In addition to Lane Labs-USA, Inc., the complaint names as defendant its President, Andrew J. Lane.

The government's complaint, filed by the United States Department of Justice in the United States District Court for the District of New Jersey, charges the individual defendant and his company with unlawfully promoting and marketing three products for the following diseases:

- BeneFin, which is produced from shark cartilage, as a treatment for cancer and other diseases;
- SkinAnswer, a glycoalkaloid skin cream, as a treatment for skin cancer;
- and MGN-3, a rice-bran extract, as a treatment for cancer and HIV, the virus that causes AIDS.

BeneFin is being studied as a potential cancer therapy under an Investigational New Drug application reviewed by the FDA. As such, it can be distributed for use in clinical trials. Like the other two products, however, it may not be promoted and marketed until its safety and effectiveness are demonstrated, and FDA reviews and approves the sponsor's marketing application.

Today's action against the BeneFin brand of shark cartilage does not affect brands of shark cartilage that are not intended for use in the treatment of disease and that are otherwise lawfully marketed as

dietary supplements.

FDA began warning the defendants about the illegal nature of their promotion in June, 1997. Nevertheless, the defendants have continued promoting BeneFin, SkinAnswer, and MGN-3 as remedies for cancer and other diseases through such means as books, articles, Internet web sites, and employee statements.

The governmentís request for a permanent injunction is based on the defendantsí demonstrated unwillingness to comply with the law. The government's action seeks an injunction against, among other things, the defendants' distribution of the three unapproved drugs unless the products are either approved for marketing by FDA or are distributed pursuant to an Investigational New Drug application solely for purposes of conducting a clinical trial.

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FDA HOME PAGE

For Release: November 17, 1999

FTC And FDA Warn Consumers About Ineffective and Unapproved HIV Test Kits; Announce Joint Law Enforcement Actions

Consumers were warned today by the Federal Trade Commission and the U.S. Food and Drug Administration that unapproved Human Immunodeficiency Virus (HIV) test kits can give inaccurate test results. The warning came as the agencies outlined joint law enforcement actions taken to halt the sale of ineffective and unapproved HIV test kits in the United States. The FTC also announced settlement of charges that a company that advertised on the Internet, Cyberlinx Marketing, Inc., falsely represented that its HIV home test kits accurately detected HIV.

"Cyberlinx's egregious conduct threatened the health of those consumers who relied upon the representation that the kits gave accurate results," said Jodie Bernstein, Director of the FTC's Bureau of Consumer Protection.

The FDA has taken law enforcement actions against manufacturers and distributors of unapproved HIV test kits for the illegal sale of these test kits in the United States.

Currently, there is one HIV home collection test system that is approved by the FDA and legally sold in the United States. This test, "Home Access Express HIV-1 Test System," which is manufactured by Home Access Health Corporation, allows consumers to collect a blood sample for testing in the privacy of their home. The sample is then sent to a laboratory for analysis. The results are obtained by calling a toll-free telephone number using an anonymous personal identification number.

"The approved HIV test system has been carefully reviewed by the FDA to ensure that the test system is capable of yielding accurate, dependable results," said Steven Masiello, Director of the Office of Compliance and Biologics Quality at FDA's Center for Biologics Evaluation and Research. "The consumer has no assurance of the reliability or accuracy of the test results from unapproved HIV home test kits."

The unapproved HIV test kits being marketed on the Internet are often referred to as "rapid tests," since they provide test results in the home in 15 minutes or less. These rapid tests use a simple finger prick process for home blood collection or a special sponge device for saliva collection. The sample is applied to a plastic testing device and a developing solution is added to determine if the sample is positive for antibodies to HIV. According to the FDA, these unapproved tests, which lack, among other things, medical laboratory testing and controls, may give inaccurate results.

FTC and FDA Law Enforcement Actions

Cyberlinx and its president, Jeffrey S. Stein, have settled FTC charges that their unapproved HIV home test kits gave erroneous results. The FTC alleged that Cyberlinx and Stein violated federal law when they represented on their Internet site that their "EZ MEDTEST" HIV home test kits detected HIV infection in human blood. In fact, FDA testing of Cyberlinx's HIV home test kits confirmed that the products were not reliable in detecting the presence of HIV.

Under the stipulated final order settling the charges, Cyberlinx and Stein are banned from marketing any HIV home test kits in the future and must pay back the money they received from the sale of their kits.

The complaint outlining the charges against Cyberlinx and Stein alleges that the defendants violated the FTC Act through their false representations that the products they marketed as "EZ MEDTEST HIV Type I & II home test kit" accurately detected HIV infection in humans. As part of the agencies' joint investigation, the FDA tested the "EZ MEDTEST HIV Type I & II home test kit" sold by Cyberlinx using blood serum samples known to contain antibodies to HIV (HIV-positive) and found that the test kits failed to consistently detect the presence of antibodies to HIV. On July 8, 1999, the FDA notified Cyberlinx's customers about the inaccurate test kit results. According to the FDA notification letter, the test kits were labeled "HIV 1/2 STAT-PAK Ultra Fast." (The text of this notification letter can be found at www.fda.gov/medwatch/safety/1999/ezmedt.htm)

The order imposes a lifetime ban on Cyberlinx and Stein from marketing or selling any HIV home test kit. In the event that Cyberlinx or Stein wishes to market or sell any medical device other than HIV home test kits, they are required to post a $500,000 bond, the FTC said. If Cyberlinx and Stein jointly wish to engage in such endeavors, the required bond is $1,000,000.

In addition, within 10 days after entry of the order, Cyberlinx and Stein have to transfer to the Commission the money they received from the sale of their HIV home test kits. The order also prohibits the defendants from transferring, disclosing, or selling information regarding any person who paid any money to either of them at any time prior to entry of the order in connection with the purchase of any HIV home test kit.

The Commission vote to authorize the filing of the complaint and stipulated order was 4-0. It was signed by a federal District Court judge in Las Vegas, Nevada.

NOTE: Stipulated final judgments are for settlement purposes only and do not constitute an admission by the defendant of a law violation. Stipulated final judgments have the force of law when signed by the judge.

Since 1996, the FDA has conducted several investigations of firms selling and promoting unapproved HIV test kits in the U.S. In addition to seizing HIV home-use test kits and criminally prosecuting a California businessman responsible for distributing a fraudulently marketed home-use HIV test system, the FDA also has issued 12 Warning Letters to manufacturers and distributors for the illegal sale of unapproved test kits. In the past year, for instance, the following firms were cited:

- Akers Laboratories (New Jersey - manufacturing and distributing for export "HealthTest HIV 1+2 Rapid Assay Test Kits")
- Chembio Diagnostic Systems, Inc. (New York - manufacturing and distributing "HIV 1/2 STAT-PAK Ultra Fast" test kits)
- Pan Probe Biotech, Inc. (California - manufacturing and distributing "in vitro diagnostic products")
- Sovo Tec Diagnostics, Inc. (California - distributing "HIV 1/2 STAT-PAK Ultra Fast" and "HIV 1/2 Whole Blood" test kits)

The texts of these and the other FDA Warning Letters are available on the FDA's website at: http://www.fda.gov/foi/warning.htm.

Consumers should be aware that unapproved and unreliable HIV rapid test kits may continue to be marketed on the Internet and through magazine and newspaper promotions for use in the home. "The Internet makes it easy for con artists to take advantage of consumers," said Jane Henney, M.D., Commissioner of the FDA. "Therefore, consumers need to be cautious." The FTC and FDA will continue to investigate and prosecute firms and persons involved in the sale and distribution of unapproved HIV rapid test kits.

Copies of the FTC complaint and stipulated final order in the Cyberlinx and Stein case are available from the FTC's web site at http://www.ftc.gov and also from the FTC's Consumer Response Center, Room 130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580; 877-FTC-HELP (877-382-4357); TDD for the hearing impaired 202-326-2502. To find the latest news as it is announced, call the FTC NewsPhone recording at 202-326-2710.

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(Civ.Act.#CV-S-99-1564-PMP-LRL)
(FTC File No. 992 3226)
(cyberlinx)

U.S. Food and Drug Administration

Enforcement of Existing Laws Regarding The Sale of Prescription Pharmaceuticals over the Internet

(Excerpt from July 30, 1999, statement)

FDA has established priorities for taking enforcement actions involving online sales, expanded its capability to monitor violative Internet sites through advanced technology search tools, and established a process to triage and monitor ongoing cases. Using existing resources, through this process, FDA expects to establish a higher profile enforcement presence regarding unlawful online sales.

FDA is working with other Federal agencies and State agencies to better coordinate enforcement efforts. FDA worked closely with the Federal Trade Commission (FTC) in developing the cases announced as part of Operation Cure-All and has been working with the Department of Justice (DOJ) and others regarding online sales issues.

FDA has initiated a series of meetings with state regulatory bodies and other organizations to discuss better ways to regulate online sales.

The types of unlawful conduct involving online drug sales that FDA has identified are similar to unlawful activities that occur in other sales contexts. Under the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA has the legal authority to take action against the importation, sale, or distribution of an adulterated or misbranded drug; the importation, sale, or distribution of an unapproved new drug; illegal promotion of a drug; the sale or dispensing of a prescription drug without a valid prescription; and, counterfeit drugs.

When the Internet is used for an illegal sale, FDA must establish the same elements of a case, bring the same charges, and take the same actions as it would if another medium, such as a storefront or a magazine, had been used.

FDA already has investigated and referred cases for criminal prosecution and civil enforcement actions against some online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency. FDA intends to significantly expand its enforcement activities regarding online sales. The Office of Regulatory Affairs (ORA) and the Office of Compliance in the Center for Drug Evaluation and Research (CDER) are the primary organizations within FDA with responsibility for regulating online drug sales. These offices review web sites that consumers, industry, health professionals or government personnel report as appearing violative.

Since June 1998, the Agency has taken numerous compliance actions based on violative labeling claims. In at least 27 of these cases, the violative claims had an Internet component. To date, the agency has identified over 60 cases related to suspected illegal Internet sales, with the first Internet prosecution having been undertaken in 1994. Actions included sending warning letters to firms illegally selling unapproved new drugs online and issuing Import Alerts to online sellers of illegal foreign pharmaceuticals. FDA has also contacted web site managers and asked for their voluntary cooperation in removing violative sites. Warning letters to online pharmacies based in foreign

countries are shared with the government of that country.

Additionally, CDER's Division of Drug Marketing, Advertising, and Communications has taken steps against online drug promotion that violates the FD&C Act by making unsubstantiated claims or misrepresentations of drugs, or by a lack of fair balance in describing risks and benefits. The Office of Criminal Investigations (OCI) is the entity within FDA responsible for conducting and coordinating investigations of suspected criminal violations of the FD&C Act, the Federal Anti-Tampering Act (FATA), and other statutes including applicable U.S. Criminal Code violations. OCI maintains liaison and cooperative investigative efforts with other Federal, State, Local, and international law enforcement agencies.

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(Hypertext created by clb 1999-DEC-03)

FDA
TALK PAPER

Food and Drug Administration
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, MD 20857

FDA Talk Papers are prepared by the Press Office to guide FDA personnel in responding with consistency and accuracy to questions from the public on subjects of current interest. Talk Papers are subject to change as more information becomes available.

T99-5
January 21, 1999

Print Media: 202-205-4144
Broadcast Media: 301-827-3434
Consumer Inquiries: 888-INFO-FDA

FDA WARNS ABOUT PRODUCTS CONTAINING GAMMA BUTYROLACTONE OR GBL AND ASKS COMPANIES TO ISSUE A RECALL

The Food and Drug Administration is alerting consumers not to purchase or consume products, some of which are labeled as dietary supplements, that contain gamma butyrolactone (abbreviated as GBL). FDA has also asked the companies that manufacture these products to voluntarily recall them. The agency has received reports of serious health problems -- some that are potentially life-threatening -- associated with the use of these products.

Although labeled as dietary supplements, these products are illegally marketed unapproved new drugs. Products containing GBL are marketed under various brand names including Renewtrient, Revivarant or Revivarant G, Blue Nitro or Blue Nitro Vitality, GH Revitalizer, Gamma G, and Remforce. They are promoted with claims to build muscles, improve physical performance, enhance sex, reduce stress and induce sleep.

GBL is also known by the chemical names 2(3H)-furanone dihydro; butyrolactone; gamma-butyrolactone; 4-butyrolactone; dihydro-2(3H)-furanone; 4-butanolide; 2(3H)-furanone, dihydro; tetrahydro-2-furanone; and butyrolactone gamma.

GBL related products have been associated with reports of at least 55 adverse health effects, including one death. In 19 of those cases, the consumers became unconscious or comatose and several required intubation for assisted breathing. Other reported effects included seizures, vomiting, slow breathing, and slow heart rate. There are reports of at least 5 children under 18 years of age who have been injured or who have suffered these kinds of effects.

When taken orally, GBL is converted in the body to gamma hydroxybutyrate or GHB. GHB is a very potent unapproved drug. It is currently being investigated under the supervision of doctors for the treatment of narcolepsy. Because of its serious side effects, GHB should not be taken unless in the context of these FDA approved investigations. FDA and the Justice Department have ongoing criminal enforcement actions against GHB. GBL should not be taken.

Products containing GBL are sold in liquid and powder form. They are sold via the Internet, in some health food stores, and in some gymnasiums and fitness centers.

Consumers are advised to dispose of any products of this type in their possession. If they have experienced adverse health problems from use of these products, they should promptly contact a physician. FDA requests consumers and physicians to report adverse events to FDA's MEDWATCH 1-800-332-1088.

The Trimfast Group, Inc. has agreed to recall the product Revivarant, 32 ounces of liquid in a plastic bottle, and Revivarant G, 200 grams of powder in a pill bottle. Other companies manufacturing products containing GBL are being asked by the FDA to voluntarily recall them.

FDA is considering all potential regulatory actions at its disposal if products containing GBL are not recalled. The agency will act expeditiously to protect the public health.

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FDA HOME PAGE

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TALK PAPER

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T97-26

June 17, 1997

Brad Stone: (301) 443-3285

Broadcast Media: (301) 827-3434

Consumer Hotline/Laura Alvey: (800)

FDA Warns Consumers on Dangerous Products Promoted on the Internet

FDA is warning consumers not to purchase certain unapproved products that pose significant, possibly life-threatening health risks. The products in question, which are offered for sale on the Internet, are home abortion kits and female self-sterilization kits.

The abortion kit inaccurately touts itself as a "complete kit for early pregnancy termination without surgery...scientifically proved safe and unrisky." The kit provides a combination of drugs that are not approved by FDA to terminate pregnancy. The agency conducted a health hazard assessment of this product and concluded that using the kit without a physician's supervision could cause heavy vaginal bleeding and even death. Birth defects also can result if a pregnancy is carried to term after taking these drugs.

The self sterilization kit claims to use a method similar to inserting an IUD and to have a much lower risk than that associated with surgical sterilization. The kit uses pellets of quinacrine hydrochloride, an unapproved drug, which can cause ectopic pregnancy, abnormal pregnancies, and permanent damage to a woman's reproductive organs.

FDA urges consumers not to purchase or use these or similar products promoted via Internet or any other media. The Federal Food, Drug, and Cosmetic Act prohibits the sale and promotion of unapproved medical products. The agency is continuing to investigate and monitor these products.

