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Sunday, June 25, 1995



# Fear of FDA keeps companies from making medical claims

## E KEYBÓARDS

from Page IF

"Users find that the keyboard increases comfort and reduces fa-tigue," says Peter Acly, a spokes-man for Health Care Keyboard Co., which makes a product called the Comfort Keyboard System. Other models come from

tem. Other models come from such companies as lexmark, Mi-crosoft and Kinesis. But do these keyboards actual-ty help prevent keyboard-related injuries, such as terdonitis, car-pal tunnel syndrome, repetatve strain injury or overuse syn-drome? Companies won't say — and they have a reason for being

"For any product that is going "For any product that is going to claim a medical curative property, it needs FDA (the II.S. Fond and Drug Administration) certification," says Keith Kegley, Microsoft's product marketing manager for hardware products. "To qualify as a medical device is a lengthy complicated procedure."

Even if Microsoft wanted to go aven in interests warset up of through that procedure, it couldn't, asserts Kegley: "That procedure doesn't even exist. The FVA has not defined any kind of protocol to address this kind of disease."

Sharon Saidor an FTA cookse.

disease."
Sharon Snider, an FDA spokeswnman, says that the FDA does not regulate ergonomic devices such as keyboards or chairs designed to promote better posture. And without regulatory approval from the FDA, alw said, a compaw may not make medical claims.

from the FDA, alw said, a company may not make medical claims about its product.

But Saider disputed the claim that her agency has no procedure for comparies that wants to go through the rigor of PDA approvation in the companies of the companies of the claim to treat or cure a disease is by definition a medical device, "she said. "If a manufacturer wanted to market any medical device, with any claims on it, they (would) submit us application to the FDA and present data to show that it is fully effective for its intended treatment."

### Longthy process

The process approval takes at least aix months, Snider said, and possibly much longer. She said that she was not aware of any keyboards that had been given such approval; she could not say if any companies were currently having their keyboards evaluated, since the approval process is confidential. confidential.

Microsoft funded a series of Microsoft funded a series of tests by Dr. David Rempel at the University of California, Sun Francisco. The results, resently presented at an ergonomics conference in Seattle, showed that users have a more natural poture when using the Microsoft Natural keyboard than when using a conventional keyboard. The unstated claim is that this poture will produce less injuries. unstated claim is that this pos-ture will produce less injuries. But Microsoft's sales literature curefully avoids making any med-ical claims, lusteed, the company merely claims that many people will find its keyboard more con-fortable to use.

Does this approach make mone?

What is most conviorable?
"I've been in ergonomics for 30 years. If you can make people comfortable and get them to listen to the algrade that are sent out by their body, the probability of gettleg as far that you have a modical claim will be reduced," says Betar Jahns of Centertok Associates, an ergonomics firm based in Bellingham, Wash.
But which keyboard is the most confortable? Unfortunately, that question is a little like saking which car is the most comfortable, says Jahns.

which car is the most cumfortable, says Jahns.
"I think that people should use whatever they are the most computable with, and whatever they believe is," he says.

### **TO LEARN MORE**

As you might expect, the internal has tota of information about key-boards, RSI and related topics.

For example:

- M Dan Wallach's Typing Injury Ar-Dan Wallach's Typing Injury Archive: http://www.cs. princaton.sdu/"dwallach/tifeq/archive. In the Injury archive. In the Injury archive.

  Injury archive. Injury archive. In the Injury archive. Injury archive. In the Injury a
- E Paul Marahausen's ASI Web Page: http://www.engr.unl.edu/ ee/eeshop/rsl.html — an inforeeeesnop/summ — an invor-mative site with digrams and photographs of the correct and wrong ways to use keyboards. Many articles, as well as links to other resources.
- The RS1 Network Newsletter for information, send an e-mail message "subscribe ref" to majordomo@world.ald.com

The best way to choose a key-board is to get a loaner keyboard from the manufacturer and try it out, Juhns adds: "It is a tool that needs to be worked with before you decide whether to dish out the money."

That's easy for companies that

That's easy for companies that buy lots of keyboards. Consumers shopping for an alternative key-board should make sure they can return it for a refund if they don't like it.

In Oakland, an organization called SHARE (short for Spine called SHARE (short for Spine Hand Arm Rehabilitation Ergo-nomics), uses biofeedback to help people decide which keyboard is right for thom. People who are referred to SHARE can try out different keyboards while they are wired up with a variety of monitors that sense pain and atress.

