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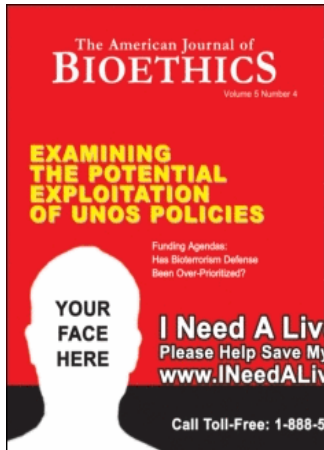
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this new science that follows on the dramatic advances arising from the HGP.

What are these issues? If genomics provides the “source code” for life, in essence its “parts list,” it must be immediately recognized and appreciated that this is just a beginning. The next steps in biology, among which systems biology is firmly placed, involve discovering (perhaps, in a sense, “writing”) the “operator’s manual” for a cell. The genome sequence is the raw information, but the manual tells us how that information is expressed and something about what it can actually do and some of these applications have considerable promise for societal benefits, for example, bioenergy use, waste treatment, and biotechnology (see relevant publications available at: <http://genomicsgtl.energy.gov/pubs.shtml>.) What societal implications emerge from possessing this knowledge? O’Malley and her colleagues (2007) identify four broad issue areas: *in silico* testing, cultural concepts of life, modifications of living material, and commercialization practices. Although this start is very reasonable, there can be little question that this list is, through no fault of the authors, incomplete and will be supplemented by other issues as the science progresses. This is because science is irreducibly unpredictable (that is its lasting glory) and we can expect surprises that are almost certain to identify additional societal issues.

O’Malley et al. (2007) surely deserve high praise for recognizing that there is great merit in encouraging early and close “cross fertilization” of bioethics and science. There should not be “Two Cultures” (in C.P. Snow’s famous phrase) separating social and scientific communities. To be a working scientist does NOT mean that one is not ethical nor does being a social scientist (in its broadest usage) mean that one always is. Ideally, we want to encourage an early intellectual integration of these perspectives so that scientists view thinking of the societal implications of their work as worthwhile and valuable. Social scientists should also

appreciate the beauty, insights, and excitement that science can provide.

Finally, science programs support science and (sometimes) analyses of societal implications, but they still exist in a larger, policy-making context. In the United States, policy is made in a complex, and often contentious, process that includes elected officials in the Congress, the President and the appointees in his/her administration, and the courts, with numerous influences by various actors in the larger society outside government. Policies are usually not made by program managers overseeing science funding programs or the scientists their programs support. They may contribute to policy formation by providing the scientific realities and analyses of various policy options, but a larger body politic makes the actual policy.

The value of the contribution by O’Malley et al. (2007) is to begin the discussion of the societal implications that can be expected to arise from systems biology research. But the process of issue identification and analyses is at a very early stage. It is an important process that should actively encourage the widest possible participation and inclusion by interested communities so that policies, as they evolve, are thoroughly explored and grounded in scientific reality. To ensure this, scientists with their expertise must become engaged and active contributors. To foster high quality, reality-based policy formulation, all “sides” must listen with respect to the views of other perspectives. ■

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Systems Bioethics

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O’Malley and her colleagues (2007) are to be commended for attempting to expand the mainstream bioethics discourse about genetics and genomics to encompass as well the prospects of systems biology. Several commentators, myself included, have lamented the stasis of this bioethics discourse, mired almost entirely as it is in the cutting edge science of 1985. When the Ethical, Legal and Social Implications (ELSI) program associated with the Human Genome Project (HGP) was first initiated in the early 1990s, it immediately

exposed bioethicists’ ignorance of science generally, and of genetics and genomics specifically. Subsequently, so-called “geneticists” voraciously consumed textbooks and popular handbooks of genetics—but largely focusing on clinical genetics of Mendelian disorders, rather than on genetics more broadly or on genomics at all. Over the past decade, while the science of genomics has progressed more rapidly than anyone should rightfully have expected, genetics has been left in its wake; there are hardly any ELSI analyses

