not detected through generally available clinical tests. For example, it is not detectable through

6. Moreover, this NDMA test is not one that practitioners could have detected; NDMA is

produced.

manufacturers; none of those materials mentioned the potential NDMA risk posed by Zantac.

5. Although I have read product labeling and other information provided by Zantac’s

formation of N-Nitrosodimethylamine (NDMA), a probable human carcinogen

MD, and provided to me by Valeant’s TEC demonstrating the risk that Zantac causes the

4. I have reviewed the recent laboratory testing results prepared for Dr. Adam Brezina:

disease, and other conditions related to stomach acid.

inhibitors (PPI’s) — to patients for treatment of stomach ulcers, gastroesophageal reflux

for other histamine H₂ receptor antagonists (histamine blockers), and for proton pump

thousands of prescriptions for ranitidine hydrochloride (Zantac or Ranitidine) — as well as

3. As a practicing gastroenterologist and internist, over my career I have written many

board certified in both internal medicine and gastroenterology.

Center in 1982, and a fellowship in gastroenterology at Rhode Island Hospital in 1984. I am

in-Neuve, Belgium. I completed my residency in internal medicine at Montefiore Medical

my medical degree in 1978 from Universite Catholique de Louvain in Ottignies-Louvain-

2. I am based in Meriden, Connecticut, and my state license number is 029772. I received

been practicing medicine in those fields for 41 years.

1. I am a medical doctor specializing in gastroenterology and internal medicine. I have

I, JON T. ERNSTOFF, M.D., STATEMENT OF DR. JON T. ERNSTOFF, MD
I would advise the same.

particularly as there are other alternatives, I believe that my fellow gastroenterologists and
conditions that cause too much stomach acid, and the like. Until the risk is clarified, and
for the treatment of the drug's indications, i.e., stomach ulcers, gastroesophageal reflux disease,
Serious reconsideration whether any Zanaze product could be regarded as "reasonable and necessary"

Given what I now know, I would advise that the Centers for Medicare & Medicaid

reconsider prescribing the drug.

important who knows what I now do about rhythm and potential complications will also
prescribing of recombinant Zanaze to my patients. I believe that any gastroenterologist or
9. Until the FDA conducts a formal safety investigation of Zanaze, I will strongly reconsider

always been safe alternatives available.

produces in humans high levels of the probable carcinogen NDMA, particularly as there have
believe if would be more appropriate to consider alternatives to Zanaze, which potentially

8. In accordance with accepted standards of medical practice, except in rare circumstances, I

available with acceptable safety, cost, and efficacy profiles.

prescribing blocker or a PPI. For the indicated conditions, there were always alternative treatments

considered prescribing alternative medications for the indicated conditions, such as another

7. Had I known of the NDMA risk associated with Zanaze, I would have strongly

(primarily available blood or urine tests).