Consumers who have suffered an adverse event as a result of using these "kits" and health professionals who have treated such patients are asked to report the event to the agency's Medwatch adverse event and product problem hot line at 1-800-FDA-1088.

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Investigators' Reports

Internet Sales of Bogus HIV Test Kits Result in First-of-Kind Wire Fraud Conviction

by Paula Kurtzweil

For the first time in FDA history, an individual has been convicted on wire fraud charges stemming from Internet use to sell an illegal medical product. Previous wire fraud charges involving illegal medical products were based only on telephone and facsimile use.

Lawrence "Larry" Greene, of Los Banos, Calif., is serving a five-year, three-month prison term for selling unapproved HIV test kits for home use over the Internet, as well as through phone solicitations to pharmacies in California's Central Valley.

Greene, 52, sold more than 100 of the test kits in 1996 and 1997, before he was jailed by local authorities on unrelated charges. An informant provided information that enabled FDA's Office of Criminal Investigations (OCI) to collect evidence that led to Greene's November 1998 conviction in the U.S. District Court for the Eastern District of California.

In fall 1997, FDA recalled the HIV test kits, as well as about 38 illegal hepatitis A test kits Greene marketed, from 35 to 40 California drugstores that had bought Greene's products. The recall was only the second in FDA history to be conducted by the agency itself. (The first was in 1977.) Generally, manufacturers recall their products voluntarily, but Greene could not recall the kits himself because he was in prison.

HIV (human immunodeficiency virus) is the virus that causes AIDS. The only approved HIV home test kit currently marketed in the United States is the Home Access HIV-1 Test System, made by Home Access Health Corp., of Hoffman Estates, Ill.

Greene sold his unapproved HIV test kit under the names Lei-Home Access HIV Test and Personal HIV Test Kit. Like the approved home-test kit, Greene's kits required a sample of blood. But unlike the legitimate kit, which requires a drop of blood to be placed on specially treated, pre-tested paper, Greene's version directed users to place a drop of blood on an opened Band-Aid attached to a card that was then returned to Greene. Even though he didn't send the blood samples to a laboratory for testing and had no scientific or factual basis for making a decision, Greene provided users with fabricated test results. He also did not provide counseling, as the manufacturer of the approved HIV test kit is required to do when it informs users of test results.

"It's unbelievable what he did," said Susan Corrales, a consumer safety officer in FDA's Center for

Biologics Evaluation and Research. "There was no evidence that the blood samples were tested by a laboratory. His wife said he could tell whether a person was HIV negative or not by holding the sample up to a light. He was basically flipping a coin and saying yes or no."

FDA learned of Greene's illegal home-test kit in September 1997 through industry complaints to the agency's Center for Biologics Evaluation and Research, which regulates HIV home sample collection kits. The complaints alleged that an unapproved HIV home-test kit was being marketed on the Internet and in newspapers and magazines.

The center identified the kit's manufacturer as Lei-Home Access Care, a division of Jin-Greene Biotechnology Inc., of Sunnyvale, Calif. Greene was the owner of both.

Despite several visits, FDA investigators were not able to gain access to the building at the Sunnyvale address. Their knocks on the door went unanswered, even though the investigators could hear people talking inside.

About this time, an informant called FDA to express concerns about Greene's activities. The informant provided sufficient information, including sales records, to link Greene to the Internet marketing of the illegal test kits.

The district office forwarded the case to OCI, which tracked down Greene's home address in Los Banos. There, an OCI special agent interviewed Greene's wife, who mentioned that Greene had sold some of his kits to drugstores in California's Central Valley. OCI also learned that Greene was incarcerated at the local county jail.

FDA investigators visited the drugstores, many of which, according to Andrea Scott, a compliance officer in the agency's San Francisco district office, were "mom-and-pop" operations. When told about the phony HIV test kits, she said, "the pharmacists were totally snowed. They were flabbergasted and [a little bit] humiliated that they had been duped."

The pharmacists reported that they had sold several of the kits to their customers. "That's when we knew we had a recall on our hands," Scott said.

FDA investigators removed the kits from the pharmacies and posted notices in English and Spanish on the doors of the drugstores, warning consumers who may have bought kits to be retested for HIV infection. The notices also were given to representatives of high-risk AIDS groups for their dissemination.

From sales records, OCI learned that Greene also had distributed kits to about 30 Internet customers as far away as New York and Florida. FDA notified the Internet customers that the test they had purchased was not reliable and that they should seek a health professional to be retested with an approved test.

On Sept. 26, 1997, FDA issued a press release, urging pharmacists to remove the unapproved HIV test kits from their shelves and advising consumers who had bought them to consult with a health professional about other available approved tests.

The press release also cautioned against use of Greene's hepatitis A kit, called the In-Home Hepatitis A Test Kit, which had been sold only to the drugstores--not over the Internet. FDA has not approved

a home-test kit to detect hepatitis A, a virus that can cause a food-borne liver disease.

Greene's kits were packaged in plain white cardboard boxes with only a computer-generated label affixed to the outside. The box's contents included the opened Band-Aid for placing a drop of blood, as well as a stylus for pricking the finger and another little Band-Aid to place over the wound.

"[They were] nothing like you and I would buy," Scott said. "They were very amateurish in appearance."

Greene's HIV home-test kits sold for about $40 each on the retail market, about the same as the legitimate kits.

A Dec. 11, 1997, OCI-obtained federal grand jury indicted Greene and his two companies on seven counts of mail fraud and 36 counts of wire fraud related to selling the unapproved kits. At the arraignment hearing on the indictment, Greene was denied bail and transferred from county jail to federal custody.

Greene waived his right to a jury and served as his own lawyer before U.S. District Judge Robert Coyle during a two-day trial in November 1998. Among those who testified were representatives of the company that set up the Website for Greene and the company that took phone orders for kits.

Coyle convicted Greene on Nov. 18, 1998, of six counts of mail fraud and 11 counts of wire fraud. Finding that Greene's conduct was extreme in the emotional impact he inflicted on his victims, Judge Coyle sentenced Greene Feb. 24, 1999, to a punishment more severe than usual for a fraud case. Also, the judge agreed with the prosecution's conclusion that Greene was a prime candidate for recidivisim. In fact, while in prison awaiting his conviction on the charges related to selling the bogus HIV test kits, Greene tried to extort $500 from a fellow prisoner's mother for legal counsel he said he provided to her son. Greene is not licensed to practice law.

FDA continues to monitor the marketplace, including the Internet, for illegal HIV test kits. According to Susan Corrales, Internet marketing of such kits tends to be common. She cited the public's heightened awareness of HIV as the reason. "People are looking for an HIV test that is confidential and provides test results in the privacy of their homes," she said. "And Internet selling of these unapproved kits is one way to take advantage of this."

Scott agreed. "[Greene's HIV test kit] was a dangerous product we were able to get off the market," she said. "But there are a lot of other companies out there trying to take advantage of people's fears by scamming them out of their money. That's the scary part."

Paula Kurtzweil is a member of FDA's public affairs staff.

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(Hypertext created by clb 1999-JUN-14)

Health

Crackdown on online drug sales?

Plan would give FDA power to review drug-dispensing sites

MSNBC STAFF AND WIRE REPORTS

Dec. 28 — Moving to tame the Wild West nature of cyberspace medicine, President Clinton is set to crack down on illegal sales of prescription drugs over the Internet, requiring sites to get federal approval or face stiff fines. His plan, if approved by Congress, would give the Food and Drug Administration unprecedented new powers to review and certify hundreds of drug-dispensing Web sites.

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Are you in favor of Clinton's plan to crack down on Internet drug sales?

○ Yes

○ No

VOTE

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PROPOSED measures include requiring the FDA to verify the quality of Internet pharmacy sites, establishing a $500,000 fine for Web sites selling drugs to people without a valid prescription, and bolstering FDA authority to investigate Internet prescription drug sales.

"Use of the Internet to buy medical products is growing rapidly ... Unfortunately, the safe use of the Internet by both consumers and businesses is now being threatened by fraudulent or disreputable Internet pharmacies that sell products illegally," the White House said in announcing its proposals.

The initiative will be included in President Bill Clinton's 2001 budget request to be submitted next February to Congress.

The move would mark a significant shift in the regulation of both the Internet and pharmaceuticals. The Internet has been largely unregulated, with policy-makers loathe to stifle its adolescent development. And the regulation of drug sales is largely the province of state government.

In fact, the only pertinent federal law on the books is a misdemeanor which carries a fine of just $1,000.

STATE MOVES

Several states have moved against Web operators. Just this month, Michigan ordered 10 online pharmacies to stop selling or face legal action. And Illinois filed suit against four operators in October.

But they are hampered when the patient lives in one state, the pharmacist in another and the operator in a third, said Dr. Jane Henney, FDA commissioner.

"Many of the traditional safeguards that have been in place for many years are breaking down," she said. "We have to have a way to keep some semblance of a safety net in place."

The initiative also includes a request for $10 million next year to hire about 100 investigators and upgrade computers. Like the new laws, new money would have to be approved by Congress.

The number of companies providing prescription drugs over the Internet has grown rapidly in the last year, mostly because of the convenience of ordering and the privacy afforded to customers. The practice has become particularly important in rural areas, the White House said.

ILLEGAL SALES CITED

But there have been several cases where Web sites sent drugs out without a valid prescription or dispensed drugs that were not legally available in the United States.

The FDA recently uncovered illegal at-home AIDS tests sold over the Internet that didn't work, meaning some people may have thought they were healthy when they actually had the deadly HIV virus.

The FDA also has pointed to a 53-year-old Chicago

man who died after taking the impotence pill Viagra he ordered over the Internet. He never saw a doctor who could have advised him that he was at risk of heart disease, which makes taking Viagra dangerous.

Among the problems cited by Clinton:

- In cyberspace, consumers have no way of telling whether an online pharmacy is a legitimate operation.
- Consumers who buy prescription drugs online from illegitimate Web sites are at risk for adverse effects from inappropriately prescribed medications, dangerous drug interactions or contaminated drugs.
- Some online pharmacies do not employ licensed pharmacists, removing an important safety check.
- And because patients can easily provide false information to obtain medications, the potential for serious abuse exists.

A congressional committee in July identified 400 online pharmacies and criticized the FDA and other agencies for failing to properly police the sites.

HELP ONLINE

Last week, the FDA opened a consumer-advice Web page to help patients ensure they're buying from legitimate stores instead of dangerous quacks.

And the National Association of Boards of Pharmacy is certifying legitimate online pharmacies. Customers can check its site to see if a particular Web pharmacy is safe.

But those are voluntary efforts. By contrast, the federal plan would:

- Require sites to demonstrate to FDA their compliance with federal and state law on pharmaceutical sales before they received approval to operate.
- Create new penalties of $500,000 per violation for the sale of prescription drugs to an individual without a valid prescription.
- Invest $10 million to develop a rapid response team and upgrade FDA's computer technology to identify, investigate and prosecute Web sites that fail to comply.

Even if implemented, however, it is unclear how these rules would affect Web sites operating out of other countries.

The Associated Press and Reuters contributed to this report.

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Science * Service * Leadership

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Comments: Some general info about our laboratory - Jeff Morelli from our Financial Management Office will be sending you information on how we would use $15 million. Please call if you have questions.

Number of pages (not including cover sheet) 6.

The Biomonitoring Program of the National Center for Environmental Health, Centers for Disease Control and Prevention

AT-A-GLANCE 1999

Measuring toxic substances in people to make better decisions for protecting health

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

NCEH
National Center for Environmental Health

NCEH Pub. No. 99-0317
August 1999

What is Biomonitoring?

Biomonitoring is the measurement of toxic substances in the human body, specifically in blood, urine, serum, saliva, or tissues. The results of biomonitoring are used to help make decisions for protecting people from illness, birth defects, disabilities, cancer, or death due to toxic substances. For example, if you think that you have come into contact with a toxic substance, biomonitoring can help answer the following important questions:

- Did a toxic substance get into your body?
- What toxic substance has gotten into your body?
- How much of a toxic substance has gotten into your body?
- Is the amount of a toxic substance that got into your body enough to hurt your health?

Public health officials use the answers to these questions to do the following:

- Identify people who need medical treatment.
- Identify the right medical treatment.
- Prevent people from coming into contact with substances that can hurt their health.
- Evaluate how well prevention activities are working.

Biomonitoring enables better decision making for protecting health.

CDC's Biomonitoring Program

The Environmental Health Laboratory of the National Center for Environmental Health, Centers for Disease Control and Prevention (CDC) conducts CDC's Biomonitoring Program. The program includes the following activities:

Biomonitoring. The lab is capable of measuring 200 toxic substances (or their breakdown products) in human blood, urine, or serum. It can measure lead, mercury, arsenic, uranium, cadmium, benzene, many pesticides, many endocrine disruptors, polychlorinated biphenyls (PCBs), vinyl chloride, and many other substances that are known to be dangerous to health. No other lab in the world can measure chemical exposure in people as quickly and reliably, and some of the exposure measurements are done nowhere else in the world.

Portable Blood Lead Analyzer

• More efficient • Less costly • Easy to use

Technology and test development. The lab develops instruments and tests for biomonitoring that improve the diagnosis, treatment, and prevention of disease due to exposure to toxic substances. For example, the lab supported development of the first portable blood lead analyzer. It is being used to screen children, wherever they may be located, for harmful exposures to lead. This tool increases the chances of identifying children whose health is at risk from lead and of referring them for prompt medical care when needed.

Quality assurance and standardization. CDC's lab helps other labs around the world standardize and improve their programs for measuring specific substances in humans that affect health. These activities result in more reliable test results. For example, through its Blood Lead Laboratory Reference System, the CDC lab helps other labs improve the overall quality of their measurements of lead in blood.

The lab uses its biomonitoring tests and technologies to help (1) protect public health during emergencies involving chemicals, (2) investigate possible exposure of people to dangerous chemicals, and (3) study the effects of chemicals on health.

Benefits of Biomonitoring

Identifies who is in danger. Some people are at greater risk of coming into contact with toxic substances. Researchers can use biomonitoring to find out which groups of people are in the most danger from toxic substances and take steps to protect them.

Improves actions to protect health. Toxic substances can be measured in people before and after taking actions to protect health. Comparing the levels of the substances before and after preventive actions can show whether the actions have helped improve or protect health and to what extent. Without this information, public health officials will have a more difficult time knowing whether their programs are actually helping people.

Improves decision making. Just because a toxic substance is in the environment doesn't mean that it is getting into people or making them sick. Biomonitoring provides a measure of people's *actual* exposure to toxic substances. Officials can use this data to find out whether a substance is causing a health problem, to determine how to treat the problem, and to plan how to prevent exposure in the future.

