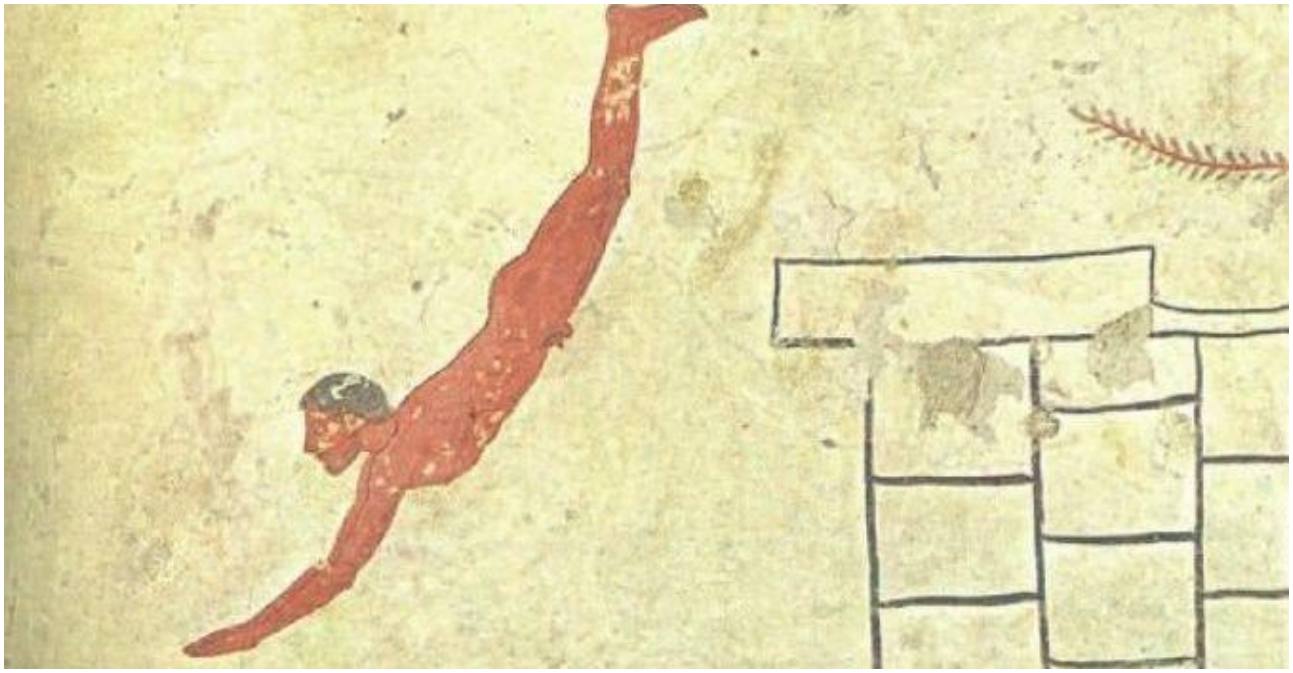
CALL FOR PAPERS

Rivista di Biodiritto – Biolaw Journal



3/2014

CALL FOR PAPERS

The Editorial Board, composed of Carlo Casonato, Roberto Bin and Antonio D'Aloia, has the pleasure of launching, in occasion of the third issue of the journal, a call for papers dedicated to the following theme.

Freedom of Scientific Research and Drug Testing

Submitted papers will be anonymously evaluated by the Steering Committee and selected for publication on the Journal.

Manuscripts shall not exceed 60.000 characters (spaces included) and could be submitted in Italian, English, Spanish or French (an abstract in English is required). Author guidelines available at http://www.biodiritto.org/images/Call14/AuthorGuidelines%20Biolaw%20Journal%20EN.doc.

The deadline for electronic submission to biodiritto@gmail.com is **January 7th, 2015**.

