Soliris is a pharmaceutical used to treat an orphan disease, atypical hemolytic-uremic syndrome (aHUS). An orphan disease by definition effects 200,000 people or less in the United States. aHUS is a genetic disease [2], where blood elements (cells and platelets) are destroyed by the immune system, and their debris interferes with kidney function resulting in high blood pressure and ultimately renal failure. Before 2011 treatment consisted of transfusions to replace the blood elements lost, use of blood pressure medications to control hypertension and as necessary plasmapheresis. Plasmapheresis clears the blood of the debris that injures the kidney. Plasmapheresis, like dialysis, involves being ‘hooked’ to a machine for 3 to 4 hours as the blood is rinsed. But in 2011, the FDA approved Soliris now “recommended as first-line therapy [3] in both children and adults with a confirmed or strongly suspected diagnosis of aHUS.” It also has the dubious distinction of being the most expensive drug in the United States averaging $18,000 per dose or about $500,000 annually.

This week Bloomberg continues its series [4] on the high cost of Soliris and Alexion’s (the company that manufactures Soliris) aggressive and at times ethically challenged sales practices. But two thoughts came to mind in reviewing the article that I thought were worth sharing.

In setting the price for a drug that treats an orphan disease, the cost of research and development must be shared with by necessarily a much smaller market. Spreading the costs out to 200,000 results in a greater individual share than if the market was 2 million and the costs spread out in this much larger population. So there is an expectation that these pharmaceuticals would be more expensive.
“In 2007, Wall Street analysts eagerly awaited a price tag for Soliris. Most expected it would cost more than $100,000. But Alexion factored in other things, such as the savings Soliris offered by cutting down trips to the hospital and blood transfusions.”

Accounting for ‘savings’ is involved. In most scenarios when I consider setting the price, the value of a drug for the individual is most important. But patients do not have ‘deep pockets,’ insurance and government do. So is it ethical to use the value of these drugs to society in my price calculus? And if I do, is there an obligation to consider the harmful impact of my decision. In some ways, the pricing by Alexion took the savings for society and monetized and consumed it. It took an externality (an economic term for a factor outside an economic model) and internalized it for their benefit. Do they have an obligation to society, that supports the largest pharmaceutical market in the world, to make a more equitable sharing of those savings? Rather than focus on price should we not reframe the discussion around the societal costs Alexion is exploiting while freely consuming societal benefits like patent protection or a smart workforce?

Federal privacy laws require that patient identities be safeguarded and protected and the fines for flouting the law are prohibitive.

“Unbeknown to patients and many of the doctors, several of these preferred labs have agreements with Alexion to provide it with a copy of the test results. These are “blinded” to remove the patient’s name, so they don’t run afoul of medical privacy laws. But in some cases, the lab provides everything else: a patient’s age, gender, and ZIP code, the hospital, and doctor ordering the test, and a summary of the results.”

In our world of big data, removing a patient’s name and address does not constitute protection of privacy. Using other associated information I can, with a high statistically, probability identify patients. As a healthcare professional, I am appalled by this behavior. Shame on the laboratories that participated. But my greater concern is that this unethical behavior will result in data sets being stripped of demographic information that in turn provides socioeconmic information. It is socioeconomics that helps us understand the interaction between society and disease and that can identify maldistribution of illness or its treatment. Is there a way to reshape our privacy concerns to protect the individual and the legitimate needs of society? What are Alexion’s and its partner laboratories obligation in this setting?
Source URL: https://www.acsh.org/news/2017/05/27/why-soliris-most-expensive-drug-us-11333

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[3] https://www.acsh.org/Eculizumab%2520is%2520now%2520recommended%2520as%2520first-line%2520therapy%2520in%2520both%2520children%2520and%2520adults%2520with%2520confirmed%2520HUS.