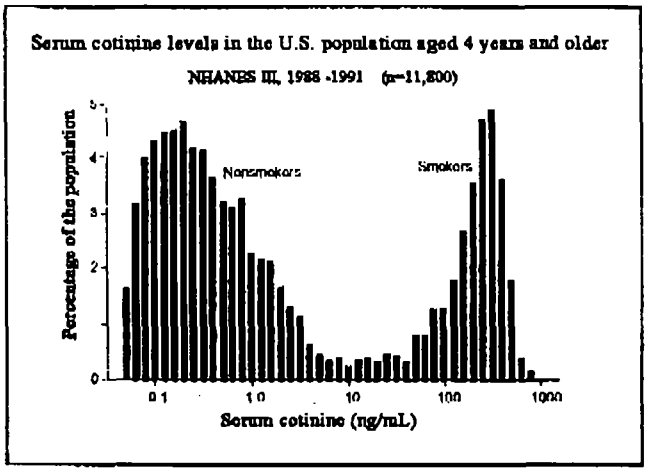
Improves emergency response. Sometimes there is an outbreak of what seems to be the same illness among many people, and the cause of the illness is unknown. Biomonitoring can be used to test people to find out exactly what is making them sick, how to treat them medically, and how to prevent future exposure.

Recent Biomonitoring Results

Dieldrin. Researchers at CDC and in Denmark found that the risk of breast cancer significantly increased with increasing levels of dieldrin, a pesticide, in women's blood. This result suggests that exposure to organochlorine compounds, such as dieldrin, may increase the risk of breast cancer.

Methyl parathion. Methyl parathion is a dangerous pesticide that should never be used indoors. Over the past 2 years, it has been sprayed illegally inside thousands of homes in at least seven states and has resulted in the death of two children in Mississippi. In response to this emergency, the lab developed a method to measure methyl parathion in urine and measured methyl parathion in more than 15,000 people. The results helped identify who needed medical treatment and who needed to be moved out of their homes until the homes could be cleaned.

Trihalomethanes. Trihalomethanes are chemicals that evaporate easily into the air and are thought to be linked to birth defects, bladder cancer, and colorectal cancer. These chemicals are often found in drinking water because they are formed during the water sanitation process. In 1998, the lab developed a method to measure trihalomethanes in blood. This method is being used in studies to find out how much of these chemicals are getting into people's bodies and whether the chemicals are causing illness.



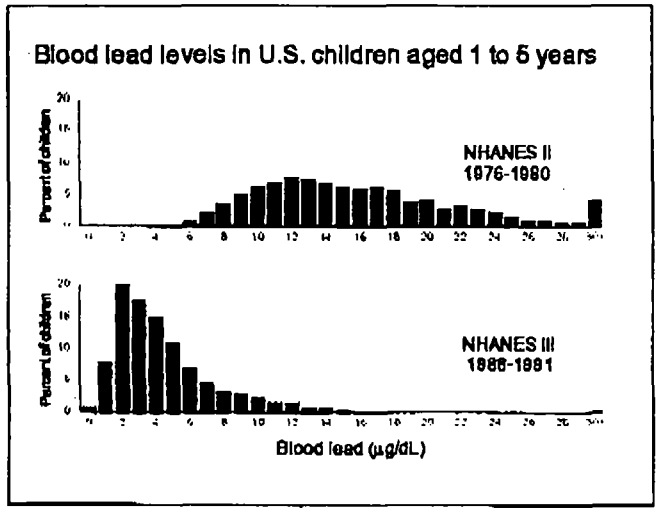
These lab results indicate that secondhand smoke is getting into the bodies of nonsmokers.

Cotinine. Cotinine is a chemical formed by the breakdown of cigarette nicotine in the body. The lab developed methods to measure cotinine in saliva, blood, and urine. These methods are being used to find out (1) how much secondhand smoke is getting into children, adolescents, and adults; (2) what levels of chemicals in tobacco smoke cause health problems; (3) how well actions to protect people from secondhand smoke are working; and (4) how well actions to help current smokers stop smoking are working.

Partnerships and Collaborations

The lab has and will continue to share with federal, state, and local agencies its pioneering work in biomonitoring to measure human exposure to toxic substances. Federal partners include the Agency for Toxic Substances and Disease Registry, the U.S. Department of Defense, the U.S. Environmental Protection Agency, the Food and Drug Administration, and the National Institutes of Health.

NHANES. In collaboration with CDC's National Center for Health Statistics, the lab has served as the central laboratory for the National Health and Nutrition Examination Survey (NHANES) since 1971. The surveys provide information on the prevalence of exposure to toxic substances and disease and risk factors for disease (including genetic risk factors) in the U.S. population. NHANES data are used to develop sound health policies, to direct and design health programs and services, and to evaluate whether these policies, programs, and services are helping to improve the nation's health. In 1998, the lab developed analytical methods and completed the pilot phase for the next survey, NHANES IV. Work on the survey began in March 1999.



The lab has measured blood lead levels in U.S. children for more than 20 years. These graphs indicate that efforts to prevent lead poisoning of children are working and need to continue.

What's New?

Rapid Toxic Screen. The lab is developing a Rapid Toxic Screen that medical personnel will use to protect health during emergencies or terrorist acts involving chemicals. This tool will rapidly measure 150 chemicals in samples of human blood and urine. Officials will use the test to find out which chemicals are involved, who has been exposed to the chemicals, and how much of the chemicals have gotten into people. Medical personnel need this information in order to respond quickly enough during chemical emergencies to save the lives of those exposed and to protect those not yet exposed. The lab is working to develop tests for the first 50 chemical agents for the Rapid Toxic Screen in 1999.

Examples of Chemicals To Be Detected Through the Rapid Toxic Screen

- **Nerve agents**
- **Sulfur and nitrogen mustards**
- **Hydrogen cyanide**
- **Lewisites**
- **Heavy metals**
- **Pesticides**
- **Volatile organic compounds**
- **Dioxins**

National Exposure Report Card. Each year the lab plans to measure and report the exposure of the U.S. population to 25 priority toxic substances. By comparing the results over time, public health experts will be able to see how health is being positively or negatively affected as levels of exposure to toxic substances in the environment change. The lab will report the data according to the age, sex, race/ethnicity, geographic area, and income level of the people tested to see whose health is most at risk. The annual report card will be used to identify exposures to toxic substances that can hurt health, to identify whose health is most at risk, and to monitor how well actions to prevent exposure are working. The lab's goal is to expand the report card to cover 100 priority toxic substances per year.

Support for States. Many Americans are concerned that they are being exposed at home and at work to substances that can cause cancer and other diseases. States are frequently called upon to investigate geographic clusters of cancer, birth defects, and other diseases and to find out whether exposure to toxic substances causes these health problems. The lab's biomonitoring results and exposure profiles for geographic areas will help states answer these questions. The lab is also developing less expensive, simple-to-use, and more rugged biomonitoring methods for state labs to use. In the future, CDC would like to increase support for the number of state and local health and exposure investigations to 50 per year.

Other Environmental Health Laboratory Activities

Besides biomonitoring-related activities, CDC's lab conducts activities that help ensure better diagnosis, treatment, and prevention of selected chronic diseases.

Quality assurance and standardization. In addition to ensuring the quality of blood lead measurements, CDC's lab provides quality assurance, standards, references, and technical assistance through the following programs: (1) the CDC Lipid Standardization Program for assisting labs in measuring lipids and cholesterol, which are factors in cardiovascular and other diseases; (2) the Newborn Screening Quality Assurance Program for assisting labs in conducting tests to detect treatable, inherited metabolic disorders such as sickle cell disease; (3) the HIV Quality Assurance Program for assisting labs in detecting antibodies for HIV in dried-blood-spot specimens; and (4) the Diabetes Reference Laboratory Program for improving the diagnosis, treatment, and prevention of diabetes.

NHANES and nutrition. The lab not only measures the levels of *toxic* substances in people for NHANES, but also measures *nutritional* factors that can cause or decrease the risk of disease. These measurements are important in assessing the health of the U.S. population and in preventing disease. The lab also performs a quality assurance role for NHANES measurements.

National DNA Bank. For NHANES, the lab collects and preserves DNA from a nationally representative sample of the U.S. population. This National DNA Bank is unique and valuable for determining the prevalence of genetic risk factors for disease in the population and for conducting research on genetic risk factors.

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THE WALL STREET JOURNAL INTERACTIVE EDITION
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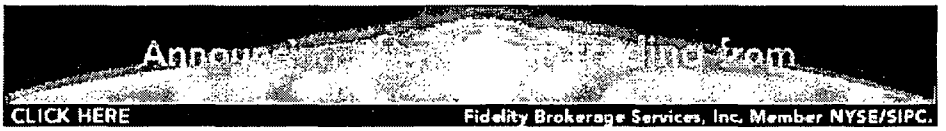

November 29, 1999

Drug Maker Protests Dispensing Viagra Via Internet, but the Practice Flourishes

By LAURIE P. COHEN
Staff Reporter of THE WALL STREET JOURNAL

JERSEY, England -- At Spar Pharmacy, situated on this small island best known for its cows and its status as a tax haven, Viagra is big business.

In May alone, the pharmacy dispensed 3,698 Viagra pills. But only two dozen of the blue tablets ended up in the hands of local residents, who largely shun the anti-impotence drug for religious and moral reasons. Most went instead to people far away from straight-laced Jersey, who had ordered them through what is now the fastest-growing method of distribution for Viagra and other "lifestyle" drugs: the Internet.

Jersey is also home to Direct Response Marketing, an 18-month-old Web site that so far has racked up about $2.5 million in sales, mostly from Viagra. DRM, founded by an ex-barber, is a stone's throw from Spar Pharmacy, which fills the Viagra **prescriptions** for the Web site's far-flung customers.

Direct Response Marketing
www.directresponsemarketing.co.uk/index.html
Drugstore.com
www.drugstore.com
CVS.com
www.cvs.com

Viagra is the best-selling **prescription** drug bought online, says its maker, Pfizer Inc. Although demand for the drug has cooled since its sensational U.S. debut in April 1998, the online-pharmacy business is booming. For Viagra users in particular, the Internet's embarrassment-sparing anonymity has immense appeal.

Special Reports
Weather

STOCK QUOTES
Select exchange:
U.S
Enter symbols:
Go
Symbol lookup

Other wsj.com Sites:
Careers
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Net-Friendly

Viagra "is a perfect product for the Internet," says Christopher Young, a founder of Cyveillance Inc., an Arlington, Va., firm that monitors drug Web sites for Pfizer and other pharmaceutical companies. "No one really wants to go into a store to purchase it if they don't have to."

But only a few cyberpharmacies, such as Drugstore.com and CVS.com, behave like the corner drugstore, offering a wide range of drugs and filling **prescriptions** issued by unaffiliated doctors. In the wide-open realm of cyberspace, most of the other 500 or so online drug sites -- a number that has exploded in the past year -- operate more or less like DRM. They offer just a handful of popular drugs, which consumers get following approval by a doctor who is affiliated with the site -- and who never sees the patient.

Pfizer has repeatedly urged government authorities to crack down on this business. It has sought action from the U.S. Federal Trade Commission, on the theory that the practice is akin to consumer fraud, and it has written to state medical and pharmacy boards, asking them to discipline doctors or pharmacists involved in the sites and to urge federal authorities to act as well. "Immediately after Viagra was first introduced in the U.S., Pfizer began calling attention to the problem of Internet sale of **prescription** drugs without an in-person diagnosis by a physician," a company spokesman says. "Our position has always been clear: Bypassing the doctor-patient relationship is bad medicine."

On the Market

What Pfizer has not done, however, is try to block DRM and similar sites from gaining access to Viagra. It says it can't, for antitrust reasons. Yet antitrust authorities don't appear to agree.

Now Pfizer's stance is bringing some heat to bear on it and other drug manufacturers as, for the first time, the Internet's fast-growing drug traffic comes under attack. Although it is perfectly legal for manufacturers to make their drugs available to wholesalers that, in turn, sell to nontraditional pharmacies, some critics contend that by continuing to feed the online market, the drug makers knowingly expose people to potential peril. The risk: that the drugs will be taken by people who have medical conditions that are inconsistent with their use, and might have been discovered by an examination.

In the case of Viagra, urologists say a physical exam is important not just to be sure the patient is a proper candidate for the drug, but also because erectile difficulty can reflect undiagnosed diabetes or heart disease.

Rumblings in Congress

In July, a House subcommittee held hearings investigating the potential for fraud and other abuses at the Web sites. Rep. Ron Klink, a Pennsylvania Democrat, has introduced legislation that could halt many prescription-drug sales in cyberspace. He has made Viagra a prime target, asserting that those who buy the drug via the Internet

"can suffer severe injury and even death."

However, although more than 100 men have died after having taken Viagra, none of the deaths involved online **prescriptions**. More than two-thirds of the men had at least one cardiovascular risk factor, and some had ignored warnings not to mix Viagra with certain heart drugs; Pfizer says none of the deaths can be shown to have been caused by Viagra.

Cynthia Culmo, who heads a division of the Texas Health Department that monitors Internet drug sales, argues that because the pharmaceutical industry closely monitors the sales patterns of individual drugs, Pfizer probably has the data necessary to control distribution of its product; if the company doesn't do so, in her view, "it appears to be putting money ahead of the health and well-being of consumers."

Pfizer, which is based in New York, says it doesn't know what part of its Viagra sales, which total more than $1.5 billion to date, come by way of Internet pharmacies, but it thinks "only a very small portion" do. It figures it has spent more money trying to combat Web-site dispensing of Viagra than it has made from such sales. But it doesn't agree that it could cut off the sites' access to Viagra. Pfizer says it sells its medicines to licensed wholesalers, who, in turn, sell to licensed pharmacies. "Any attempt by Pfizer to influence the selling practices of these wholesalers," says a spokesman, "would be illegal under restraint-of-trade laws."

However, lawyers in the FTC's Bureau of Competition and several private antitrust lawyers say that it isn't illegal for a manufacturer to refuse to do business with particular wholesalers and their customers, provided the manufacturer isn't colluding with anyone else and discloses the reasons for its action.

Stephen Axinn, a New York antitrust lawyer, says that if a drug company "says to distributors, 'I determine that you are selling my drugs to a pharmacy that, in turn, sells them without an ethical **prescription**,' no one will have a leg to stand on if they challenge that in court." After all, he adds, the drug manufacturer "has the ultimate exposure here."

Mark Schecter, a lawyer who spent 18 years with the U.S. Justice Department's Antitrust Division, says that if someone leveled a restraint-of-trade allegation against a drug maker that blocked distribution to certain online pharmacies, the manufacturer could argue effectively that it was doing so to safeguard its reputation and protect itself in the event of harm to a user. FTC lawyers agree that this would be a strong argument, though they note that the matter hasn't been tested in court.

A Pfizer lawyer, told of such arguments, calls the issue "a red herring." Senior Corporate Counsel Arnold Friede says: "This is not a distribution problem; it's an issue of improper **prescription**. This is an activity that is regulated already... . The best thing for Pfizer is to do what we're doing: bring it to the attention of those responsible for it."

Others' Policies

The producers of two other drugs DRM now offers, the diet drug Xenical and the hair-growth drug Propecia, also see their hands as tied. "It is probably not possible to identify and cut off supply of Xenical to illegitimate Internet distributors," says a spokesman for Xenical's maker, Roche Holding Ltd. "We try very hard to ensure we deal with legitimate distributors, but we can't be totally sure where every product goes."

Merck & Co. says that it can't monitor all dispensing of Propecia, but that when it has found out Web sites were "involved in unauthorized prescribing, we have directly contacted those sites and asked them to stop distributing" the drug. As for asking distributors to cut off the pharmacies that fill such Web sites' **prescriptions**, a Merck spokesman says this is "a proprietary issue with our customers, and we can't comment on that issue."

