

## Letter to the editor

**Pandemic, public policy and ethics*****Pandemia, política pública y ética***

Dear Editor:

The reality has been overwhelmed by the pandemic: tensions between the different national and regional authorities, high costs (still unknown), constantly changing and contradictory protocols, infection of large numbers of health workers and consequences on individual health and rights not always justifiable. This event do not occur in isolation but linked to economic, political and social processes.<sup>1</sup> Define a public policy is making a judgment in a context where the results and probabilities are simply unknown. Decisions must be based on the best scientific evidence available, but often there is no evidence. A public health emergency disrupts the normal processes of patient care. An ethically sound framework must balance the duty of care that requires patient loyalty, the alleviation of suffering and respect for the rights and preferences of patients with the duties of promoting equity, public safety, and protecting the health of the community and fairly allocate limited resources. Health care leaders have a duty to plan for the foreseeable ethical challenges. Classification decisions need to be made regarding the level of care, decisions regarding the shortage of personal, space and supplies, safeguard workers and protect vulnerable populations.<sup>2</sup>

Actions on the population, although they are intended to guarantee a benefit for the aggregate health of the community, do not necessarily do so for each person, who must assume limitations on their freedom and personal losses. Public health introduces tensions in people's autonomy. The concern caused by the imposition of obligations or restrictions on the group of still healthy citizens in name of possible additional improvements, of doubtful benefits or of an uncertain balance between their damages and benefits requires more justification than has been provided, since it leads to interference in elections and personal lives.<sup>3</sup> What offers a lot of good to the community can be catastrophic for the individual. It has had a tremendous cost: the victims, those affected by the virus with its morbidity and mortality, and their families, with the consequent economic and social repercussions, the suspension of educational activities and restriction of our personal liberties. So are those who have not received enough attention from the health system due to the amount of resources dedicated to the prevention and control of the epidemic.<sup>4</sup>

Clinical medicine has an ethical contract to care for patients, maximizing beneficence and minimizing maleficence, respecting

autonomy and equity. However, public health lacks that consensus. The objectives of caring for the entire population lead the goods of society (the health of citizens) to prevail over the right of people to make their decisions autonomously. Better training and more transparent information can help us.

In this context uncoordinated and unusual responses are not surprising, with contradictory interventions that demonstrate the lack of coherence. Coordination mechanisms must be established that do not depend solely on the good understanding of the parties involved. Crises are challenges from which we must learn, with mistakes and successes, since they serve to adjust the devices and refine our response to other future, unavoidable and unthinkable crises.<sup>1,5</sup> Crises are anything but unexpected.

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**Conflicts of interest**

None.

**References**

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**Medicamentos huérfanos, incentivos e incertidumbre sobre su relación beneficio-riesgo*****Orphan drugs, incentives and uncertainty about their risk-benefit balance***

Sr. Director:

El artículo de Vicente et al.<sup>1</sup> nos ha llevado a compartir algunas reflexiones. El término «enfermedad rara» está indudablemente ligado al concepto «medicamento huérfano».

Bajo la premisa de garantizar la equidad en el acceso a tratamientos a personas que padecen patologías con una prevalencia limitada, el Reglamento (CE) N.º 141/2000 establece incentivos para el desarrollo y la comercialización de medicamentos huérfanos, como la exención total o parcial de tasas, asesoramiento metodológico y la exclusividad comercial. Además, una vez en el mercado, tienen un coste desorbitado. En ocasiones se trata de medicamentos con larga experiencia de uso en otras enfermedades, cuyo precio se multiplica al obtener una nueva indicación para una enfermedad rara. Estos aspectos han suscitado un gran interés en las compañías farmacéuticas, y se ha observado un incremento en las solicitudes y las concesiones de designación de «medicamento huérfano»<sup>2</sup>.