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Studies on a new drug show comedy of errors when not enough patients are tested

A lesson in the safety and efficacy of new drugs is very simple: small studies are bad, big studies are good. This lesson has been proven all over again with a big trial of a heart failure drug called Natrekor (generic name: nesiritide).

Small studies made the drug look worrisome for some bad side effects. Now a big study has found those worries misplaced -- but it also found the drug doesn't work all that well for its main purpose of preventing fluid accumulation in the lungs of heart failure patients -- symptoms that give them a terrible feeling of near drowning.

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As quoted in the New York Times, a leader of the study of nesiritide, Dr. Robert M. Califf, a Duke cardiologist, said:

“Once again, small studies give us the wrong answers. There was no safety issue at all. To me, the really important message is that the drug got very widely used for reasons that are incorrect, and then it got bashed for reasons that are incorrect. Unless we do these kinds of large clinical trials we are engaged in a comedy of errors.”

And more from Dr. Califf, talking about both nesiritide and another heart drug -- Zetia -- now under a big study:

“F.D.A. by mandate could require studies, but that wouldn’t be necessary if clinical trialists and academic medical centers stuck to their guns and demanded the evidence before they used the drugs on a wide scale. Huge amounts are spent on marketing that could have been spent on a clinical trial.”

Listen up, Big Pharma.

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