How might distributors respond to such a request? By honoring it, says one, Skipper Dickson, president of Morris & Dickson Co. in Shreveport, La. "If Pfizer or any other manufacturer called me and told me they didn't want me to sell a drug to a pharmacy because they determined there was a marketing situation that wasn't good, I'd be bound to honor their professional opinion," he says. "Distributors serve at the mercy of manufacturers."

But "Pfizer isn't going to turn away customers -- they want to make a profit," says Christopher Etherington, a marketing executive at Alliance Unichem PLC, a British distributor that supplies Viagra to Spar Pharmacy and thus, indirectly, to DRM's customers.

Starting the Site

The founder of DRM, Tom O'Brien, came to the Internet after operating a direct-mail company that offered minoxidil, the hair-growth drug, while it was a **prescription** remedy. Next, he founded DRM with the aim of selling Restore, a nonprescription cream marketed as an impotence cure. But he shifted his focus after the U.S. Food and Drug Administration approved Viagra in late March 1998.

When he relaunched the Web site two months later to offer Viagra, Mr. O'Brien was expecting trouble both from its manufacturer and from Jersey's conservative officials, so he took just a short-term lease on an office and rented a couple of computers. To deflect the attention of local authorities and of Pfizer itself, he listed on the Web site an address on the nearby island of Sark. "I thought we'd be shut down by Pfizer, by Jersey officials or both," he recalls. But he wasn't.

Mr. O'Brien, who is neither a doctor nor a licensed pharmacist, enlisted the aid of a Spar Pharmacy's owner, Lionel Lerner. Mr. Lerner at first bought Viagra from a U.S. pharmaceutical exporter, but after the United Kingdom approved the drug in September 1998, he started getting it from Alliance Unichem and the London unit of Germany's Gehe AG. Did they consider the propriety of supplying a pharmacy that was filling **prescriptions** for a Web site? Alliance Unichem says it isn't a distributor's job to ask such questions, although it does sometimes inform a manufacturer if it notices a

pharmacy ordering an unusually large volume of a drug. Gehe declines to comment.

Questions and a Caution

When Viagra seekers contact DRM's Web site, it sends them a questionnaire asking questions such as whether they have high blood pressure or heart problems and what other drugs they take, if any. The form warns that Viagra "must NEVER be taken" with nitrate-based drugs. Uwe Eichner, a Jersey doctor, spends four hours a day reviewing such questionnaires. He says he turns down a couple of patient requests for Viagra per week, or about 2% of them.

Some urologists in the U.S. say they turn down about 15% of patients seeking Viagra, most commonly because they have a cardiovascular condition for which they take nitrate drugs or because they don't appear to have the erectile dysfunction Viagra is meant for. DRM's Mr. O'Brien says the Web site's rejection rate is actually higher than 2%, because some would-be customers phone first, and if they disclose information that clearly disqualifies them, they are discouraged from seeking Viagra.

Each morning, Mr. O'Brien drops off a stack of Viagra **prescriptions** at Spar Pharmacy. Later in the day, he returns to pick up nondescript brown envelopes containing the pills, and mails them out.

Although Pfizer sells Viagra to wholesalers for $7 a tablet, and some conventional U.S. pharmacies retail tablets for less than $10, the customers of DRM end up paying more than $20 a tablet. The profits are divided. DRM takes about a third, as does Dr. Eichner; his cut came to about $200,000 in DRM's first full year. The designer of the Web site gets a cut as well. Spar Pharmacy receives a set amount per **prescription** filled, plus a bonus.

Name Game

Pfizer clearly knows about DRM. After the site's launch, lawyers for Pfizer wrote to DRM demanding it stop unauthorized use of the trademarked term "Viagra" in Internet domain names and text. Although Pfizer has managed to shut down some other Viagra Web sites this way, DRM said the law didn't apply to it on the isle of Jersey, and it refused to stop using the word.

Around October 1998, Spar Pharmacy's Mr. Lerner says, he got a call from a man who identified himself as a medical information officer at Pfizer's U.K. headquarters in Kent, England; the caller noted that Spar had ordered a large amount of Viagra and wanted to make sure it was being dispensed properly. Mr. Lerner says he told the caller about DRM and identified its doctor, and the caller said he was "quite happy," as long as the **prescriptions** were written by a licensed doctor. Pfizer officials say they have no knowledge of such an exchange.

Some product-liability lawyers, when the situation is described to them, suggest that Pfizer's familiarity with how sites like DRM operate could hold legal risk if an online Viagra customer suffered injury after taking it. Mr. Friede, the Pfizer lawyer, says, "We won't

speculate about our liability. Our behavior speaks for itself."

Company's Efforts

That behavior includes an August 1998 visit by a team of Pfizer lawyers to the FTC to press for legal action against Web sites that peddle Viagra without an in-person exam. "Pfizer warned us if something wasn't done, someone was going to die," says an FTC lawyer, Richard Cleland. Pfizer's Mr. Friede says company lawyers didn't mention any potential for Viagra-related death.

Pfizer's action was more than other drug companies did, Mr. Cleland says. "Pfizer made this issue a priority for us," he says. "None of the other drug companies had stepped forward."

The FTC felt it wasn't in a position to act. It can move against deceptive advertising by a Web site, but it saw no evidence of such deception, it told Pfizer in November 1998. The agency remained unswayed after Pfizer, in early 1999, enlisted the help of state pharmacy and medical boards to pressure the FTC to act.

Pfizer -- whose chairman, William C. Steere, is a board member of Wall Street Journal publisher Dow Jones & Co. -- also aired its concerns at the FDA. That agency says that in recent months, it has begun tracking more than 100 Web sites and is also working with state boards to help them bring enforcement actions.

Local Efforts

Several state medical boards and prosecutors have moved against cyberdoctors and the online pharmacies they work for. Among the grounds: That such pharmacies need a license in any state where they sell, or that they or their doctors are violating professional standards of care. Ohio has criminally charged one doctor with drug trafficking for such **prescriptions**; the doctor is fighting the charges.

Although Pfizer says state bodies that oversee doctors and pharmacists are in the best position to halt the Web-site trade, Ms. Culmo, the Texas health official, says that in the end, states can't effectively oversee online drug vendors. "No sooner do these guys get shut down in one place but they open up in another," she says.

In recent months, many have moved overseas, eluding U.S. regulators entirely. Mr. O'Brien, though, is going the other direction: He has just unveiled a clone of his Jersey operation based in Miami.

His hope is to get the drug to American customers more cheaply, he says, and spare them a two-week wait for their packages. "When people order Viagra," he says, "they want it now."

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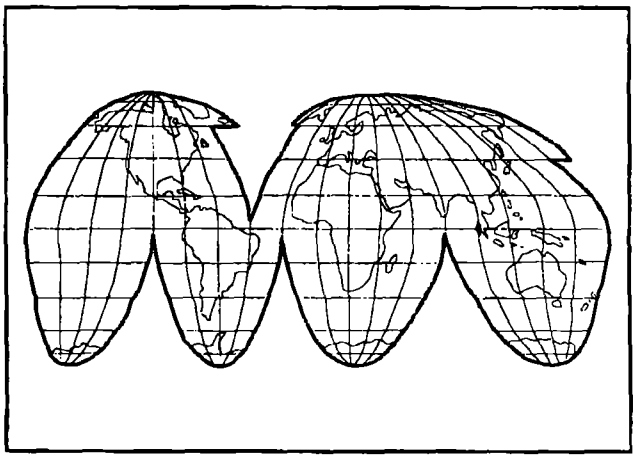

DATE: May 21, 1999

TO: Devora Adler
FAX: 202-456-5557

FROM: Kelly Malone for Jeff Shuren

NO. OF PAGES: (Including Cover Sheet) 4

COMMENTS: Attached are the Q's & A's regarding Internet drug sales that we prepared for our office of the Public Affairs. Please call me if there is anything else I can provide.

Q & A's: Internet Sales of Drugs

Are there any advantages to buying prescription drugs online?

Online purchases offer consumers the opportunity for lower costs and convenience, if the purchase is made from a reputable site.

Are there any disadvantages to buying prescription drugs online?

The downside of buying prescription drugs online is that the consumer can be far less certain about what they are purchasing. Particularly if purchasing from an overseas site, the buyer may not be getting a legitimate, FDA-approved drug. The FDA urges consumers to check with their personal health care providers before purchasing medications from Internet sites.

What agency or department, either state or federal, is the primary regulator of Internet pharmacies?

While no agency is the "primary regulator" of Internet pharmacies, the States have traditionally regulated the dispensing and prescribing of drugs. Pharmacies and pharmacists must be licensed by the States where they dispense drugs. Physicians and other prescribers must be licensed in the State where they practice, and, in some jurisdictions, in the State where their patient is located, as well. Moreover, the States review pharmacy records for accuracy and pharmacy sites for sanitary conditions. In general, FDA regulates drug products and certain promotional activities pertaining to drugs. Other Federal agencies have authority over certain aspects of drug sales, distribution or promotion.

Does online dispensing change the role of pharmacists?

The pharmacist plays an important role in health care, and is often the best-informed professional for the consumer to consult with regarding drug actions and interactions. One drawback to online pharmacies is the absence of the face-to-face contact between pharmacist and consumer that helps ensure that the consumer is properly using these medications.

How do Internet pharmacies deal with issues such as medical records and privacy?

The States generally regulate issues pertaining to medical records and privacy protection.

How do online pharmacies prevent unqualified persons from receiving prescriptions?

Various on-line pharmacies have different policies and procedures relating to this issue. Clearly, many on-line pharmacies do require valid prescriptions, but FDA is very concerned that some pharmacies do not. Consumers should not purchase prescription drugs without first getting a prescription from their health care provider.

Should consumers obtain prescriptions over the Internet?

Unlike the traditional relationship between a patient and their health care provider, online prescribers give the consumer prescriptions in the absence of a physical examination or a medical history tailor-made to the consumer's health needs. By sidestepping these traditional safeguards, consumers are at greater risk for suffering life-threatening adverse events. These risks include side effects from inappropriately prescribed medications, dangerous drug interactions, and the possible ill effects of impure or unknown ingredients found in unapproved drugs. In addition, consumers run the risk that the online prescriber is not a health care provider licensed to prescribe medications. FDA encourages consumers to only obtain prescriptions from their personal health care provider.

Are there certain drugs that should not be ordered from online pharmacies?

Consumers should never order a drug not approved by the FDA. If you aren't sure, ask your local pharmacist, your personal health care provider, your State board of pharmacy, or the FDA. Consumers should also consult with their personal health care provider before ordering prescription medications from Internet sites.

Should consumers buy medications from pharmacies located in foreign countries?

Some of the medications sold on the Internet may be legal in foreign countries but not approved for use in the United States. These products may include addictive and dangerous substances. The system in this country assures that drugs are safe and effective through testing by drug companies and review of that testing by FDA scientists. Products not approved for sale in the United States generally do not conform to good manufacturing practices and quality assurance procedures required by U.S. laws and regulations.

Isn't it legal to buy drugs from overseas for personal use?

It is illegal to bring unapproved drugs into the United States. Under certain circumstances, however, FDA has exercised its enforcement discretion to permit individuals who travel to foreign countries to bring back small quantities of an unapproved drug for their personal use. This policy does not apply to FDA-approved drugs or to unapproved drugs promoted over the Internet or by other means to U.S. residents.

What can consumers do to protect themselves?

Consumers can, and should, be cautious when purchasing drugs online. There is no foolproof way of checking a site's reliability. Although there are legitimate sites that sell drugs, some sites do not employ licensed professionals and may not sell you the real drug. Check with your State Board of Pharmacy or the National Association of Boards of Pharmacy to see if the online pharmacy possesses a valid pharmacy license and has met State quality standards. In addition, consumers should use the same common sense they would apply to anyone they have never purchased a product from before: Does the site have a good reputation for the service it provides? Have people you trust used them and were they satisfied? If it's a site that cannot be verified – such as an overseas site – it may be best to avoid it. There is usually a local pharmacy that will have what the consumer needs.

DRAFT - NOT FOR IMPLEMENTATION

Guidance for Industry

Promotion of FDA-Regulated Products on the Internet

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Docket Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1601, Rockville, MD 20857. All comments should be identified with the docket number listed in the notice of availability that published in the *Federal Register*. For questions regarding this draft document contact XXX

DRAFT - NOT FOR IMPLEMENTATION

Guidance for Industry -- Promotion of FDA-Regulated Products on the Internet[1]

I. INTRODUCTION AND SCOPE

FDA-regulated industries use the Internet to provide a wide range of information about their products.[2] FDA generally views this information in the same manner as it would if the information appeared in other media. At the same time, FDA recognizes that the Internet possesses certain unique technological features, such as the ability to link between pages on various web sites (see Section II for definitions), that permit users to quickly access a wide variety of information. Consistent with the Administration's policy that the federal government refrain from overburdening electronic commerce,[3] FDA, at this time, is not issuing any new rules regarding promotional activities on the Internet. Instead, the agency is making available this guidance document to address how existing statutory provisions, regulations, and guidances apply to Internet promotion of human and animal drugs, biological products,

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1 This draft guidance represents the agency's current thinking on the promotion of FDA-regulated products on the Internet. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. Additional copies of this draft guidance are available from the XXXX, or via Internet at http://www.fda.gov/XXX

2 The term product refers to both proper or trade name and generic substances.

3 Memorandum From President William Clinton to the Heads of Executive Departments and Agencies: Framework for Global Electronic Commerce, July 1, 1997.

4 In the First Annual Report of the U.S. Government Working Group on Electronic Commerce, November 1998, the Administration placed emphasis on consumer protection as a goal for 1999. Consistent with this goal, the Agency's intention, as described in the draft guidance, is an effort to assure the protection of the public health.

medical devices, cosmetics, and foods, including dietary supplements.[4] Many of FDA's constituencies have requested this guidance and the agency anticipates that the guidance will help clarify the agency's expectations for those using this rapidly evolving medium to promote FDA regulated products. The agency will continue to monitor the promotion of FDA-regulated products on the Internet and evaluate whether changes to this guidance document are necessary.

II. REGULATING PRODUCT INFORMATION ON THE INTERNET

As explained below, FDA will generally consider promotional information about FDA-regulated products disseminated on the Internet by, or on behalf of, regulated industry to be labeling. Product-specific promotion on the Internet that is very similar, if not identical, to messages the agency has traditionally regulated as advertisements in print media (e.g., advertisements published in journals, magazines, periodicals, and newspapers) will be considered advertisements when presented on non-company web sites. Labeling and advertisements on the Internet must meet all statutory and

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[4] In the First Annual Report of the U.S. Government Working Group on Electronic Commerce, November 1998, the Administration placed emphasis on consumer protection as a goal for 1999. Consistent with this goal, the Agency's intention, as described in the draft guidance, is an effort to assure the protection of the public health.

[5] All biological products are also regulated as either drugs or devices. Therefore, all sections of the Act and its implementing regulations pertaining to drug promotion apply to biological products that are also regulated as drugs, and all sections of the Act and its implementing regulations pertaining to device promotion apply to biological products that are also regulated as devices.

