

chair as a result of her Pompe disease. The court noted that many other patients must live their lives in a wheel chair without having to be given a drug that might cost 500 000 Swiss francs per year. But this is a *non sequitur*. Patients who are paraplegics will be medically stable for many years in a wheel chair. They have no medical need for additional costly life-sustaining interventions. But this Pompe patient will deteriorate without enzyme replacement therapy and die prematurely. This is a morally relevant factor to which this court seems to have given no weight. Again (without knowing all the medical details for this patient), if this patient were doomed to die within the next year or two and enzyme replacement therapy would not alter that outcome more than marginally, then a good case could be made for saying she had no just claim to this therapy. But this would be irrelevant to other patients with adult-onset Pompe disease diagnosed sooner with much better life-prolonging prospects if they have access to enzyme replacement therapy. Regrettably, the court failed to call attention to this distinction.

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## A wise and just decision

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The Swiss Supreme Court revealed an expensive bill in its reasons for the judgment. The annual drug cost for treating a patient with constrained breathing ability (Pompe's disease) is half a million Swiss Francs. 2.8 percent of the Swiss adult population is estimated to suffer from a similar restraint due to chronic obstructive pulmonary disease (COPD). If each of these patients received half a million francs worth of medical treatment, the total bill would amount to 90 billion francs and the current average monthly social health insurance premium would have to increase by 1100 francs to cover it.

Are Swiss citizens really willing to ensure that patients with Pompe's disease and similar sicknesses are treated with the latest medical technologies, and also willing to accept the corollary of paying five times more for health insurance? This decision requires a valuation of the utility of medical outcomes. And, since the potential outcomes are improvements in the quantity and quality

of life, one has to follow the Supreme Court and value life itself. More precisely, not the specific life of Mrs A and Mr B is at issue, but a statistical life – a computed number that combines changes in mortality risk and quality of life and that can be tagged with a price.

A generic measure for health outcomes, often used in health economics and medical studies, is the QALY (quality-adjusted life year), which considers quantity and quality of life in a multiplicative way. Quality of life is measured on a cardinal scale ranging from 0 for the worst possible outcome (usually death) to 1 for the best outcome (perfect health). A well-founded procedure to measure the quality of life is the so-called standard gamble for decisions under uncertainty, which was axiomatized by von Neumann and Morgenstern [1]. In this approach a respondent is faced with an illness that leaves him in a defined suboptimal health state and a treatment which would cure him with probability  $p$  and lead to immediate death with probability  $1-p$ . The suc-

cess probability  $p$  is then varied until the respondent is indifferent between the certain health state without treatment and the gamble implied by the treatment. The resulting indifference success probability marks the weight that is attached to the given health state in the QALY calculation [2].

Evidenced-based literature on the treatment of Pompe's disease with the drug Myozyme® is thin. The LOTS study [3] showed a significant effect on patient performance in the six-minute walk test and in forced vital capacity (FVC) of the lung. Patients in the treatment group were able to walk 28.1 meters further on average than the control group over the 78 week observation period. With respect to FVC, the difference between the treatment group and the placebo group was 3.4 percentage points (56.7% and 53.0%, respectively). No effect on mortality has been reported, and no QALY calculation is available to date. Kaplan [4] offers a quality of life weight for the effect of surgical treatment for COPD equal to 0.03 on the 0–1 scale. If we use this figure as a proxy, the Pompe's disease patient would have to be treated for about 33 years to produce a benefit equivalent to one year of life at full health. According to the QALY ruling by the Supreme Court, the drug treatment cost of 500 000 francs per year implies that a patient's life year had to be valued at 16.5 million francs to justify the investment.

Empirical studies on the value of a statistical life are based on questionnaires or data from markets where risks are traded – e.g. the labour market or markets for airbags and other safety features. Viscusi and Aldy's [5] survey of the pertinent literature offers a range of 5.5–7.5 million US\$ for a statistical life. From this figure, the value of a life year can be calculated as follows. The average residual life expectancy of an adult Swiss person is around 50 years. Dividing a value of life of 5 million francs by 50 years gives a value of a life-year of 100 000 francs, which corresponds to the figure quoted by the Supreme Court. Whether or not 100 000 francs is the appropriate threshold for one year in perfect health is of course a political matter. The high standard of living in Switzerland might well imply that an average Swiss citizen's willingness to pay for a QALY exceeds this threshold. On the other hand, it is certainly doubtful that the average citizen would accept the 16.5 million francs per QALY in the Myozyme case.

The valuation of life, by the way, is really a decision we make all the time. In a hurry, we sometimes cross a dangerous street even though we may end up dead in the worst case. Many of us also voluntarily engage in additional risks such as rock climbing, skiing off-piste or riding motor bikes; risk for fun is the trade-off in these cases, and it always involves a valuation of life. If individuals do it, the government acting on their behalf should to do it as well in order to allocate resources among health and safety purposes in a more rational way. It is noteworthy that a government allocates rations when defining the public health basket. It does

not deprive citizens of services since they can, on principle, access medical care through private markets. The public coffers would be overstrained in no time if they were required to cover all medical services that are available today and that will be in the future. Recent studies indicate that the share of health care costs in the gross domestic product of the USA could rise as high as 40 percent by 2050 [6]. It is unimaginable that the government or a social health insurance collect 40 percent of the citizens' income and reallocate it to their medical needs. The expected efficiency loss of such an endeavour would be huge. Confining the social health basket represents a major challenge for governments in the Western world. Nobody knows how societies will deal with it, but quite obviously there is no way around this decision.

The Supreme Court ruling on Myozyme concerned an identified life rather than a statistical life. Does the above reasoning still apply? Two further points are of relevance here. First, the success of treating the Pompe's disease patient is doubtful. Even if the patient's health did improve, it is difficult to relate this causally to the drug treatment. The Supreme Court convincingly argues that, if outcomes are uncertain, it is the expected value that is relevant not the individual outcome. Second, the drug treatment cannot stop the progression of the illness, which will finally lead to an early death. Hence, this case is not about the successful treatment of a life-threatening illness, which might allow for a rule of rescue. The concept of the value of a statistical life thus fits this specific case quite well, making the Supreme Court's ruling a wise decision.

Why is the ruling also just? If money is spent for one purpose, it will not be available for other uses. It must therefore be allocated to those uses that provide the highest value to society. To the extent that the citizens of Switzerland are all equal before the law, the good is also the just.

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