Letter

Advertisement and Legal Liability for Falsifying Data

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The manipulation of data in clinical trials of the blood pressure drug, Diovan, is a major medical scandal. Studies using the data were published in several journals, but were later retracted. On the one hand, articles were used for advertising campaigns for Diovan until they began to be viewed with suspicion, and were then retracted. On the other hand, Japan's pharmaceutical law prohibits the advertising, description or circulation of false statements regarding pharmaceuticals. The Japanese subsidiary of Novartis and its former director were accused of falsifying the data to highlight the benefits of Diovan.[1] Based on the background of this case, the main issue of the trial was whether articles published in journals using the falsified data should be considered false advertising.

In June 2021, Japan's Supreme Court upheld the Lower Court's ruling that the subsidiary and the former director were not guilty.[2] In relation to pharmaceutical law, the court defined an advertisement as an act of informing unspecified or large numbers of people to encourage them to purchase the medication that is advertised. The court concluded that the articles using falsified data did not fulfil the definition because the main readers of the articles were experts, such as researchers and doctors.[3]

Interestingly, the court described the peer review system as highly reliable. Publishing the results of studies in academic journals is naturally expected to be verified and critiqued by experts in the same field to confirm the reliability of the contents.

Furthermore, one of the judges, Atsushi Yamaguchi, shared his opinion that, if the writing, submission and publication were to be subject to such regulations, it could have chilling effects on academic activities.[3] Therefore, such regulations are also inappropriate in consideration of academic freedom.

However, this decision is problematic, and the court should have passed a harsher judgement in this case. First, given that Diovan is a prescription medication, the court must have considered that the journal articles do exert advertising effects. By the court's definition, the problem is beyond the scope of advertising because the main readers are experts and not unspecified or large numbers of people. This definition raises problems where prescription medications are concerned. With regard to over-the-counter medications, it is important to consider whether advertisements exert their effects on numerous people, especially potential users, as can be understood in court's definition. However, advertisements for prescription medications, as in this case, do not require such pervasive effects. That is, if advertisements exert their effects on doctors who then prescribe them for patients, it is sufficient to encourage them to purchase the medication. In this sense, the court used an excessively narrow definition of an advertisement.

Second, the peer review system is a fundamental part of academia, but it is imperfect. Here, it is important to consider peer review before publication (pre-peer review) and after publication (post-peer review) separately. The court focused on post-peer review, as verification and criticism after publication are mentioned. In some cases, however, it is too late for verification and critique by other experts because products have already been sold and may even have resulted in health problems. Therefore, excessive trust in post-peer review is dangerous to public health. In addition, pre-peer review cannot prevent the use of falsified data because it assumes the authors' integrity. Reviewers are not obliged to verify whether the data have been falsified. Even if this should be the case, it is not always possible to detect such falsification of data.

Third, a classification system for regulations is necessary. The judge, Yamaguchi, raised concerns over the possible chilling effects on academic activities and made the decision that no steps should be taken in this case. Clearly, this is feasible, but it is also possible for regulations to be tailored to avoid such chilling effects whilst punishing undesirable actors in academia. Here, intentionality is important, and should not be confused with carelessness or negligence, which may occur but is not always legally liable. The court could have made it clearer when and under what conditions legal liability would be imposed whilst avoiding negative effects on academic freedom.

In conclusion, the court should have ruled that the use of falsified data in the journal article represented illegal advertisement in this case. By not doing so, the judgement leaves room for future undesirable false advertisement of prescription medications.

References

1. McCurry J. Former Novartis employee arrested over valsartan data. Lancet 2014; 383: 2111.

2. Japan's top court upholds not-guilty ruling over Novartis data. Jiji press, June 29, 2021. https://sp.m.jiji.com/english/show/13243 (accessed August 8, 2021)

3. Supreme Court. The case of violation of pharmaceutical law (in Japanese). June 28, 2021. https://www.courts.go.jp/app/files/hanrei_jp/456/090456_hanrei.pdf (accessed August 8, 2021)