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Declaración de la Academia Chilena de Medicina sobre el Título V de la Ley 20.850 (Ley Ricarte Soto) y su proyecto de reglamento “De los ensayos clínicos de productos farmacéuticos y elementos de uso médico”.

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Abstract

Declaration of the Chilean Academy of Medicine of Law 20.850 "On clinical trials of pharmaceutical products and medical devices" and of the bylaw that will regulate its application.

In Chile, high cost treatments required by selected medical conditions are financed by the State, according to Law 20.850. A bylaw under discussion by the Senate regulates clinical trials, posing complex issues that will endanger local interest in front-line research: 1) The exclusive and mandatory control bestowed to the Institute of Public Health during all stages of the trials and also the surveillance of institutions performing clinical trials, overriding their Clinical Research Review Boards; 2) The 10 year period during which any adverse event is assumed to have been caused by the medication or devise evaluated by the trial, unless the contrary is proven in a judicial process; 3) Individuals submitted to the trials are entitled to free post trial access to the treatment received during the study, financed by the trial supporting entities and as long as the drug or devise is considered to be useful. While agreeing with the need to have a National Registry of Clinical Trials, we predict that the mentioned critical issues in the bylaw will lead to difficulties and unnecessary judicial processes, thus limiting clinicians' interest in performing research. We propose to modify the bylaw, excluding responsibilities on events associated with the natural evolution of the medical condition, with patients' ageing or with comorbidities and clinical events considered unpredictable when the protocol was accepted. We recommend that the free post trial access should be a joint decision involving the patient and the attending physician, taking in consideration that the volunteer has been exposed to risks and burdens, or when discontinuation of treatment entails a vital risk until the treatment under study has been approved and becomes available in the national market.