

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 Declaración de la Academia Chilena de Medicina sobre el Título V de la Ley

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©, 2017 Sociedad Chilena de Infectología. All rights reserved. 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 device 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 device is considered to be useful. While agreeing with