[6] Manufacturers who are interested in providing links to journal articles or reference publications that contain information on unapproved uses of approved drugs or devices should consult Sections 551-557 of the Act and FDA's implementing regulations at 21 CFR Part 99. These provisions permit drug, biologic, and device

regulatory requirements.[5,6]

A. *Labeling*

"Labeling" is defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the Act) as "all labels and other written, printed, or graphic matter upon any article. . . or accompanying such article." The Supreme Court has construed the definition of labeling broadly and practically, focusing on the nature and function of the information provided rather than the means by which the information is provided. The Court has made clear that the written, printed, or graphic material need not physically accompany the product in order to satisfy the definition of "labeling." If the written, printed, or graphic matter supplements or explains a product, then the material is deemed to accompany the product as "labeling" under section 201(m) of the Act. The Supreme Court has deemed the textual relationship between the materials and the products to be fundamental. (See *Kordel v. United States*, 335 U.S. 345 (1948); *U.S. v. Urbuteit*, 335 U.S. 355 (1948)).

In defining labeling, the courts also have considered whether the information and

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manufacturers to disseminate certain unabridged peer-reviewed journal articles or reference publications concerning the safety, effectiveness, or benefits of a use that is not described in the product's approved labeling provided that the manufacturer complies with certain requirements. The agency's policies on the dissemination by manufacturers of journal articles and reference publications containing information on unapproved uses of approved drugs and devices and Sections 551-557 of the Act/21 CFR Part 99 are being examined by the United States District Court for the District of Columbia in a pending case, *Washington Legal Foundation v. Henney*, Civ. No. 1:94CVO1306.

[5] All biological products are also regulated as either drugs or devices. Therefore, all sections of the Act and its implementing regulations pertaining to drug promotion apply to biological products that are also regulated as drugs, and all sections of the Act and its implementing regulations pertaining to device promotion apply to biological products that are also regulated as devices.

the product are part of an "integrated distribution program," where, for example, the information and the product originate from the same source or the information is designed to promote the eventual distribution and sale of the product. (See also *U.S. v. 47 Bottles, More or Less, Jenasol RJ Formula "60"*, 320 F.2d 564 (3d Cir. 1963); *U.S. v. Guardian Chemical*, 410 F.2d 157 (2d Cir. 1969)). Pursuant to these and other court decisions, FDA has generally considered textually related product information about drugs, biological products, medical devices, and foods disseminated by the manufacturers[7] of such products to be labeling, even though the product is not distributed contemporaneously with the product information. FDA provides examples of drug information regarded as labeling in 21 CFR 202.1(l)(2):

> Brochures, booklets, mailing pieces, detailing pieces. . . bulletins. . . catalogs. . . motion picture films, film strips. . . sound recordings, exhibits, literature, and reprints and *similar pieces of printed, audio, or visual matter descriptive of a drug* and references published (for example, the "Physicians' Desk Reference"). . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor. . . (emphasis added)

FDA considers product information about drugs, biological products, medical devices, and foods disseminated by the manufacturers of such products to be labeling because the information "accompanies" the products for purposes of section 201(m) of the Act. Product information disseminated on the Internet accompanies the products

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[7] When used in this document, the terms "manufacturer" and "company" refer to any FDA-regulated entity or an agent acting on the entity's behalf.

because it supplements, explains, and is textually related to the products, and is part of an integrated distribution program, designed to promote the products for purposes of eventual distribution and sale. Promotion on the Internet also constitutes labeling because it is detailed and focused (information is targeted at users who have expressed an interest in the product by choosing web sites and searches), and it performs the function of labeling (users may obtain full or additional product information). In addition, through a manufacturer's web site, a user may be able to interact with the company to purchase products or obtain information by e-mail communications. Moreover, some regulated companies include their web site addresses on product labels, directing consumers and health care professionals to the companies' web site for additional product information. Finally, considering promotional information about FDA-regulated products on the Internet as labeling is consistent with how the agency regulates promotional information in other media.

In summary, for the reasons described above, FDA will generally consider promotional information about FDA-regulated products disseminated on the Internet by regulated industry to be labeling. This includes, for example, (a) product information disseminated by a manufacturer on the manufacturer's web site, and (b) product information disseminated by a manufacturer on a non-manufacturer's web site that has been historically considered by FDA to be labeling (e.g., reprints and newsletters on non-manufacturer web sites). The information described in (a) and (b) above fits within the meaning of labeling under the Act.

B. *Advertisements*

The Act does not define the term "advertisement," which appears in sections 502(n) (prescription drugs) and 502(r) (restricted devices), or the term "advertising,"

which appears in section 403(a) (foods). However, the Act makes it clear that advertisements are to be regulated separately from labeling. Sections 502(n) and 502(r) of the Act state, "[t]his paragraph [pertaining to advertisements] shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act." The legislative histories of the 1938 Act and the 1962 amendments to the Act support a broad construction of the terms "advertisement" and "advertising." Thus, FDA has traditionally taken the position that an advertisement is information or an activity other than labeling, by a regulated entity, that is intended to promote a product. FDA has, in its prescription drug advertising regulations in 21 CFR 202.1(l)(1), provided examples of what are considered to be advertisements in print media. These include: "advertisements in published journals, magazines, other periodicals, and newspapers...."

Although FDA believes that most product information on the Internet is labeling, the agency recognizes that there are promotional messages on the Internet that are very similar, if not identical, to messages the agency has traditionally regulated as advertisements published in print media (e.g., advertisements in journals, magazines, periodicals, and newspapers). To maintain consistency across media, FDA will view product information issued by a manufacturer on a web site not sponsored by, or on behalf of, the manufacturer that resembles advertisements in print media to be advertisements (e.g., advertisements in online journals, magazines, periodicals, and newspapers, and advertisements on directories, such as Yahoo).

C. *Public Health*

FDA's mission is to promote and protect the public health. Historically, the agency has taken action against individuals and companies that have promoted or sold

medical products and foods in a manner that violates the Act. Because the Internet offers an avenue through which products can be and are unlawfully promoted and sold, FDA believes that it should apply its traditional view of labeling to Internet promotion in order to adequately protect the public health.

The unlawful promotion and sale of FDA-regulated products on the Internet places the American public at risk for injury and undermines the regulatory safeguards enacted by Congress to protect the public from such harm. Congress created a regulatory system that requires approval by FDA before new drugs can be sold in the U.S. As part of the approval process, manufacturers of such products must meet specific scientific criteria to prove that their products are both safe and effective for their intended uses. The law requires that this information be conveyed accurately and truthfully in the product's labeling. If manufacturers can promote and sell new drugs without first receiving FDA approval, these safeguards are eroded and manufacturers will have very little incentive to adequately study their products for safety and effectiveness. An important basis for FDA's enforcement efforts to adequately protect the public health against new drugs that have not been reviewed by FDA for safety and effectiveness stems from claims made in labeling.

The laws and regulations relating to the Agency's mission to promote and protect the public health vary from product type to product type. The Agency's Centers responsible for regulating product promotion have different enforcement programs. Their focuses may vary, depending on the relevant laws and regulations for the type of product they respectively regulate. However, FDA's Internet promotion enforcement activities will generally focus on violations that potentially affect the public health.

III. LINKS AND INTERNET PROMOTION

A. *General Principles Regarding Use of Links*

A special characteristic of the Internet is its ability to link information on different pages and web sites. Regulated companies are responsible for maintaining the links from their web sites, monitoring the information to which they link, and ensuring compliance with applicable statutory and regulatory requirements.

B. *Required Product Information*

For some types of products, the Act and its implementing regulations require that certain information accompany their labeling or advertisements (e.g., approved product labeling, "brief summary," or "brief statement"). Sponsors may meet these requirements through the following methods: 1) by including the product information on the same web page as the labeling or advertisement, so that the information is found by scrolling through the page or by using links to connect to the information; or, 2) by posting the required information on a different web page and linking from the body of the labeling or advertisement to the required information.

When the required information is located on the same web page as the labeling or advertisement, the labeling or advertisement should state the location of the information, such as "For full prescribing information, scroll to the bottom." Alternatively, the labeling or advertisement could include links to send the user to the required information on the same page. When the required information is located on a separate web page, the labeling or advertisement should include clearly labeled direct links to the required product information.

The labeling or advertisement should prominently identify how to reach the required product information, to ensure that the user can easily find it. This applies whether the required information is located on the same web page or a different page,

and whether the information is identified by statements or links. A prominent location within labeling or an advertisement is not as easily identified on a web page as it is on paper, however, because a web page often contains running text and graphics equivalent to many pages of printed material. Given this, sponsors can help ensure that the statement about, or link to, the required information is placed prominently on the origination page[8] by using one of the following approaches:

- For short pages, by placing it at the beginning or end of each web page of the labeling or advertisement;
- For longer pages, by placing it at regular intervals throughout the web page containing labeling or an advertisement (e.g., every fifth paragraph of text, next to each major graphic);
- By placing it in a separate sidebar.

Sponsors may use other approaches than those listed above.

C. *Determining When Links Cause a Regulated Product to be Violative*

Internet technology allows companies to create links between various documents and web sites on the Internet. When a manufacturer creates a link, the manufacturer has chosen to disseminate the information posted on the link's destination page[9] to users who access the information via the manufacturer's link, even if the manufacturer

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[8] "Originating" or "origination page" refers to the web page that contains a link to another page.

[9] The "destination page" is the web page to which a manufacturer links.

did not post the information on the destination page. The link provides direct and quick access to the information on the destination page. Providing a link from the manufacturer's web site to a document on another site would be similar to the manufacturer sending that document in paper form to the user by mail. Therefore, a link from information a manufacturer posts on a web page to information on another page may cause the manufacturer's product to be violative (i.e., it is misbranded, it is adulterated, or its claimed use is unapproved by FDA).[10]

FDA will examine the origination page and the destination page to decide whether destination information causes a product to be violative. This approach applies regardless of whether the link is between pages within a specific U.S. web site, between a U.S. company's web site and another domestic web site, or between a U.S. company's web site and a foreign web site. However, a link to a destination page that does not contain violative information may still cause the company's product to be violative if the destination site as a whole generally contains violative information. FDA

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[10] For example, a drug, device, or food is misbranded if its labeling is false or misleading (section 502(a) and 403(a) of the Act). In addition, a drug or device is misbranded if its labeling fails to bear adequate directions for its intended use (section 502(f)(1) of the Act). A prescription drug is also misbranded if an advertisement is false, lacking in fair balance, or otherwise misleading (21 CFR 202.1 and section 502(n) of the Act). A restricted device is misbranded if its advertising is false and misleading (section 502(q) of the Act) or if it does not include certain information, including a brief statement of intended use and relevant warnings, precautions, side effects, and contraindications (section 502(r) of the Act). The promotion of unapproved uses in the labeling or advertising of a device may cause the device to be adulterated for failure to have an approved application for premarket approval (section 501(f)(1)(B) of the Act) and misbranded for failure to file a premarket notification (section 502(o) of the Act). The promotion of unapproved uses in the labeling of a drug causes the product to be an unapproved new drug (sections 505(a) and 201(p) of the Act for human drugs, and sections 512(a) and 201(v) of the Act for animal drugs).

would make such a determination on a case-by-case basis.

FDA will consider a company's product to be violative if the company links to a destination page that (a) contains information that causes the product to be violative (e.g., information that represents the product for a use that has not received FDA approval, contains unsubstantiated claims, or contains other false or misleading statements about the product); or (b) directs the user via a working link to information that causes the product to be violative.

Example 1: A company provides a link from a discussion of Product A to a page that discusses a disease for which Product A is not an FDA-approved treatment. This link causes Product A to be violative. A link to a destination page that discusses uses of Product A as approved by FDA would not cause Product A to be violative.

Example 2: A company provides a link from its web page for Product A, approved only for the treatment of condition X, to a page on a non-company web site. This destination page includes a link titled "Product A's Use in Condition Y." The link from the company's page to the destination page causes Product A to be violative, because the title of the link on the destination page describes a use not approved by FDA.

Example 3: A company provides a link from its web page for Product A, approved to treat hypertension, to the home page of the American Heart Association web site. The home page does not contain information that would cause the product to be violative. The web site offers a wide variety of medical

and scientific information, including some information about uses for Product A that are not in the approved labeling. This link does not cause Product A to be violative.

Example 4: A company provides a link from its web page for Product A, approved only for the treatment of condition X, to a page on a non-company web site. The destination page contains only a table of contents for the site. Although the destination page does not contain violative information, the destination site is entitled the "Y Condition Site" and the information on the site generally focuses on the use of Product A in the treatment of condition Y. This link would cause Product A to be violative.

Example 5: A U.S. company manufactures products for U.S. and European markets. The company creates a U.S. web site that discusses its U.S. products and the company's foreign subsidiary creates a web site that discusses its European products. The company provides a link from the home page of its U.S. site to the home page of its foreign subsidiary's web site. Information on the foreign subsidiary's home page would not cause the company's products to be violative, as long as the home page did not contain product discussions or links that direct the user to information that would make the U.S. products violative.

If a company manufactures products for U.S. and foreign markets, the agency would not object to a single web site containing discussions of both the U.S. and foreign products. However, the company should not create a direct link between the discussion of its U.S. products and information about products or uses that are intended

only for residents of foreign countries.

Example 6: A U.S. company that manufactures products for U.S. and European markets creates a single web site, which contains separate discussions regarding its products distributed in the U.S. and its products distributed in Europe. The company provides a link from the web page of a U.S. product to the web page of its European product counterpart, which is approved for different uses. This link causes the U.S. product to be violative, because the discussion of the U.S. product connects to a discussion of uses not approved by FDA for this product.[11]

On the same web site, the company provides a link between general headings such as "U.S. Products" and "European Products" or "U.S. Markets" and "European Markets." This link does not cause the U.S. products to be violative, because the domestic and international product discussions are in separate sections of the web site.

IV. INDUSTRY-SPONSORED SEARCH TOOLS

A search tool maintained by a company on its web site can be programmed either to search documents and web pages under the control of the company, or to search documents and pages outside the control of the company. Search tools generally display query results as a list of descriptive links to other web sites or web pages. The two most commonly accessed search tools are search engines and

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[11] When a company manufactures products in the U.S. for export only, it is recommended that the company take the added precaution of clearly indicating that such products are not available in the U.S.

directories. Search engines routinely perform automated searches across the Internet or portions of the Internet and create catalogs of this information. By comparison, directories only search entries placed into the directory. To generate entries, either an editor at the directory writes descriptions for numerous pages, or web site owners submit short descriptions of their pages to the directory.

When a company has a search tool on its web site or sponsors a search tool, the search tool should not prompt the user to request information that would cause the company's products to be violative and should provide only material on the topic explicitly requested by the user. Product-specific material retrieved, as a whole, should be comprehensive and fairly balanced both in content and in the order of presentation. To the extent possible, companies maintaining search tools that search only select web sites and databases should identify the sites and databases that will be searched.

V. INDUSTRY-SPONSORED NEWS GROUPS, CHATROOMS, AND OTHER INTERACTIVE FORUMS

Companies that sponsor or link to interactive forums should not use these forums to illegally promote their products. Links from industry-sponsored interactive forums should be consistent with the discussion of links in Section IV of this document. If misinformation about a manufacturer's product is discussed in a forum, the manufacturer may enter the discussion to correct the misinformation.

