Reviewer's report

Title: Re-Focusing the Ethical Discourse on Individualized Medicine: A Qualitative Interview Study with Stakeholders in the German Healthcare System

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Reviewer: Leonard Fleck

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First, the authors did a reasonably good job of identifying potential ethical issues associated with Individualized Medicine [IM]. My most fundamental criticism, however, is that I was puzzled by the overall intent of the essay. These questions capture the source of my puzzlement: Is the essay intended as essentially a purely descriptive sociological inquiry into what various researchers in the field of IM believe to be the most important or salient ethical issues in this emerging field of medicine/ science? Or, alternatively, is this some sort of empirical ethical inquiry with some critical commentary? In either case, I am not confident that the authors have succeeded in presenting something novel, interesting or important.

If we start with the first of our questions, only 17 individuals were interviewed as sources of “sociological data” about these emerging ethics issues. The researchers write that at that point they had reached “saturation.” That seems to mean something like “we got all the information we wanted.” Does that mean that all the relevant ethical issues were identified by these 17 non-ethically trained researchers? I can think of other issues that were not identified. So it was not obvious to me that “saturation” had been achieved. But then I am not sure what saturation would mean in this context. What precisely is the social or ethical importance of knowing what these 17 individuals believe are the ethical issues deserving attention in the IM field? Some of their comments are insightful and interesting. Others are bizarre [the comment that IM is just “humoralism’] (but no critical comment is offered to this effect). How much weight should we attach to the casually expressed ethical concerns (or what they are willing to call ethical concerns) of these 17 individuals? I could not give a good answer to this last question, which (for me) detracts from the value of this essay. The question that kept going round in my mind was this: why couldn’t the authors have done a careful analytic explication and critical assessment of what are the clear ethical issues that are emerging in the field of IM? That would have been more interesting and valuable since (it seems) not that much moral attention has been given to the field so far. Certainly the issue of costs and marginal benefits is worthy of careful ethical analysis and argument. Likewise, the stratification of patients according to their likelihood of being responsive to these extraordinarily expensive cancer drugs is also worthy of extended ethical analysis and critical comment. There is a real threat to the notion of solidarity that is central to much European ethical commitment because the vast majority of patients will be partial responders rather than non-responders to these extraordinarily expensive drugs. And “partial responders” will include individuals who will be known from the
beginning to gain only extra weeks of life for $100,000 as opposed to extra months or extra years.

There were a couple other things that concerned me. One other interviewee (#11) is quoted as saying “I just heard that if breast cancer patients are between the ages of 35 and 45…….” This sounds like the worst sort of rumor-mongering, not the sort of stuff that ought to be reported in a respectable academic journal, unless this is just “pure” sociological reporting. The other thing that bothered me is that some of the most morally challenging research in the field went entirely unmentioned (though there is a lot in recent medical literature on this topic). I am referring to the problem of tumor heterogeneity and clonal evolution. This, of course, is in the field of oncology. But the authors point out (correctly) that this is the most active area of IM now and for the foreseeable future. This is related, in all likelihood, to the potential for profit in this field, given the number of individuals in the economically advanced world diagnosed with cancer each year and the social anxiety related to cancer as well.

Finally, in my judgment the concluding section expressed a number of judgments that I would reached (or any other thoughtful person would easily reach and endorse) without having done this empirical research. That too takes away from the value of this essay.