Freedom of Scientific Research and Drug Testing

In the field of BioLaw, the commercialization process of drugs is a highly debated topic, involving different potentially competing interests that need to be assessed. For example, think about possible interferences between the individual right to freedom of research and (constitutionally relevant) public interests, concerning safety, public health and human dignity or about risks connected to trials carried on in legal systems characterised by low standards of fundamental rights' protection.
Moreover, the identification of boundaries between public interests and individual freedoms is a hard challenge. For example, is it possible to draw a public understanding of the freedom of scientific research, emphasizing the public interest to the advancement of scientific knowledge? Do patients have a right to drugs testing and to their outcomes?
Moreover, new legal interests, emerging from an increasing social awareness, should be taken into account by regulators in realizing the described balancing processes. These include, for example, the protection of animals, addressed by EU Directive 2010/63/EU. In this field, conflicting interests should be carefully managed, as they are sometimes addressed by strict regulations, consisting of legislative prohibitions. This approach raises serious concerns as to their reasonableness and proportionality.

In the context of pharmaceutical research, special attention should be paid to the legal problems regarding the so-called "abuse drugs". This category is quite difficult to be defined from a legal point of view, as it is not always overlapping with the legal definitions concerning "narcotic substances". Many legal orders introduced less restrictive regulations concerning the clinical uses of

these so called “abuse drugs”, such as cannabis and its derivatives. All of these considerations, and many other comparative arguments, cast serious doubts on the adequacy, appropriateness and rationale of the Italian legislation on the matter. The procedures regulating research and experimentation of drugs containing active principles derived from these substances are among the most critical points of this debate: in the underlying balancing process many interests – often morally pregnant (e.g. testing “abuse drugs” on pregnant women with the purpose of investigating effects on the fetus) – should be taken into account.
In this respect, additional questions arise as to the validity of experimental data drawn from studies and research conducted abroad, following procedures that would not meet national and European standards.

A further point to be considered is that of pharmacovigilance and the role of medicines agencies in the regulation and control of the pharmaceutical drugs market. A specific focus might concern the problem of further adverse effects that drugs may produce during time and that should be included into therapeutic indications and conditions of use and printed on warning labels. It follows that producers should be held responsible for the adverse effects that were not promptly made public, causing therefore a delay in the quick withdrawal of products from the market.
Other relevant issues concern off-label drugs prescription, that is to say the prescription of drugs for uses other than those approved by Authorities: specific difficulties arise in coordinating the freedom of scientific research, the autonomy of the physician and the safety of patients, even with reference to “head-to-head” clinical trials, designed to evaluate not only the effectiveness and safety of a treatment, but also its costs on a comparative basis. Compassionate use of drugs may further arise thorny issues in balancing hope of patients and scientific concrete reliability of employed products.

Clinical trials data (see art. 81 U.E. Reg. n. 536/2014 and European Medicines Agency policy “on publication of clinical data for medicinal products for human use” of 2 October 2014) and the related aspect about their ownership should also be adequately addressed.

The above listed issues obviously involve many scientific fields requiring lawyers to get in touch and dialogue with “hard” scientists. For this reason a multidisciplinary framework of debate is particularly valuable.

Submitted papers could deal with the following main issues:
- drug development, clinical trials and public incentives that lead to scientific research;
- patients’ right to claim public effort in scientific research;
- freedom of scientific research and threats to “new” protected interests;
- limitations to animal testing, in relation to other protected interests;
- legal definitions of “abuse drugs” and coordination with narcotics laws; clinical trials on “abuse drugs”; acquisition of sufficient knowledge about those drugs (e.g. cannabis) and threats to competing protected interests;
- use of experimental data taken abroad with procedures banned by national and EU legislation;
- clinical trials, pharmaceutical drugs supervision and regulation authorities;
- advanced therapy medicinal products regulation;
- cost-related motivations for conducting clinical trials;
- *off label* drug prescription (benefits, risks, public healthcare costs and “head to head” clinical trials) and compassionate use of drugs.