VI. DEFINITIONS

The following definitions apply for purposes of this guidance:

A. *Chatroom* is a multi-user, real-time discussion among users on the Internet.

B. *E-mail (electronic mail)* is a tool that allows mail or messages to be sent and

received over the Internet.

C. *Home Page* is the entry point or main web page for a World Wide Web site. The home page often serves as the starting point for navigation.

D. *Internet* is a worldwide electronic network interconnecting thousands of smaller networks and millions of computer users.

E. *Link* is either a textual or graphical marker on a web page that, when clicked on, takes the user to another part of the Internet, such as to another web page or a different area of the same web page, or from an e-mail message to a web page.

F. *News Groups* are ongoing discussion groups on the Internet among people who share a mutual interest. These discussions are not live; rather, they consist of questions, comments, and responses that are posted on an electronic bulletin board for a certain amount of time.

G. *Screen* refers to the portion of a page that is visible to the user without scrolling.

H. *Search Tools* are computer programs accessible on web pages that allow users to search for information using key words or phrases.

I. *User* refers to an individual using the Internet.

J. *Web Page or Page* consists of the contents of a unique universal resource locator (URL) address on the World Wide Web (WWW) that can be many screens long. A user scrolls up or down a page to view off-screen contents.

K. *Web Site or Site* is a collection of one or more pages located within a particular domain on the Internet or World Wide Web.

L. *World Wide Web* (WWW) is the global multimedia database of information on the Internet consisting of web pages connected together through links.

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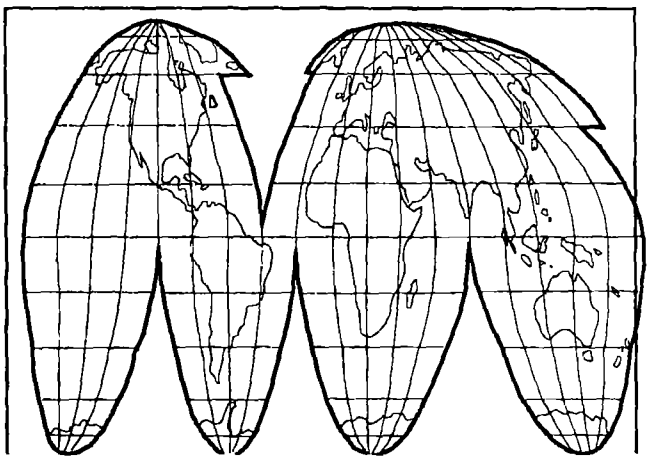

DATE: June 17, 1999

TO: Devora Adler

FAX #: (202) 456-5557

FROM: Kelly Malone for Jeff Shuren

NO. OF PAGES: (Including Cover Sheet) 19

COMMENTS: Attached is a copy of FDA's draft guidance document on Internet promotion. Please send any comments Chris may have to Jeff Shuren or Bill Hubbard. If you have any questions or if there is anything else Jeff can provide, please do not hesitate to call him at (301) 827-0353.

DRAFT - NOT FOR IMPLEMENTATION

Guidance for Industry

Promotion of FDA-Regulated Products on the Internet

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Docket Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1601, Rockville, MD 20857. All comments should be identified with the docket number listed in the notice of availability that published in the *Federal Register*. For questions regarding this draft document contact XXX

U.S. Department of Health and Human Services
Food and Drug Administration

DRAFT - NOT FOR IMPLEMENTATION

Guidance for Industry -- Promotion of FDA-Regulated Products on the Internet[1]

I. INTRODUCTION AND SCOPE

FDA-regulated industries use the Internet to provide a wide range of information about their products.[2] FDA generally views this information in the same manner as it would if the information appeared in other media. At the same time, FDA recognizes that the Internet possesses certain unique technological features, such as the ability to link between pages on various web sites (see Section II for definitions), that permit users to quickly access a wide variety of information. Consistent with the Administration's policy that the federal government refrain from overburdening electronic commerce,[3] FDA, at this time, is not issuing any new rules regarding promotional activities on the Internet. Instead, the agency is making available this guidance document to address how existing statutory provisions, regulations, and guidances apply to Internet promotion of human and animal drugs, biological products,

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1 This draft guidance represents the agency's current thinking on the promotion of FDA-regulated products on the Internet. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. Additional copies of this draft guidance are available from the XXXX, or via Internet at http://www.fda.gov/XXX

2 The term product refers to both proper or trade name and generic substances.

3 Memorandum From President William Clinton to the Heads of Executive Departments and Agencies: Framework for Global Electronic Commerce, July 1, 1997.

medical devices, cosmetics, and foods, including dietary supplements.[4] Many of FDA's constituencies have requested this guidance and the agency anticipates that the guidance will help clarify the agency's expectations for those using this rapidly evolving medium to promote FDA regulated products. The agency will continue to monitor the promotion of FDA-regulated products on the Internet and evaluate whether changes to this guidance document are necessary.

II. REGULATING PRODUCT INFORMATION ON THE INTERNET

As explained below, FDA will generally consider promotional information about FDA-regulated products disseminated on the Internet by, or on behalf of, regulated industry to be labeling. Product-specific promotion on the Internet that is very similar, if not identical, to messages the agency has traditionally regulated as advertisements in print media (e.g., advertisements published in journals, magazines, periodicals, and newspapers) will be considered advertisements when presented on non-company web sites. Labeling and advertisements on the Internet must meet all statutory and regulatory requirements.[5,6]

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[4] In the First Annual Report of the U.S. Government Working Group on Electronic Commerce, November 1998, the Administration placed emphasis on consumer protection as a goal for 1999. Consistent with this goal, the Agency's intention, as described in the draft guidance, is an effort to assure the protection of the public health.

[5] All biological products are also regulated as either drugs or devices. Therefore, all sections of the Act and its implementing regulations pertaining to drug promotion apply to biological products that are also regulated as drugs, and all sections of the Act and its implementing regulations pertaining to device promotion apply to

A. *Labeling*

"Labeling" is defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the Act) as "all labels and other written, printed, or graphic matter upon any article. . . or accompanying such article." The Supreme Court has construed the definition of labeling broadly and practically, focusing on the nature and function of the information provided rather than the means by which the information is provided. The Court has made clear that the written, printed, or graphic material need not physically accompany the product in order to satisfy the definition of "labeling." If the written, printed, or graphic matter supplements or explains a product, then the material is deemed to accompany the product as "labeling" under section 201(m) of the Act. The Supreme Court has deemed the textual relationship between the materials and the products to be fundamental. (See *Kordel v. United States*, 335 U.S. 345 (1948); *U.S. v. Urbuteit*, 335 U.S. 355 (1948)).

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biological products that are also regulated as devices.

[6] Manufacturers who are interested in providing links to journal articles or reference publications that contain information on unapproved uses of approved drugs or devices should consult Sections 551-557 of the Act and FDA's implementing regulations at 21 CFR Part 99. These provisions permit drug, biologic, and device manufacturers to disseminate certain unabridged peer-reviewed journal articles or reference publications concerning the safety, effectiveness, or benefits of a use that is not described in the product's approved labeling provided that the manufacturer complies with certain requirements. The agency's policies on the dissemination by manufacturers of journal articles and reference publications containing information on unapproved uses of approved drugs and devices and Sections 551-557 of the Act/21 CFR Part 99 are being examined by the United States District Court for the District of Columbia in a pending case, *Washington Legal Foundation v. Henney*, Civ. No. 1:94CVO1306.

In defining labeling, the courts also have considered whether the information and the product are part of an "integrated distribution program," where, for example, the information and the product originate from the same source or the information is designed to promote the eventual distribution and sale of the product. (See also *U.S. v. 47 Bottles, More or Less, Jenasol RJ Formula "60"*, 320 F.2d 564 (3d Cir. 1963); *U.S. v. Guardian Chemical*, 410 F.2d 157 (2d Cir. 1969)). Pursuant to these and other court decisions, FDA has generally considered textually related product information about drugs, biological products, medical devices, and foods disseminated by the manufacturers[7] of such products to be labeling, even though the product is not distributed contemporaneously with the product information. FDA provides examples of drug information regarded as labeling in 21 CFR 202.1(l)(2):

> Brochures, booklets, mailing pieces, detailing pieces. . . bulletins. . . catalogs. . . motion picture films, film strips. . . sound recordings, exhibits, literature, and reprints and *similar pieces of printed, audio, or visual matter descriptive of a drug* and references published (for example, the "Physicians' Desk Reference"). . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor. . . (emphasis added)

FDA considers product information about drugs, biological products, medical

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[7] When used in this document, the terms "manufacturer" and "company" refer to any FDA-regulated entity or an agent acting on the entity's behalf.

devices, and foods disseminated by the manufacturers of such products to be labeling because the information "accompanies" the products for purposes of section 201(m) of the Act. Product information disseminated on the Internet accompanies the products because it supplements, explains, and is textually related to the products, and is part of an integrated distribution program, designed to promote the products for purposes of eventual distribution and sale. Promotion on the Internet also constitutes labeling because it is detailed and focused (information is targeted at users who have expressed an interest in the product by choosing web sites and searches), and it performs the function of labeling (users may obtain full or additional product information). In addition, through a manufacturer's web site, a user may be able to interact with the company to purchase products or obtain information by e-mail communications. Moreover, some regulated companies include their web site addresses on product labels, directing consumers and health care professionals to the companies' web site for additional product information. Finally, considering promotional information about FDA-regulated products on the Internet as labeling is consistent with how the agency regulates promotional information in other media.

In summary, for the reasons described above, FDA will generally consider promotional information about FDA-regulated products disseminated on the Internet by regulated industry to be labeling. This includes, for example, (a) product information disseminated by a manufacturer on the manufacturer's web site, and (b) product information disseminated by a manufacturer on a non-manufacturer's web site that has been historically considered by FDA to be labeling (e.g., reprints and newsletters on

non-manufacturer web sites). The information described in (a) and (b) above fits within the meaning of labeling under the Act.

B. *Advertisements*

The Act does not define the term "advertisement," which appears in sections 502(n) (prescription drugs) and 502(r) (restricted devices), or the term "advertising," which appears in section 403(a) (foods). However, the Act makes it clear that advertisements are to be regulated separately from labeling. Sections 502(n) and 502(r) of the Act state, "[t]his paragraph [pertaining to advertisements] shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act." The legislative histories of the 1938 Act and the 1962 amendments to the Act support a broad construction of the terms "advertisement" and "advertising." Thus, FDA has traditionally taken the position that an advertisement is information or an activity other than labeling, by a regulated entity, that is intended to promote a product. FDA has, in its prescription drug advertising regulations in 21 CFR 202.1(l)(1), provided examples of what are considered to be advertisements in print media. These include: "advertisements in published journals, magazines, other periodicals, and newspapers...."

Although FDA believes that most product information on the Internet is labeling, the agency recognizes that there are promotional messages on the Internet that are very similar, if not identical, to messages the agency has traditionally regulated as advertisements published in print media (e.g., advertisements in journals, magazines,

periodicals, and newspapers). To maintain consistency across media, FDA will view product information issued by a manufacturer on a web site not sponsored by, or on behalf of, the manufacturer that resembles advertisements in print media to be advertisements (e.g., advertisements in online journals, magazines, periodicals, and newspapers, and advertisements on directories, such as Yahoo).

C. *Public Health*

FDA's mission is to promote and protect the public health. Historically, the agency has taken action against individuals and companies that have promoted or sold medical products and foods in a manner that violates the Act. Because the Internet offers an avenue through which products can be and are unlawfully promoted and sold, FDA believes that it should apply its traditional view of labeling to Internet promotion in order to adequately protect the public health.

The unlawful promotion and sale of FDA-regulated products on the Internet places the American public at risk for injury and undermines the regulatory safeguards enacted by Congress to protect the public from such harm. Congress created a regulatory system that requires approval by FDA before new drugs can be sold in the U.S. As part of the approval process, manufacturers of such products must meet specific scientific criteria to prove that their products are both safe and effective for their intended uses. The law requires that this information be conveyed accurately and truthfully in the product's labeling. If manufacturers can promote and sell new drugs without first receiving FDA approval, these safeguards are eroded and manufacturers

will have very little incentive to adequately study their products for safety and effectiveness. An important basis for FDA's enforcement efforts to adequately protect the public health against new drugs that have not been reviewed by FDA for safety and effectiveness stems from claims made in labeling.

The laws and regulations relating to the Agency's mission to promote and protect the public health vary from product type to product type. The Agency's Centers responsible for regulating product promotion have different enforcement programs. Their focuses may vary, depending on the relevant laws and regulations for the type of product they respectively regulate. However, FDA's Internet promotion enforcement activities will generally focus on violations that potentially affect the public health.

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requirements through the following methods: 1) by including the product information on the same web page as the labeling or advertisement, so that the information is found by scrolling through the page or by using links to connect to the information; or, 2) by posting the required information on a different web page and linking from the body of the labeling or advertisement to the required information.

When the required information is located on the same web page as the labeling or advertisement, the labeling or advertisement should state the location of the information, such as "For full prescribing information, scroll to the bottom." Alternatively, the labeling or advertisement could include links to send the user to the required information on the same page. When the required information is located on a separate web page, the labeling or advertisement should include clearly labeled direct links to the required product information.

The labeling or advertisement should prominently identify how to reach the required product information, to ensure that the user can easily find it. This applies whether the required information is located on the same web page or a different page, and whether the information is identified by statements or links. A prominent location within labeling or an advertisement is not as easily identified on a web page as it is on paper, however, because a web page often contains running text and graphics equivalent to many pages of printed material. Given this, sponsors can help ensure that the statement about, or link to, the required information is placed prominently on

the origination page[8] by using one of the following approaches:

- For short pages, by placing it at the beginning or end of each web page of the labeling or advertisement;
- For longer pages, by placing it at regular intervals throughout the web page containing labeling or an advertisement (e.g., every fifth paragraph of text, next to each major graphic);
- By placing it in a separate sidebar.

Sponsors may use other approaches than those listed above.

C. *Determining When Links Cause a Regulated Product to be Violative*

Internet technology allows companies to create links between various documents and web sites on the Internet. When a manufacturer creates a link, the manufacturer has chosen to disseminate the information posted on the link's destination page[9] to users who access the information via the manufacturer's link, even if the manufacturer did not post the information on the destination page. The link provides direct and quick access to the information on the destination page. Providing a link from the manufacturer's web site to a document on another site would be similar to the

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[8] "Originating" or "origination page" refers to the web page that contains a link to another page.

[9] The "destination page" is the web page to which a manufacturer links.

manufacturer sending that document in paper form to the user by mail. Therefore, a link from information a manufacturer posts on a web page to information on another page may cause the manufacturer's product to be violative (i.e., it is misbranded, it is adulterated, or its claimed use is unapproved by FDA).[10]

FDA will examine the origination page and the destination page to decide whether destination information causes a product to be violative. This approach applies regardless of whether the link is between pages within a specific U.S. web site, between a U.S. company's web site and another domestic web site, or between a U.S. company's web site and a foreign web site. However, a link to a destination page that does not contain violative information may still cause the company's product to be violative if the destination site as a whole generally contains violative information. FDA would make such a determination on a case-by-case basis.