"Because there are so many different kinds (of alternative keyboards), you really need to match the person and their body type and their size to the key-board that is going to help them the most," says Kathy Bender, a biofeedback therapist at the clin-

nomic keybuard.

"We teach people to key differ-ently — to lighten their key-stroke and reduce movement of their wrists while keying, and to let their upper body relax and improve their posture," she says. "Most people slam the space bar with the right thumb, and most people hold their little finger up in the air," habits that can lead to problems.

### **Good Instruction**

Bood instruction

Experts say it's more important for employees to receive good instruction in how to use normal keyboards than for exployers to rush out and purchase expensive ergonomic devices. That approach can also be much cheaper. For instance, one common keyboard problem in corporate America is the height of the dask. Wheroas must desks in the workplace are 29 or 30 inches high, the American National Standards Institute recommends that key

### **ALTERNATIVE** KEYBOARDS

All of the alternative keyboards on sale in the United States work with ISM-compatible computers, but some companies offer adapt-ers for Apple Mischigath comput-

- Apple Adjustable Keyboard, Apple Computer Inc. 989 (Mac only) Note: No longer menufac-tured in United States, must be special-ordered, typically through any retailer.
- E Comfort Keyboard System. Health Care Keyboard Co. (414) 536-2160. \$796 (PC, Mac. Sun and others)
- B. FlexPro. Keytronic (600) 262-6005, \$199 (PC)
- Kinesie Keyboard, Kinesis. (800) 454-6374; (206) 402-8100. 8390 (PC): 8490 (Mac)
- M Select-Ease, Lexmerk, (800) 359-5636; (806) 232-2000, 6176
- III Microsoft Nature) Kayboard Microsoft. \$98 (PC) An adaptor for Msc computers can be purchased through retailers.

all users. It's important, they say for users to try a range of differ-ent keyboards and see which one suits them best.

ent keyboards and see which one suits them best.
Here are a few models:
Here are a few models:
At \$796, Health Care Keyboard Co.'s Comfort Keyboard System consists of three key-board come and a left-hand section, a right-hand section and a numeric keypad — such mounted on universal joints, which let the aections be tilted or swiveled to any possible angle. A second adjustment on the Constort Keyboard allows the user to move the segments closer together or further apart, in order to accommodate users with different shoulder widths.

If for roughly half the price of the Comfort bystem, you can purchase the Kinesis keyboard. This keyboard takes a different approach, by doing away with rows of keys altogether. Instead, Kinesis places the keys in two wells in which you can rest your flugers. But unlike the Comfort Keyboard, the Kinesis is not adjustable: one slie fits all.

With a street price of under

But white she's seen hundreds of people helped by the alternative keyboards — many have had good results with the Kinesis in not adjustable: one size fits all.

But white she's seen hundreds of people helped by the alternative keyboards — many have had good results with the Kinesis model, she says — Bender believes k's more important for people to adopt good working habits than to have a high-tech, ergonomic keyboard. But had not a shallow "V" shape. The keyboard's sole adjustment allows the user to change the keyboard's height and vertical angle. According to the creating the neground a neight and vertical angle. According to the company, "The Microsoft Natural Keyboard features a carefully re-searched, attractive design that provides a more comfortable al-ternative to standard key-boards."

boards."

Lexmark takes a slightly sim-

Ill Lexmark takes a slightly almpier approach. Its keyboards have a hinge in the middle, making it possible to change the angle between the keys used for the right and the left hands.

All of the alternative keyboards on sais in the United States work with 12M-compatible computers, but some companion offer adapters for Apple Macintosh computers.

B. Although Apple salts its own Apple Adjustable Keyboard for the Macintosh, the product has been all but withdrawn from the U.S. market. "The status with the Adjustable Keyboard is that we are no longer manufacturing it in

Whereas misst desics in the workplace are 29 or 30 inches high, the
American National Survivadred in
attitute recommends that keyboards should be placed on surlaces that are 24 inches high,
any Microsoft's Kegley.
What's keeping desks half a
foot too high? "A combination of
tradition, lack of knowledge...
and skepticism that deak height is
a risk (actor," says Microsoft's
Kegley.

Choices

Professional ergonomicists say
that no single keyboard is best for