to its maximum effectiveness," one staffer told D&DL. The realignment appears to be a reward for Mohan, who came to the Devices Center only about 18 months ago from the White House Office of Management & Budget. Mohan is well respected by the center top-side, the staffer said. No successor for his job at device evaluation has been named.

Schneider will be "the principal science advisor" to the Devices Center, an FDA spokesman said. FDA Commissioner Frank Young has made it clear that beefing up the agency's science base is one of his priorities.

In a conversation with D&DL, Schneider said he will study computer regulation, the biological effects of radiofrequency and ultrasound energy, and materials used in device manufacture. He will also do new technology assessment, develop science policy, do science problem analysis, science planning and develop a research plan for the Center.

Schneider will not "compete with the science & technology office," the spokesman said, which will be responsible for actually doing the research. For the time being at least, Schneider will not have a staff of his own, but will be able to "borrow" staffers from various parts of the Center. He said he also expects to have considerable contact with device company officials.

FDA MAY MAKE MEDTRONIC PAY FOR REPLACEMENT OF LEADS

FDA may be on the brink of a wide-reaching policy decision that will affect all device companies whose products are recalled. A decision is expected soon on whether the agency will tell Medtronic to pay for the repair or replacement of its defective Model 6972 pacemaker leads. A third alternative is to force the firm to refund the cost of the devices, which had an unusually high failure rate. Prodding by several congressional offices, including that of Sen. William Proxmire (D-Wis.), may spur an agency decision (D&DL, 9/14, page 4).

The decision-making process appears scattered over several parts of FDA -- reaching from a part of the Devices Center compliance office to Commissioner Frank Young. The four criteria which FDA is using to decide whether to invoke the "repair, replace or refund" provision of the Food, Drug & Cosmetic Act are:

** The device must present a substantial hazard to public health.
** The device was not made at the level of state-of-the-art technology. "That's the toughest one to prove," a compliance staffer said.
** The defect was not caused by someone other than the manufacturer.
** The notification -- in the case of Medtronic, a Class I recall -- was not adequate to correct the problem.

GUIDE FOR MICROWAVE DEVICES NEEDS CLARIFICATION

Manufacturers of medical devices that are sealed or protected with instruments using microwave radiation should follow developments with a new FDA guideline. Such devices include syringes sealed in blister packs or plastic bags, or those protected with plastic coating.

Such coatings are applied with microwave radiation, and FDA's draft guide seeks to limit worker exposure to radiation that escapes during the sealing process. This is especially true for sealers on the market 10 years or longer. According to industry comments on FDA's draft "guideline for human exposure to emissions from

radiofrequency dielectric sealers and heaters" (D&DL, 10/19, page 6) microwave equipment should be uniformly regulated throughout the country.

Westinghouse Electric does not make sealers and has only one division directly regulated by FDA, Corporate Industrial Hygiene Manager C.W. Bickerstaff told D&DL. The company owns 13% of 7Up Bottling, but sealers are not used there. Still, in Nov. 5 comments(*), the company said the guide is an opportunity to influence "the development of federal protection guidance."

> "I'm just an interested person," he said, adding that Westinghouse favors a single, nationwide guide. "Industry wants one federal standard," Bickerstaff said. "We're concerned that if FDA comes out with something, OSHA may put something out," he added, alluding to a mandatory standard.

He criticized the fact that exposure limits differ from state to state. He also pointed out that the Occupational Safety & Health Administration's "should " (i.e., voluntary) standard would work better if coordinated with the one now being formulated by FDA. The FDA guide counts only for FDA-regulated firms.

He lamented the practice, whose extent is not documented, of users modifying microwave ovens and other microwave devices. These include increasing the cavity size or defeating a switch to allow operation with doors ajar.

Narda, which manufactures detectors and surveyors that measure the microwave radiation coming from the sealing devices, told FDA in Nov. 6 comments that the guideline must "be readily understandable to those...[determining] compliance." The firm also urged that the guide specify a testing procedure that would yield "repeatable, accurate results."

MORE PACER EQUIPMENT RECALLS THREATENED FOR CORDIS

FDA compliance staffers are still deciding whether to ask Cordis to do more recalls. Two are already in progress, but whether more are coming is unclear (see story, page 1). "It's possible we may ask the firm to do additional notification" on the printed wiring boards, an FDA staffer told D&DL. These are parts of certain models of the Lambda, Theta and Stanicor pacers that may malfunction, possibly resulting in a "no output" situation that "could be serious," Cordis Executive Vice President Harold Hershenson said. About 15,000 doctors would have to be contacted.

> According to an agency memo(*), Cordis has logged four complaints on the wiring board. "Two of the patients had a cardiac arrest, one patient suffered a concussion after fainting, and one patient had a heart rate of 40 in the emergency room," the memo said.

On the topic of the allegedly faulty Pacer Programmers 255 A III and 265 IAP, FDA appears to have at least temporarily acquiesced to the firm's continuing to sell the devices pending a final resolution of the matter.

"They didn't outright cease distribution," the staffer said, "but FDA agreed to hold up on a recommendation to stop distribution until the firm provided an updated addendum" explaining steps already taken to alert physicians. The problem involves mismatched labeling for new programming software sold with the device. FDA is deciding whether the updates are enough to flag the problem. A Sept. 27 Cordis letter to FDA sought to explain the sequence of events. "Even though various software revisions are available simultaneously," the situation should not cause