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Drug Injury Watch

Prescription Drug Side Effects News and Information from Attorney Tom Lamb

Natrecor Safety Controversy Considered In Two May 2007 Medical Journal Articles

Thursday, May 10, 2007

Is Natrecor An Example Of Why Dr. Steven Nissen Thinks That The FDA Is Dysfunctional And In Need Of Reform?

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

Natrecor (nesiritide) is approved for the treatment of patients with acutely decompensated heart failure who suffer from symptoms at rest or with minimal exertion.

In the past couple of years there have been serious concerns, however, about whether Natrecor causes excess mortality and worsening renal insufficiency. In short, the issue is whether the benefits of Natrecor outweigh the associated risks.

The [May 2007 edition of Current Radiology Reports](#) includes two articles of interest to those of us who are following this issue of drug safety for Natrecor.

The first article, "[Nesiritide for acute decompensated heart failure: does the benefit justify the risk?](#)", is co-authored by Jonathan Sackner-Bernstein, M.D., of Clinilabs, Inc. in New York. Dr. Sackner-Bernstein is a long-standing critic of Natrecor, and has consistently argued that more testing of Natrecor is necessary. In this article Dr. Sackner-Bernstein reiterates that position, as seen in the free Abstract available online:

[Natrecor's] approval was based on a clinical development program that focused on surrogates and short-term effects on symptoms rather than clinical outcomes. The association between its use and subsequent risk of death raises the question of whether the endpoints assessed in the clinical development program were adequate, and provides the opportunity to evaluate the process of weighing risks with benefits. We conclude that with nesiritide, the risks of therapy outweigh the benefits demonstrated to date.

The second article, "[Safety and efficacy of nesiritide for acute decompensated heart failure: recent literature and upcoming trials](#)", examines the background of the ongoing controversy about the safety of Natrecor and looks forward to the future clinical trials that are intended to resolve the risk-benefit issue for this heart-failure drug. From the free online Abstract for this article:

We review the recent evidence regarding the efficacy and safety profile of nesiritide, and discuss upcoming trials designed to address concerns regarding safety and the comparative efficacy of nesiritide.

Finally, the same [May 2007 edition of Current Cardiology Reports](#) has a commentary by this medical journal's editor-in-chief, Steven E. Nissen, M.D. His piece is entitled "The US Food and Drug Administration: A Dysfunctional Agency in Need of Major Reforms". Unfortunately for us there is no free Abstract available for this item.

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1
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6
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