

# Medical Doctor and Researcher W. Scott Harkonen to Take His Case to Ninth Circuit Court of Appeals

*Appeal will focus on freedom of scientific speech*

## FOR IMMEDIATE RELEASE

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SAN FRANCISCO, CA – Today, attorneys for W. Scott Harkonen, M.D. filed notice of his appeal of the U.S. District Court's decisions denying the former InterMune CEO a judgment of acquittal or a new trial.

In 2009, Dr. Harkonen was convicted of wire fraud for approving the contents of a single press release issued in 2002. That press release announced the preliminary results of a clinical trial of the drug Actimmune, which was being tested as a treatment for Idiopathic Pulmonary Fibrosis ("IPF"), a deadly lung disease for which there was and remains no FDA-approved medical treatment. More of the patients who took Actimmune were alive at the end of the trial than who received a placebo. Dr. Harkonen was acquitted of a related charge of off-label promotion of the drug.

Neither Dr. Harkonen nor InterMune was ever charged with falsifying the data from the clinical trials. Rather, Dr. Harkonen was prosecuted for the conclusions he drew from data accurately reported in the press release. Dr. Harkonen maintains that medical researchers have the right to draw conclusions from accurately reported data, even if the government disagrees with those conclusions. In the appeal, Dr. Harkonen's attorneys will argue that his right to express his professional opinion in the press release is a basic freedom that the United States Constitution guarantees to all. Given that constitutional protection, Dr. Harkonen and his legal team have appealed the lower court's rulings to the U.S. Ninth Circuit Court of Appeals.

"The prosecution of Dr. Harkonen has been not only manifestly unfair to him, but will serve to chill the scientific discussion that is critical to vibrant and productive medical research," stated Mark E. Haddad, Esq., of Sidley Austin, LLP. "Particularly where potentially life-saving medicines are at issue, the constitutional freedom to speak freely about the opinions one draws from newly available data should be given the highest protection."

At Dr. Harkonen's sentencing hearing, the Court rejected the Department of Justice's assertions that Dr. Harkonen's actions caused any loss or harm to anyone. Indeed, the one individual whom the DOJ tried to highlight as a "victim" of the fraud turned out, upon

examination of the individual's medical records, to be someone who benefited greatly from taking Actimmune.

In her sentencing ruling, Judge Marilyn Hall Patel questioned the government's criminal prosecution of Dr. Harkonen. "It strikes me that there may be other ways of handling violations of this nature besides through criminal charges."

Pointing to his long career of good work, and the lack of any evidence of harm from the press release, the Court rejected the DOJ's requested punishment of 10 years in prison and a \$1M fine, instead sentencing Dr. Harkonen to three years probation, 200 hours community service, a \$20,000 fine, and six months home detention (the latter to be served only if the appeal is unsuccessful).

Dr. Harkonen's lifelong focus as a medical researcher has been on rare diseases like IPF – those often overlooked by the pharmaceutical industry because of the lack of financial incentive to develop a treatment for them. He is responsible for FDA approval of five drugs, three of which involved rare diseases, and most recently was working on potential treatments for Alzheimer's disease. He has spent the better part of the last three years, however, defending his work and his reputation.

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