FDA will consider a company's product to be violative if the company links to a

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destination page that (a) contains information that causes the product to be violative (e.g., information that represents the product for a use that has not received FDA approval, contains unsubstantiated claims, or contains other false or misleading statements about the product); or (b) directs the user via a working link to information that causes the product to be violative.

Example 1: A company provides a link from a discussion of Product A to a page that discusses a disease for which Product A is not an FDA-approved treatment. This link causes Product A to be violative. A link to a destination page that discusses uses of Product A as approved by FDA would not cause Product A to be violative.

Example 2: A company provides a link from its web page for Product A, approved only for the treatment of condition X, to a page on a non-company web site. This destination page includes a link titled "Product A's Use in Condition Y." The link from the company's page to the destination page causes Product A to be violative, because the title of the link on the destination page describes a use not approved by FDA.

Example 3: A company provides a link from its web page for Product A, approved to treat hypertension, to the home page of the American Heart Association web site. The home page does not contain information that would

cause the product to be violative. The web site offers a wide variety of medical and scientific information, including some information about uses for Product A that are not in the approved labeling. This link does not cause Product A to be violative.

Example 4: A company provides a link from its web page for Product A, approved only for the treatment of condition X, to a page on a non-company web site. The destination page contains only a table of contents for the site. Although the destination page does not contain violative information, the destination site is entitled the "Y Condition Site" and the information on the site generally focuses on the use of Product A in the treatment of condition Y. This link would cause Product A to be violative.

Example 5: A U.S. company manufactures products for U.S. and European markets. The company creates a U.S. web site that discusses its U.S. products and the company's foreign subsidiary creates a web site that discusses its European products. The company provides a link from the home page of its U.S. site to the home page of its foreign subsidiary's web site. Information on the foreign subsidiary's home page would not cause the company's products to be violative, as long as the home page did not contain product discussions or links that direct the user to information that would make the U.S. products violative.

If a company manufactures products for U.S. and foreign markets, the agency would not object to a single web site containing discussions of both the U.S. and foreign products. However, the company should not create a direct link between the discussion of its U.S. products and information about products or uses that are intended only for residents of foreign countries.

Example 6: A U.S. company that manufactures products for U.S. and European markets creates a single web site, which contains separate discussions regarding its products distributed in the U.S. and its products distributed in Europe. The company provides a link from the web page of a U.S. product to the web page of its European product counterpart, which is approved for different uses. This link causes the U.S. product to be violative, because the discussion of the U.S. product connects to a discussion of uses not approved by FDA for this product.[11]

On the same web site, the company provides a link between general headings such as "U.S. Products" and "European Products" or "U.S. Markets" and "European Markets." This link does not cause the U.S. products to be violative, because the domestic and international product discussions are in separate sections of the web site.

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[11] When a company manufactures products in the U.S. for export only, it is recommended that the company take the added precaution of clearly indicating that such products are not available in the U.S.

DRAFT - NOT FOR IMPLEMENTATION

IV. INDUSTRY-SPONSORED SEARCH TOOLS

A search tool maintained by a company on its web site can be programmed either to search documents and web pages under the control of the company, or to search documents and pages outside the control of the company. Search tools generally display query results as a list of descriptive links to other web sites or web pages. The two most commonly accessed search tools are search engines and directories. Search engines routinely perform automated searches across the Internet or portions of the Internet and create catalogs of this information. By comparison, directories only search entries placed into the directory. To generate entries, either an editor at the directory writes descriptions for numerous pages, or web site owners submit short descriptions of their pages to the directory.

When a company has a search tool on its web site or sponsors a search tool, the search tool should not prompt the user to request information that would cause the company's products to be violative and should provide only material on the topic explicitly requested by the user. Product-specific material retrieved, as a whole, should be comprehensive and fairly balanced both in content and in the order of presentation. To the extent possible, companies maintaining search tools that search only select web sites and databases should identify the sites and databases that will be searched.

V. INDUSTRY-SPONSORED NEWS GROUPS, CHATROOMS, AND OTHER INTERACTIVE FORUMS

Companies that sponsor or link to interactive forums should not use these

forums to illegally promote their products. Links from industry-sponsored interactive forums should be consistent with the discussion of links in Section IV of this document. If misinformation about a manufacturer's product is discussed in a forum, the manufacturer may enter the discussion to correct the misinformation.

VI. DEFINITIONS

The following definitions apply for purposes of this guidance:

A. *Chatroom* is a multi-user, real-time discussion among users on the Internet.

B. *E-mail (electronic mail)* is a tool that allows mail or messages to be sent and received over the Internet.

C. *Home Page* is the entry point or main web page for a World Wide Web site. The home page often serves as the starting point for navigation.

D. *Internet* is a worldwide electronic network interconnecting thousands of smaller networks and millions of computer users.

E. *Link* is either a textual or graphical marker on a web page that, when clicked on, takes the user to another part of the Internet, such as to another web page or a different area of the same web page, or from an e-mail message to a web page.

F. *News Groups* are ongoing discussion groups on the Internet among people who share a mutual interest. These discussions are not live; rather, they consist of questions, comments, and responses that are posted on an electronic bulletin board for a certain amount of time.

G. *Screen* refers to the portion of a page that is visible to the user without scrolling.

H. *Search Tools* are computer programs accessible on web pages that allow users to search for information using key words or phrases.

I. *User* refers to an individual using the Internet.

J. *Web Page or Page* consists of the contents of a unique universal resource locator (URL) address on the World Wide Web (WWW) that can be many screens long. A user scrolls up or down a page to view off-screen contents.

K. *Web Site or Site* is a collection of one or more pages located within a particular domain on the Internet or World Wide Web.

L. *World Wide Web* (WWW) is the global multimedia database of information on the Internet consisting of web pages connected together through links.

FINAL DRAFT – July 26 – 6:00 p.m.

MASTER COPY -

Regardless, be sensitive to privacy values on line — importance of passing legislation, regulation, guidelines ahead, etc.)

Statement of

Janet Woodcock, M.D.

Director, Center for Drug Evaluation and Research

U.S. Food and Drug Administration

Before the

Subcommittee on Oversight and Investigations

Committee on Commerce

U.S. House of Representatives

July 30, 1999

Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA or Agency). I am pleased to have this opportunity to participate in this discussion of the benefits and risks of pharmaceutical sales over the Internet. The sale of consumer products over the Internet has grown rapidly, including the sale of drugs. While the growth in online drug sales by reputable pharmacies is a trend that can benefit consumers, online drug sales also present risks to unsuspecting purchasers and some unique challenges to regulators, law enforcement and policymakers. FDA is concerned about the public health implications of Internet drug sales, and we are responding to these concerns as part of our overall goal of developing and implementing risk-based strategies to protect public health and safety.

It is important to recognize that other products regulated by the Agency, such as medical devices, biological products, and foods, including dietary supplements, also are sold online, and when sold unlawfully, may pose risks to the public health. This testimony, however, will focus on the advantages and risks of online pharmaceutical sales, outline the authority and enforcement activities of FDA in this area, and discuss new initiatives that FDA is taking to better respond to the regulatory challenges. FDA believes these initiatives are consistent with the Administration's July 1, 1997 Framework for Global Electronic Commerce and the President's November 30, 1998 Memorandum on Successes and Further Work on Electronic Commerce.

burdensome restrictions on legitimate sellers. Therefore, the Agency's efforts should help foster consumer confidence in electronic commerce through effective consumer protection online without imposing undue restrictions on legitimate electronic commerce.

BENEFITS OF ONLINE DRUG SALES

The growth and development of the Internet in recent years has opened up vast new opportunities for the exchange of information and for the enhancement of commerce. E-mail and chat groups have facilitated communications dramatically. Information gathering that once took hours or days of research, whether for a highly technical scientific paper or an elementary student's homework assignment, can now be accomplished in minutes.

Perhaps the chief attractions to purchasing consumer goods online are the speed and ease of choosing and ordering products, and the relative privacy in which medical products can be purchased. Many reputable online pharmacies allow patients to consult with a pharmacist from the privacy of their home. In addition, Internet pharmacies can offer a wide array of products and because products are shipped from central distributors, the physical retail building is eliminated. Moreover, online pharmacies are able to provide customers with written product information and references to other sources of information much more easily than in the traditional storefront. Finally, as the use of computer technology to transmit prescriptions from doctors to pharmacies expands, a reduction in prescription errors is possible.

[More can be said here - more advantages include:
- availability of drugs to shut ins, largely elderly, persons for whom going to pharmacy can be difficult
- availability to rural persons who live far from a pharmacy
- price competition for prescription drugs, among licensed sellers.]

including these points can be taken explanation of Internet benefits, I can form to Admin's testimony support for e-commerce.

We are not aware if composite sales figures for online pharmacies have been compiled. But the increasing recognition of the Internet as a legitimate and important vehicle for drug sales is evidenced by the recent activity of major drugstore companies and Internet retailers in financing, supporting and sponsoring online pharmaceutical outlets. Earlier this year, for example, CVS Corporation acquired the online pharmaceutical retailer Soma.com, and announced last month that the online retail sites of the two companies will merge. Also last month, Rite-Aid Corporation announced a partnership with Drugstore.com to combine the benefits of online ordering with access to traditional retail locations and insurance reimbursement services. We expect this expansion of the online drug sales industry to continue over the next few years. As beneficial as this new technology is, however, there are some concerns.

CONCERNS ABOUT ONLINE SALES

As you know, the establishment of FDA as it exists today grew out of a time early in the century when consumers were victimized by dishonest purveyors of fraudulent potions and compounds that were ineffective, dangerous, or both. A system of drug regulation was established in this country that has served us well. Under this system, the FDA reviews new drugs to ensure their safety and effectiveness. In addition, certain types of drugs must be prescribed and dispensed by health care professionals licensed and overseen by the State in which they practice. But even with this system in place, there are those who still try to sell unapproved or unsafe drug products, and the Internet provides them with new opportunities for

reaching unsuspecting and vulnerable consumers and undermining established safeguards. It is fair to say that the speed and ease of ordering products on the Internet that attract consumers likewise entices some unscrupulous sellers to use the Internet as their new medium of choice.

Internet drug sales raise public health issues similar to those raised by sales, in other contexts, of unapproved new drugs (including counterfeit drugs); the sale of prescription drugs without a valid prescription; the sale of expired or illegally diverted pharmaceuticals; and the marketing of products based on fraudulent health claims.

Congress and State legislatures have enacted laws to protect patients from harm resulting from the use of unsafe drugs, counterfeit drugs, and the improper practice of medicine and pharmacy. Under these laws, to receive a prescription drug for the first time, a patient must be physically examined by a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets State practice standards. However, the Internet makes it easy for individuals to bypass these safeguards when selling drugs to patients. A web site can be easily created to look like a legitimate pharmacy when in fact both the seller and product are illegitimate.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering life-threatening adverse events. For example, one type of dangerous product commonly sold on

the Internet is a kit for preparing gamma hydroxy butyrate (GHB). This unapproved drug, which is sold for bodybuilding and recreational use and is used also in sexual assaults to incapacitate the victims, is a clear threat to public health when sold in this manner. Other risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions and contaminated drugs, as well as the possible ill effects of impure or unknown ingredients found in drugs manufactured under substandard conditions. Further risk to patients is posed by their inability to know what they are really getting when they buy these drugs. Although some patients may be purchasing the real thing, some may be buying counterfeit copies that contain inert ingredients, outdated legitimate drugs that have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent versions that were improperly manufactured.

Besides magnifying existing problems by reaching millions of consumers worldwide, online drug sales create unique issues for regulatory and law enforcement bodies. Internet technology can obscure the source of the product as well as the persons responsible for making and shipping the product. As Internet sales involve electronic transactions, they not only afford the consumer the possibility of privacy, but also provide the seller with intangible anonymity. The participants in a transaction can be widely dispersed geographically and they may well never meet. For example, a consumer in one State, using an Internet site emanating from a computer in a second State, may order a drug actually dispensed from a third State, under a prescription from a doctor in a fourth State. Thus, issues cross traditional regulatory boundaries as well as Federal

and State jurisdictional lines. If one or more participants in the transaction are located outside of the United States, the task of regulating the activity is further complicated. Similarly, the fact that sellers can easily change the location and appearance of their Internet sites makes enforcement all the more difficult.

The Agency is particularly concerned about the apparent absence of a doctor-patient relationship in some Internet transactions. FDA believes that the selection of prescription drug products or treatment regimens for a particular patient should be made with the advice of a licensed health care practitioner familiar with the patient's current health status and past medical history. In situations where the customary physician-patient relationship does not exist, the patient is essentially practicing self-diagnosis. Consequently, the risk of negative outcomes such as harmful drug interactions, allergic reactions, contraindications, or improper dosing is greatly magnified. We also are concerned about the proliferation of sites that substitute a simple questionnaire for a face-to-face examination and patient supervision by a health care practitioner. According to the American Medical Association, a health care practitioner who offers a prescription for a patient they have never seen before and based solely on an online questionnaire has generally not met the appropriate medical standard of care.

The sale of drugs to U.S. residents via foreign web sites is another area of concern to the Agency. Some medications sold on the Internet may be legal in foreign countries but not approved for use in the United States, and some products may include addictive and dangerous

substances. Products not approved for sale in the United States generally do not conform to the good manufacturing practices and quality assurance procedures required by U.S. laws and regulations. Generally, the prescription drug available from a foreign pharmacy is either a product for which there is no U.S. approved counterpart or a foreign version of an FDA-approved drug. It is illegal for a foreign pharmacy to ship such drugs into the U.S. Additional requirements, enforced by the Drug Enforcement Administration, are imposed on the importation of controlled substances. Foreign sales pose a difficult challenge for U.S. law enforcement because the seller is not within U.S. jurisdiction.

FDA AUTHORITY AND ENFORCEMENT ACTIVITY

The types of unlawful conduct involving online drug sales that FDA has identified are similar to unlawful activities that occur in other sales contexts. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA has the legal authority to take action against:

- the importation, sale, or distribution of an adulterated or misbranded drug;
- the importation, sale, or distribution of an unapproved new drug;
- illegal promotion of a drug;
- the sale or dispensing of a prescription drug without a valid prescription; and,
- counterfeit drugs.

When the Internet is used for an illegal sale, FDA must establish the same elements of a case, bring the same charges, and take the same actions as it would if another medium, such as a storefront or a magazine, had been used.

investigated and referred cases for prosecutions

FDA already has ~~brought~~ criminal and civil ~~enforcement actions~~ against some online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency. FDA intends to significantly expand its enforcement activities regarding online sales. The Office of Regulatory Affairs (ORA) and the Office of Compliance in the Center for Drug Evaluation and Research (CDER) are the primary organizations within FDA with responsibility for regulating online drug sales. These offices review web sites that consumers, industry, health professionals or government personnel report as appearing violative. Since June 1998, the Agency has taken numerous compliance actions based on violative labeling claims. In at least 27 of these cases, the violative claims had an Internet component. In addition to the cases involving labeling claims, the Agency has identified over 60 cases related to illegal Internet sales. Actions included sending warning letters to firms illegally selling unapproved new drugs online and issuing Import Alerts to online sellers of illegal foreign pharmaceuticals. FDA has also contacted web site managers and asked for their voluntary cooperation in removing violative sites. Warning letters to online pharmacies based in foreign countries are shared with the government of that country.

