BY ALAN ROCKOFF, M.D.

Under My Skin

Computer Correspondence

Ah, Monday morning. Time to check e-mails from far-flung patients. Miranda, a music major at Michigan, will remind me about her mometasone. Murray's mellowing on Minocin in Morocco.

Goodness, that inbox has certainly filled up over the weekend. What's this? Mortgage rates are that low? Wouldn't you know it—we just refinanced!

Look, I've been preapproved for credit. We have enough credit cards already, thanks.

Hmm, I knew they're importing medications from Canada and Mexico, but what kind of quality controls do they have in Bulgaria? Let's see, they're running a special on phentermine. Looks like a good price. I wonder what phentermine is. What else do they have … narcotics, anxiolytics … never mind. Why no topical steroids?

Finally, an e-mail from a patient! Don't recognize the name, though. I think I'd remember someone named Dirk Centagord. He's just canceling an appointment … what's this? This Dirk sure needs an editor. What kind of message is, "stethoscope mercy brunhilde huzzah buffalo carson allure?"

Now what? Look, I'm a physician, so don't expect me to believe you can change the size of anything with a cream. Besides, size doesn't matter. It does? She would? I never thought about it. … More drugs for sale. Judging by TV ads and cyberpromotions, half the world has fungal toenails and the other half has erectile dysfunction.

Another patient confirming an appointment. … Thelma Fontenot? A Rolex for $9.95? I wonder if it's genuine.

OK, knock it off—I got the mortgage stuff already. And phentermine, too. I'm just going to delete this stuff. Mortgage, delete. Credit cards, delete. Viagra, delete. Latin gibberish, delete. This is fun! Levitra, Cialis, Vicodin, delete, delete, delete. Ha! Hold on a second. … I think one of those messages I just deleted was the one I was waiting for from Miranda in Michigan. Great, how am I going to find it in the 3,000 messages in the deleted folder?

It's too bad. E-mail could be such a nice way to communicate. No phone tag, no trying to find a good time to call in a different time zone, no interruptions in the middle of patients. I installed a spam filter, but it worked so well that I couldn't even e-mail myself from home. How would I know if a patient tried to reach me and got his or her message blocked?

Now what? Great, first they enlarge you, then they shrink you back down. Alice in Wonderland had nothing on these guys. A revolutionary new diet pill that makes you lose up to 30 pounds in 30 days or less, automatically while you sleep? Body wrap at home to lose 6-20 inches in 1 hour! Put lindane under that overnight, and the scabies mites won't even find you in the morning.

Gustavo Fontenot? Must be Thelma's cousin from Caracas. … What? "Sehr geehrte Damen und Herren, die Weihnachtszeit naht und haben wir sicherlich noch einen guten Tipp!" Hey, Gustavo, I'll give you a guten Tipp in your guten Keester! A monkeypox on all the Fontenots. …

Another canceled appointment? Hey, fool me once—Paris Hilton is not a real name! Video? What video?

More credit card come-ons. Look at that, they're coming in bunches, 5 in a row, 10 in a row, 50, same message. More mortgages, 10, 20, 50, REFINANCE NOW, REFINANCE NOW, REFINANCE NOW. … Buy a Rolex, buy a Seiko, buy Vicodin, buy Cialis. The e-mails are like locusts, I can't kill them fast enough. … I don't want any of those drugs! Nobody by that name missed an appointment! I'm not going to update personal information for a bank I never heard of! I'm not shrinking or enlarging anything! How am I supposed to respond to marion allegiant asphalt tally-ho torture confrontation? I refuse to answer Verzieren Sie die Uhr mit einer Gravur und sie warden! They're coming faster and faster. … I can't see the screen … everything's going black. OK, that's it, I'm bailing out, I'm deleting the whole Outlook. Mayday! Mayday! SOS! Abort! Abort! Control! Select All! Alt! DELETE, DELETE, DELETE. …

Darn—I think I deleted Murray. ■

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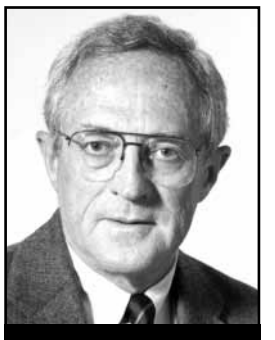
Guest Editorial

The Quandary That Is Called the FDA

In the wake of the Vioxx scandal, the Food and Drug Administration has suddenly become the whipping boy of both the press and Congress, a combination that is certainly hard to beat. A feeding frenzy has erupted, with charges coming from inside and outside the agency.

I, too, have been critical of the FDA at times and have expressed concern about some of its premature decisions and lack of postapproval surveillance of drugs. Nevertheless, let's place some of the blame where it should be placed; there is enough to go around. The FDA, created in 1906 as part of the Pure Food and Drug Act, has gone through a number of iterations in response to changes in the industry it is intended to control and in the human beings it is expected to protect. In its nearly 100 years of life, drugs have become more complex, and Americans have grown older. The acceleration of technology and pharmacology that has occurred in the last half century has provided physicians and patients a breathtaking array of medical options to prolong and improve the quality of life. At the same time, many of these products have the potential to adversely affect the safety of those individuals who are the treatment targets.



BY SIDNEY GOLDSTEIN, M.D.

It was but a short 12 years ago that Congress pressured the FDA to get into bed with the pharmaceutical industry in order to expedite drug approval and get new drugs to market faster. The pharmaceutical industry convinced Congress that unless the drug approval process was not accelerated, thousands of patients would die. Examples of this threat have so far been illusory. Industry also convinced Congress that it cost them too much to bring products to market, many of which were "me too" drugs. As a result of these initiatives, the approval of new molecular entities increased from 30 in 1991 to 53 in 1996. Now Congress, in its infinite wisdom, charges that the FDA has been too hasty and superficial with its drug approval process.

As medical therapy has changed in the last half century, so too has the role of the FDA in evaluating drugs' efficacy and safety. Mid-20th century medical therapy was focused on the treatment of episodic short-term diseases like pneumonia. Safety and efficacy could be measured in days or weeks.

Major changes occurred in the 1970s and 1980s that led to the consideration of drugs for the long-term prevention and treatment of chronic diseases that affect an increasingly aging population. Drugs and devices to treat atherosclerotic cardiovascular disease, hypertension, and diabetes mellitus were developed. Clinical trials suggested that drugs should be taken for a lifetime, and that could be a very

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