

## STATEMENT OF DR. JON J. ERNSTOFF, MD

I, JON J. ERNSTOFF, of my own personal knowledge and information, state as follows:

1. I am a medical doctor specializing in gastroenterology and internal medicine. I have been practicing medicine in these fields for 41 years.
2. I am based in Meriden, Connecticut, and my state license number is 025772. I received my medical degree in 1978 from Université Catholique de Louvain in Ottignies-Louvain-la-Neuve, Belgium. I completed my residency in internal medicine at at MetroHealth Medical Center in 1982, and a fellowship in gastroenterology at Rhode Island Hospital in 1984. I am board certified in both internal medicine and gastroenterology.
3. As a practicing gastroenterologist and internist, over my career I have written many thousands of prescriptions for ranitidine hydrochloride (“Zantac” or “ranitidine”) — as well as for other histamine H<sub>2</sub> receptors antagonists (“histamine blockers”), and for proton pump inhibitors (“PPIs”) — to patients for treatment of stomach ulcers, gastroesophageal reflux disease, and other conditions related to stomach acid.
4. I have reviewed the recent laboratory testing results prepared for Dr. Adam Bretholz, M.D. and provided to me by Valisure LLC demonstrating the risk that Zantac causes the formation of N-Nitrosodimethylamine (“NDMA”), a probable human carcinogen.
5. Although I have read product labeling and other information provided by Zantac’s manufacturers, none of these materials mentioned the potential NDMA risk posed by Zantac products.
6. Moreover, this NDMA risk is not one that practitioners could have detected; NDMA is not detected through generally available clinical tests. For example, it is not detectable through

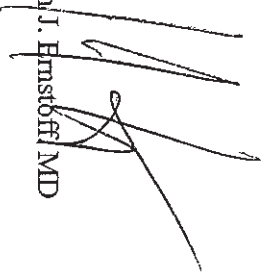
typically available blood or urine tests.

7. Had I known of the NDMA risk associated with Zantac, I would have strongly considered prescribing alternative medications for the indicated conditions, such as another histamine blocker or a PPI. For the indicated conditions, there were always alternative treatments available with acceptable safety, cost, and efficacy profiles.

8. In accordance with accepted standards of medical practice, except in rare circumstances, I believe it would be more appropriate to consider alternatives to Zantac, which potentially produces in humans high levels of the probable carcinogen NDMA, particularly as there have always been safe alternatives available.

9. Until the FDA conducts a formal safety investigation of Zantac, I will strongly reconsider prescribing or recommending Zantac to my patients. I believe that any gastroenterologist or internist who knows what I now do about ranitidine's potential carcinogenicity will also reconsider prescribing the drug.

10. Given what I now know, I would advise that the Centers for Medicare & Medicaid Services reconsider whether any Zantac product could be treated as "reasonable and necessary" for the treatment of the drug's indications, *i.e.*, stomach ulcers, gastroesophageal reflux disease, conditions that cause too much stomach acid, and the like. Until the risk is clarified, and particularly as there are other alternatives, I believe that my fellow gastroenterologists and internists would advise the same.



Jon J. Ernstoff MD