

be closer to the surface of the star the faster the star happens to be spinning. Particles close to the surface will be in a stronger magnetic field and will therefore radiate at higher frequencies than those at greater distances. On this basis, says Prof. Gold, "you can expect hard X-rays from the Crab pulsar. On the same calculation you can almost get visible light from the Vela pulsar (the next fastest) and nothing but radio for the other known pulsars."

Furthermore, he says, "If you see 100 keV X-rays, this implies that particles of energy necessary to make the rest of the Crab shine" are being expelled from the pulsar. Once they are

loose, these particles could also be the source of cosmic-rays, he says.

Spectral analysis by the NRL scientists leads them to suggest that the radio emission could be synchrotron radiation produced by protons at distances from the neutron star surface where the magnetic field is about a few hundred gauss. The optical and X-ray emission, they say, could come from electrons operating in fields of comparable strength.

**This does not** mean the experimenters favor Dr. Gold's model, or any other. "Our orientation is experimental," says Fritz. "We want to avoid tying ourselves to any one model."

Higher energy is where the Rice

scientists have made their observation, and, says Harnden, "We should have a better idea of the intensity of the high-energy pulsar when we complete our spectral analysis." Meanwhile they have calculated what they call a more accurate figure for the rate at which the pulsar's pulses are slowing down: They get  $36.51 \pm .02$  billionths of a second per day.

At NRL analysis also continues. "We haven't milked this set of data dry," says Fritz. "We expect to find significant structure in the pulsations. The X-ray profile differs from the optical and the difference is not due to the equipment."

## THE PANALBA CASE

### FDA vs. the boss

High level political intervention in the affairs of the Food and Drug Administration poses a considerable threat to the agency's regulatory power, particularly as FDA moves into the sophisticated and revolutionary area of making fine distinctions about drug efficacy. Such a threat was posed recently when Health, Education and Welfare Secretary Robert H. Finch took the virtually unprecedented step of making a decision that would otherwise have been the sole responsibility of FDA Commissioner Herbert L. Ley Jr.

**The Secretary's** action raises questions about his future role in FDA affairs and about Ley's position as official watchdog over the powerful \$3-billion drug industry.

The case involved an FDA decision to ban from the market a best-selling combination antibiotic called Panalba on grounds that it is neither effective nor safe (SN: 1/11, p. 33). In 1962, by order of a law pushed through the Congress by the late Sen. Estes Kefauver (D-Tenn.), FDA was charged with assuring that all drugs are not only safe but also effective. Only now is the agency ready to move on that mandate, which applies to drugs approved prior to the law's passage as well as since. In making that move, Ley is in for a bitter battle with industry.

Round one has just begun, and he had to take on Finch as well as the Upjohn Company of Kalamazoo, Mich., one of the country's largest drug houses.

From 1962 through 1966, FDA did little to evaluate drugs marketed prior to the passage of the Kefauver-Harris amendments. Then Dr. James F. Goddard took command of the agency, and asked the National Academy of Sciences to do the evaluating job for him. Ley took Goddard's position last September, just as the results of the NAS study were coming in.

In December, concurring with con-



FDA

*Ley: Guarding the patient's health.*



FDA

*Finch: Intruding in FDA business.*

clusions of the academy's panels on antibiotics, FDA announced its intentions of banning combination products. Commissioner Ley called them a shotgun approach where a rifle is called for. Drug houses had 30 days to file objections to the FDA maneuver.

**Upjohn retorted** that it needed more than 30 days to assemble convincing arguments in defense of Panalba, which had \$16.8 million worth of sales last year, and Ley granted the company another 120 days and a hearing. Then the academy released more results of its drug scrutiny, this time challenging the safety of one of the components of the Upjohn product: Novobiocin. That drug, it said, has a high incidence of side effects, including rash, liver dysfunction and blood disorders. In view of the fact that other, safer drugs have come along since 1957 when the product was first approved, the FDA concurred that Novobiocin singly should be sold under new, strict labeling and decided that Panalba should be removed from pharmacy shelves and banned, by June 14, before any hearing was held.

Upjohn, aided by Kalamazoo's Rep. Garry E. Brown (R-Mich.), took its case directly to Finch, Ley's boss, and the Secretary intervened. He instructed the commissioner to hold off action until a hearing could be held. Ley objected and eventually won Finch to his side. Though the Secretary has refused to comment publicly on the situation, a spokesman suggests that he did not realize, at first, the threat to health Panalba might represent.

**In another** virtually unprecedented act of interference, Finch also kept the House Intergovernmental Relations subcommittee, which oversees FDA from obtaining agency files on Panalba until he personally approved their release. A spokesman for subcommittee chairman Rep. L. H. Fountain (D-N.C.) says, "We do not intend to go through this again. We have not had to ask the Secretary's permission to see FDA files in the past and do not plan to in the future." Finch had issued orders that all potentially explosive issues, such as this, be channeled through his office, an order which still stands.

may 31, 1969/vol. 95/science news/523