Additionally, CDER's Division of Drug Marketing, Advertising, and Communications has taken steps against online drug promotion that violates the FD&C Act by making unsubstantiated claims or misrepresentations of drugs, or by a lack of fair balance in describing risks and benefits. The Agency also is in the process of developing draft guidance for industry to provide clarification on the use of the Internet to promote regulated products.

The Office of Criminal Investigations (OCI) is the entity within FDA responsible for conducting and coordinating investigations of suspected criminal violations of the FD&C Act, the Federal Anti-Tampering Act (FATA), and other statutes including applicable U.S. Criminal Code violations. OCI maintains liaison and cooperative investigative efforts with other Federal, State, Local, and international law enforcement agencies.

In November 1998, a defendant in California began serving a five year Federal prison term after being convicted of selling online unapproved HIV home test kits which used fabricated test results. For the first time in FDA history, the individual was convicted on wire fraud charges stemming from the use of the Internet to sell an illegal medical product. Previous wire fraud charges involving illegal medical products were based only on telephone and facsimile use.

In another case, in November 1998, a police department in Illinois advised OCI it had discovered an unconscious male individual in a hotel parking lot. The subject was taken to a

local hospital and treated for a drug overdose. Police contacted family members and determined that the individual had been taking GHB. Police found suspected GHB in the subject's possession and found additional suspected GHB in his hotel room. Police requested OCI assistance with lab work and a technical computer search as they suspected the subject had obtained GHB kits and preparation instructions from the Internet. OCI identified the subject's source of supply, which was on an Internet site located in Canada. The investigation by OCI and the police department established that the subject had purchased a quantity sufficient to warrant a GHB felony distribution charge under Illinois law. The individual was found guilty of possession of a controlled substance in Illinois and sentenced to two years state probation.

In a third case, OCI was advised by a State Board of Pharmacy that an Internet site was offering prescription drugs to U.S. customers from foreign manufacturers, by acting as an authorized "buyers club" using the "personal importation policy" of the FDA. OCI notified the U.S. Customs Service (USCS) at a particular U.S. international mail facility to watch for suspicious shipments bound for the operator of this Internet site. As a result, USCS intercepted what appeared to be steroid shipments to the web site's address. Search warrants were obtained and over a period of approximately four weeks, nine incoming shipments of steroids were searched and control delivered by USCS and OCI agents. Deliveries coordinated with surveillance of the suspect revealed a sophisticated operation centered out of an apartment building. OCI and USCS arrested the suspect and simultaneously served a search warrant at

the business location. The primary suspect was sentenced in Federal court.

As a last example, in July of 1996 OCI headquarters was contacted by a women's health care provider to advise that several clients had directed her to an Internet site promoting an abortion kit. She believed the site contained several unfounded statements. The FDA Division of Urologic and Reproductive Drug Products reviewed the Internet site and determined that the drugs in the kits presented a serious health risk to women when used without a doctor's supervision because of a possibility of heavy vaginal bleeding and death. Using computer technology and the help of computer security companies, OCI traced the site to Easy Life Labs in Colombia, South America. OCI placed an anonymous order for the kit. The company responded and FDA laboratory analysis showed the drugs to be those warned against by the Agency's experts. The company's web site temporarily went off line, but in March of 1997, the original health care provider called back to say the company was operating again using a different name. One of the drugs provided was unapproved for use in the U.S. OCI contacted the foreign drug company's U.S. internet service provider (ISP) and told them that one of their subscribers was using its service to promote and sell this unapproved drug. Additionally, the ISP was informed of FDA's public health concerns about the proposed use of the unapproved drug and that this was in criminal violation of the FD&C Act. The service provider voluntarily removed the violative ads.

Although FDA has taken action against unapproved drugs sold over the Internet and will continue to do so in the future, as you know, FDA does not generally regulate the practice of pharmacy or the practice of medicine -- the States traditionally have regulated both the prescribing and dispensing of drugs. Several States, however, have found it difficult to identify and locate violators and to bring effective enforcement actions because the seller and the purchaser of a drug may reside in different States and because it is often difficult to identify the persons responsible for a web site. As a result, FDA and State agencies need to work cooperatively to enforce the FD&C Act and State laws in this area.

FDA has initiated contacts with other agencies and States to address these issues. For example, on February 8 of this year, the Agency hosted a meeting with representatives of health professional organizations that looked at the prescribing and dispensing of drugs on the Internet. FDA, the Federation of State Medical Boards of the United States, the National Association of Boards of Pharmacy (NABP), the American Medical Association and the Association of Food and Drug Officials gave presentations. Discussions centered on the roles that each organization plays in regulating prescribing and dispensing on the Internet and how the various roles could better compliment each other. At that meeting, the NABP announced a new program to verify the legitimacy of Internet sites dispensing prescription drugs. The program, known as the Verification of Internet Pharmacy Practice Sites, or VIPPS, will provide a NABP "seal of approval" to sites meeting the organization's standards. Over time, this seal of approval may assure consumers that the designated sites are offering pharmaceuticals that meet FDA standards.

FDA believes that by working with the States, we can regulate the domestic sale of both approved and unapproved drugs (except for controlled substances where the Drug Enforcement Administration generally takes the lead for the Federal government), as well as the sale of prescription drugs without a valid prescription. When a sale involves health fraud, multiple Federal agencies have authority to take action, including the Department of Justice, the Federal Bureau of Investigation, the Federal Trade Commission, the Postal Service, the Office of the Inspector General in the Department of Health and Human Services, FDA and the States. FDA has worked with many of these agencies in bringing cases involving health fraud and will continue to do so.

The most difficult problem to address is the online sale of drugs to U.S. residents by sellers in foreign countries. FDA, and the other Federal agencies and State bodies, possess limited jurisdiction over sellers in foreign countries and must work with foreign governments to bring action against such individuals. FDA, the Customs Service, the Postal Service, and the Drug Enforcement Administration have greater authority to stop drugs imported illegally into the United States when the product reaches the U.S. border. These agencies have been successful in stopping some products from entering the country. The difficulty of finding these products at the border ~~combined with limited resources makes this an impractical, if not impossible, task~~ makes this a very challenging task. The sale of drugs to U.S. residents by foreign sellers poses the greatest challenge for the Federal government.

FDA's INTERNET DRUG SALES ACTION PLAN

FDA has drafted an action plan outlining expanded activities the Agency will take to address the unlawful sale of drugs over the Internet. ~~This plan is based on internal deliberations, meetings with Federal and State regulatory and law enforcement bodies, as well as organizations representing consumers, health care practitioners, and the pharmaceutical and pharmacy industries~~. FDA has identified ~~six~~ Five major areas of focus pertaining to the regulation of online drug sales, which are to:

- customize and expand the Agency's regulatory and criminal enforcement efforts;
- identify when and with which Federal agencies FDA should partner in joint activities;
- partner with State bodies to address domestic Internet sales;
- engage in public outreach;
- provide input to Congress regarding legislation; and
- ~~develop fiscal year 2001 budget requests.~~

1) Customize Enforcement Efforts

FDA's role in regulating online drug sales should be consistent with its traditional regulatory role. We also believe that, given the Agency's current limited resources, our existing approaches to enforcement should be adapted to focus more effectively on the problems posed by online drug sales. An effective Internet enforcement process requires establishing priorities, identifying and monitoring potentially violative web sites, ~~and coordinating triage to determine when a case will be pursued and whether criminal, civil, or regulatory actions (or all three)~~

~~should be undertaken~~. The Internet action plan calls for FDA to enhance its enforcement efforts by undertaking the following actions.

Establish Priorities – FDA will initially focus, but not confine, its online drug sales-related enforcement activities to the following areas, particularly where there is a significant public health risk:[1]

- Unapproved new drugs,
- Health fraud,
- Prescription drugs sold without a valid prescription.

Increase Data Acquisition -- FDA will expand its capability to monitor the Internet and identify violative sites by acquiring an advanced search tool and upgrading its data capabilities. This will allow the Agency to determine the kind and extent of unlawful conduct on the Internet and provide a measurement by which the Agency can judge whether its enforcement efforts have had an impact on illegal Internet behavior.

Coordinate Triage – The Agency has established a three-member case assessment team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs (ORA) and from CDER. This team will evaluate violative sites; and make appropriate ~~determine whether to proceed~~

[1] A *significant public health risk* exists when a consumer is at risk for harm (1) from the use of the product, (2) as the result of not taking approved drugs for a specific disease or condition, or (3) by delaying medical treatment recognized as safe and effective for a specific disease or condition.

referrals for criminal and/or civil prosecution.
~~criminally, civilly, or both; and ensure that criminal and civil enforcement actions are efficiently coordinated~~. Any Agency employee who identifies a potential violation on the Internet will refer the information to the team ~~for a decision on how to proceed~~. This process should ensure that decisions are made in a timely way with appropriate balance in terms of achieving a maximum deterrent effect while taking action, if needed, to remove harmful products from the market. The team will continue to oversee Internet-related enforcement activities while they are being investigated and will ensure that they are brought to appropriate completion.

Increase Enforcement Presence -- FDA believes that to effectively curb unlawful conduct involving online drug sales, more cases must be pursued. ~~it must bring more Internet-related cases~~. To do this, the Agency will draw from existing activities to increase its current enforcement efforts because we believe that illegitimate online drug sales pose a significant public health risk. The Agency will begin this effort with a modest reallocation of current fiscal year funds. ~~Without additional resources, however, FDA does not believe it will be able to act effectively against unlawful online conduct over the long term.~~

Issue Draft Promotion Guidance Document -- The pharmaceutical industry has asked FDA to issue guidance to explain how the Agency will regulate promotion of pharmaceutical products on the Internet. In response, we are developing a draft guidance for industry to address how the Agency will apply its statutory and regulatory provisions

to promotional activities on the Internet.

2) Identify Federal Agency Partners

Several Federal agencies, as well as the States, have the authority to regulate and/or enforce U.S. laws related to the sale of drug products online. Due to the growth of potential cases involving the Internet, there may be instances when working with another agency or State could result in a more effective enforcement action. In fact, FDA worked closely with FTC in developing the Operation Cure-All cases and also has been working with DOJ and State regulatory bodies.

To ascertain whether and when FDA should coordinate efforts with one or more governmental bodies, above and beyond the relationships that exist today, the Agency has researched the roles that the various Federal and State bodies should play regarding online drug sales. FDA also has met with several of those agencies, as described above, to identify opportunities for partnering in enforcement actions.

FDA believes that an important area where cooperation among Federal agencies can be quite beneficial is the sale of drugs to U.S. residents by foreign sellers. The Customs Service, the Postal Service, FDA, and the Drug Enforcement Administration all play important roles in taking action against the illegal importation of drugs. However, the Federal government's limited ability to bring enforcement actions against sellers in other countries, as well as the

feasibility of stopping drugs from entering the United States, pose difficult challenges for law enforcement. Generally, a determination of when and with whom FDA would engage in joint enforcement should be based on the kinds and severity of violative conduct identified through continuous Internet monitoring. Although FDA is expanding its Internet monitoring capabilities, the Agency also is

developing partnering arrangements with other agencies. In addition, FDA will participate in any Administration-led working groups that address online drug sales.

3) Partner with State Bodies and Other Organizations

FDA has met with and continues to meet with organizations representing State regulatory and law enforcement bodies, consumers, health care practitioners and industry. The purpose of these meetings is to gather information on 1) how issues relating to online drug sales should be addressed, 2) who should regulate and how they should regulate,

3) whether and what changes to the current law should be enacted, and 4) when to develop partnering arrangements. These organizations include:

- the National Association of Boards of Pharmacy,
- the Federation of State Medical Boards,
- the National Association of Attorneys General,
- the American Medical Association,
- the American Pharmaceutical Association,
- the American Association of Retired Persons,

- the National Consumers League,
- the American Society of Health-Systems Pharmacists,
- the National Association of Chain Drug Stores,
- the National Community Pharmacists Association, and,
- the Pharmaceutical Research and Manufacturing Association.

FDA believes that illegal selling and prescribing of approved prescription drugs over the Internet can be effectively addressed through cooperative efforts by FDA and the States. FDA is drafting partnering agreements with several State bodies to coordinate Federal and State activities aimed at illegitimate sellers and prescribers of prescription drugs.

4) Engage in Public Outreach

Every drug sale involves at least a purchaser and a seller. Although different purchasers buy drugs on the Internet for different reasons, all may be targets of unscrupulous business practices, such as the selling of unsafe, expired, or counterfeit drugs. Public outreach offers one mechanism by which the Agency can help protect consumers from dangerous or inappropriate drugs. Using the following media, FDA will expand its public outreach to explain what compliance and enforcement actions we already have taken and to inform the public about dangerous practices involving Internet purchases:

- Talk papers
- Articles in FDA Consumer Magazine

- Information on FDA's web site to inform consumers about what to avoid if purchasing drugs online, for example, buying prescription drugs without a prescription
- Work with the media.

The Agency also chairs the public education subgroup of the Interagency Internet Sales Working Group. The subgroup met last week to begin addressing whether and in what coordinated outreach activities the Federal agencies could engage. Some agencies have already issued educational materials. The subgroup will seek to build on existing activities and avoid pursuing duplicative efforts.

Finally, the Agency will keep working with consumer groups, health care practitioner organizations, and industry to encourage these parties to keep their constituents and the public informed about safe practices for purchasing drugs online.

5) Provide Input to Congress Regarding Legislation

Congress did not enact the current laws governing drug sales with the Internet in mind. Additional fact-finding will be needed to determine whether and to what extent existing regulatory and law enforcement frameworks do not adequately address Internet-related conduct. FDA believes that any decision to pursue new legislation should be made only after a careful and thorough analysis of the issues based on sufficient information, including discussions with relevant non-governmental bodies. FDA has met with and continues to meet with Federal

and State governmental bodies and non-governmental organizations to obtain their perspectives on how online drug sales should be regulated. Where appropriate, the Agency will provide input to Congress regarding whether and what legislation is needed in this area.

~~6) Request Additional Resources~~

~~As electronic commerce grows, unlawful Internet activities are expected to increase as well. The rapid growth in cyber technology will provide both new tools for law enforcement bodies and new mechanisms for violators to engage in illegal conduct.~~

~~FDA will need additional resources to effectively enforce the FD&C Act in the area of online drugs sales both now and in the future. New funding would be used to:~~

- ~~Further develop an Internet monitoring system~~
- ~~Investigate and bring more cases~~
- ~~Inform the public about dangerous online practices~~
- ~~Keep pace with rapidly changing cyber technology~~

Conclusion

Mr. Chairman, online shopping for pharmaceutical products clearly provides certain benefits for consumers. But it also has a number of risks. Additionally, the nature of this technology presents law enforcement and policy makers with unique challenges. FDA is grappling with the challenges posed by online drug sales, and with our need to carefully balance consumer access to information and products with protecting the public health. We believe we can adapt

our compliance and enforcement techniques to the new electronic marketplace, and we will continue to assess what changes in our procedures or the law might be appropriate. We look forward to working with Congress on this important issue.

I would be happy to answer any questions you may have.