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Back to the Future: Nesiritide (Natrecor)

A recent editorial in The New England Journal of Medicine commented on the negative results of a clinical trial (published in the same issue) of nesiritide, a drug that had been approved by the FDA in 2001 (conditionally approved by Health Canada in 2007) for relief of dyspnea in patients with acutely decompensated heart failure. The authors of the recent clinical trial concluded: “On the basis of these results, nesiritide cannot be recommended for routine use in the broad population of patients with acute heart failure.”1 The editorials lamented the inadequacy of the data that had led to the approval of the drug in the first place, the 10 years of “fuzziness and ambiguity” that had followed regarding its use, and the “more than $1 billion” wasted on buying it.2

In 2001, when nesiritide was first approved in the US, The Medical Letter also expressed dissatisfaction with the quality of the data criticized by the 2011 editorialists, and concluded its assessment of nesiritide as follows: “Until more published data become available, nesiritide cannot be recommended for routine use in the broad population of patients with heart failure who have not responded to nitroglycerin and cannot be treated with nitroprusside.”3