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LETTERS TO THE EDITOR

The Administrative State and The Death of Peter Gleason, MD: An Off-Label Case Report

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Sleep medicine continues to have a major impact on medical education in this country. Ironically, this impact comes from the courtroom and not the classroom. Best known is the Libby Zion case where malpractice allegations arising from sleep deprivation and shift work caused a national change in trainee work schedules.[1] Lesser known is the criminal case of Peter Gleason, MD.[2]

Dr. Gleason, a private practice psychiatrist, was a high-volume prescriber of the narcolepsy drug Xyrem (sodium oxybate, the sodium salt of GHB). He advocated its off-label use and the manufacturer frequently hired him to give promotional lectures stating his off-label opinions.[3] In 2006, without warning, Gleason was arrested for his off-label advocacy. He was indicted on four felonies, including health care fraud.[2] He faced $1 million in penalties and 28 years in prison. The indictment included allegations against his CME activities that dealt with Xyrem if funded by the manufacturer. His crime was advocating Xyrem for "…fatigue, chronic pain, weight loss, EDS not associated with narcolepsy, depression, bipolar disorders, fibromyalgia, insomnia, and movement disorders such as Parkinson's disease."[2] These uses have a basis in clinical practice and basic science, but being off-label were based on anecdotal and theoretical data.[4] Despite this, the FBI publicly stated Gleason's conduct was "…indistinguishable from a carnival snake-oil salesman…"[5] Within legal circles, the indictment was considered "creative."[6]

The indictment included a criminal forfeiture allegation. Designed as a prosecutor's tool to be used against illegal drug dealers, it freezes and isolates a defendant's finances prior to trial.[6] In 2010, Gleason acquiesced to a federal misdemeanor and was sentenced to a $25 fine and one-year probation. He was financially destitute and faced state medical board disciplinary proceedings. In 2011, one month after probation ended, he committed suicide. His sister stated his death was from governmental overreach for "truthful speech to fellow physicians about the off-label use of an FDA-approved drug."[6]

The doctor received some vindication. The sales representative indicted with Dr. Gleason was convicted of felony drug misbranding. With help from national legal foundations, that felony conviction was overturned in 2012 by the Second Circuit Court of Appeals on First Amendment grounds.[7] Some would argue that decision unleashed corporate malfeasance and undermines the FDA's authority.

The Gleason case set a lasting precedent for promotional lectures, and drug companies routinely refer to the case during promotional speaker training. The Gleason case reined in off-label statements, turning forums into rote presentations of the package insert. To protect themselves, companies require that such presentations be composed of only FDA approved slides presented in a defined order. Speakers cannot make spontaneous statements regarding off-label options.

This truth-in-advertising comes with a price. Prior to the Gleason case speakers would modify, add, or delete data from promotional presentations. New side effects, dosing deviations from the package insert, and pediatric use are all topics that cannot be spontaneously opined, even with data on such off-label parameters. Given the banality of promotional presentations, physician attendance has dropped.

Published off-label data are frequently presented in case reports, case controls or other poorly designed formats. Some argue that such data are a threat to public safety, but these data represent the "art" of medicine upon which the "science" progresses. Quality off-label data from high-impact, peer-reviewed journals should be openly available at promotional presentations. It could raise journal prestige and impact.

With full disclosures, the free exchange of quality medical information among physicians should not be limited by the CME status or funding source of an educational forum.

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REFERENCES

1. Asch DA, Parker RM. The Libby Zion case. One step forward or two steps backward? *N Engl J Med*. 1988;318(12):771–775.
2. *United States v Gleason*, No. 1:06-cr-00229-ENV - Document 28 (EDNY 2007).

3. Berenson A. Indictment of doctor tests drug marketing rules. New York Times website. https://www.nytimes.com/2006/07/22/business/22drugdoc.html. Published July 22, 2006. Accessed July 24, 2018.
4. Tunnicliff G, Cash CD, eds. *Gamma-Hydroxybutyrate: Molecular, Functional, and Clinical Aspects*. New York, NY: Taylor & Francis, Inc.; 2002.
5. The United States Attorney's Office, East District of New York website. Psychiatrist Charged with Conspiracy to Illegally Market the Prescription Medication Xyrem, Also Known as "Ghb," for Unapproved Medical Uses on Behalf of its Manufacturer. https://www.justice.gov/archive/usao/nye/pr/2006/2006apr05.html. Published April 5, 2006. Accessed July 25, 2018.
6. Silverglate H. *Three Felonies a Day: How the Feds Target the Innocent*. New York, NY: Encounter Books; 2011.
7. *United States v Caronia*, No. 09-5006 (2d Cir. 2012).

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The author, Dr. Ronald E. Kramer takes full and sole responsibility for the content of this manuscript. This study had no industry-sponsored support. The author was on the speaker's bureau for Xyrem from its release in the United States in 2002 until approximately 2014. The author was active on speaker's bureaus for just about all epilepsy and sleep medicine products from 1990-2014. The author has had only one malpractice allegation in his career and that dealt with Xyrem (*Bettenhausen v Kramer*, No. 1:04-CV-025620-RPM).