G145 Income-Based Medicine and the Avastin Dilemma: How Italian Doctors Carry the Tangled Skein on Their Shoulders

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After attending this presentation, attendees will learn about distributive justice concerns and their consequences on medical liability.

This presentation will impact the forensic science community by illustrating how evidence is not a value in itself, but needs to be interwoven with other societal values in a clear way.

The treatment of age-related macular degeneration has opened a wide-ranging discussion. Although ranibizumab (Lucentis) is a licensed and approved treatment, many ophthalmologists in Italy and worldwide continue to prescribe bevacizumab (Avastin), which is licensed for treatment of some metastatic cancers but not for the treatment of eye conditions. The off-label use of bevacizumab appears to produce comparable results, as shown by guidances of scientific societies worldwide and by the CATT Research Group, at a substantially lower cost than the licensed treatment of ranibizumab.

The practice of medicine is no doubt based on the appraisal of scientific evidence and, in such a sense, the drug licensing process plays a fundamental role. Nonetheless, the practice of medicine has long since shown universalistic attitudes.

The debate Lucentis-Aventis unveils the controversial dispute between the mere devotion to scientific evidence in clinical practice and the relative weights that some other elements (e.g., sensitive and cost-effectiveness analysis) play in medical decision-making. In the first hypothesis, the off-label use of drugs would be discouraged in favor of licensed drugs. This approach would have the side-effect of dramatically restricting the universalistic access to healthcare. In the second hypothesis, criticisms are grounded on the difficulty of balancing the role that empathy, cost-effectiveness, or other criteria should play in distributive justice. Given the need to prove the equivalence of therapeutic effect, pharmaceutical companies have not always demonstrated responsiveness to social and economic context, due to the profit loss subsequent to more cost-effective treatments. In addition, in the absence of clear guidances for the unlicensed or off-label use of drugs by regulatory authorities, it would be legitimate to doubt the universalistic attitude that inspires such controversial medical practice, as universalism is patently bounded to efficacy.

In both hypotheses, there is a small risk to subsume scientific evidence to profit maximization (income-*based medicine*), given that collection and appraisal of evidence risk to be conditioned by actual and prospective earnings of pharmaceutical companies without any referral to positive consequences for the health status of the society. In such a context, given that the responsability for the off-label use of drugs rests on the shoulders of prescribing doctors, the decision between the aforementioned hypotheses appears to be dependent on the individual professional person, directly bringing about unfair inequalities. In addition, the legal protection for those clinicians who act cost-effectively appears to be lacking under the Italian laws, on the basis that incomplete scientific evidence could be given to prove one's diligence in case of off-label use of drugs. The controversy is relevant, because the relatively wide scientific evidence gathered in favor of the off-label use of bevacizumab is uncomparable with that available in other clinical settings (e.g., Neonatal Intensive Care Units), where the off-label use of drugs is nonetheless common, even though the information about the optimal dosage, specific pharmacokinetics characteristics, as well as potential adverse reactions, is insufficient.

Off-Label Drugs, Medical Liability, Ethics

 ** Presenting Author*