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focusing specifically on genomics, or even in any scientifically serious way on the genetics of non-Mendelian disorders; most geneticists remain ignorant of developmental biology (sometimes construed as the operationalization of genetics); and now, with the rise of stem cell biology and neuroscience as the darlings of the bioethical imagination, genetics and genomics seem almost *passé*. Indeed, some bioethicists and commentators have attempted to corral the ELSI paradigm and apply it to new emerging science and technology—for instance, neuroscience (Illes and Racine 2005), and nanoscale science and engineering (Sheremata and Daar 2004)—as if the ELSI program had been successful in framing and resolving ethical, legal, and social issues associated with genetics and genomics. But that is hardly the case—and no one should have expected otherwise.

An analogy with the HGP is instructive in explaining why. When the HGP was initiated, its proponents had seemingly impossible dreams of generating a map of the complete human genome sequence, and of doing so relatively quickly. Until then, many scientists were concerned simply to identify and sequence individual genes. Now, HGP proponents were proposing to sequence the entire genome and then to extract individual genes from the complete genome sequence—bombastic! And yet, remarkably, that stage of the HGP has come to an end, with the publication over the past several years of various draft sequences of ‘the’ human genome. But considerable work remains to finalize these drafts and to begin to understand the morass of human genome sequence data. Enter systems biology. If we thus interpret genomics as an unfinished project—despite the apparent completion of the HGP—then it should come as no surprise that ELSI research is similarly unfinished.

Yet we can also go beyond analogy to the substance of ELSI to see just how much more work remains to be done. In its early days, ELSI identified several principal ethical, legal, and social issues for initial study: the privacy of genetic information, the provision of safeguards against genetic discrimination, the protection of participants in genetics research, and the secure introduction of genetic tests into clinical medical practice (Juengst 1991). Thus, ELSI scholars have been particularly concerned to establish protocols to ensure that insurers or employers do not use predictive genetic information inappropriately, leading to draft antidiscrimination legislation. But, as other ELSI scholars noted, neither proposed nor existing legislation may be sufficient to protect individual rights against potential abuses of genetic information. A related, key area of concern involves distributive justice. Many researchers have noted that genetics services may be accessible to only a small proportion of the world’s population, which may result in widening the gap between the most and least well-off within and between societies. At the other end of the spectrum, some commentators have worried about the prospect of engineering human genes both somatically and through the germline. These (and other) possibilities raise concerns about the potential eugenic implications of genetic technologies. Additionally, numerous commentators have worried about the notion of informed consent to genetic testing, including the

testing of children for adult-onset disorders. More generally, ELSI researchers have approached questions about the nature of genetic disease, the personal and social implications of genetic diagnosis, and the potential need to expand genetic counseling services.

These are all important avenues of inquiry. But, as O’Malley et al. (2007) make clear, they hardly exhaust the ethical, legal, and social issues associated with genetics, let alone genomics or systems biology. Charitable critics might refer to them as a *dégustation* menu—tiny morsels of tasty items that are interesting but hardly representative, let alone exhaustive. Less charitable critics might refer to them instead as an appetizer platter prior to the main course or, less charitably still, as the bioethical equivalent of cocktail wieners: somehow satisfying if you are starving, sickening if you are not careful, hardly enough to replace a decent meal.

I undertook to become a philosopher of biology to become a better bioethicist—a *cordon bleu* bioethicist, if you will. I was weary of yet another genetics analysis based on ignorance of either the powers or limits of genetic science. The philosophy of biology, when undertaken properly, involves deep conceptual and epistemological engagement with biology and with biologists, and with the history of biology, as well (Robert 2004). The philosophy of biology, thus construed, serves as a cornerstone of any adequate bioethics (Ankeny 2003; Robert and Smith 2004; Robert et al. 2006). Even though we do not derive prescriptions from the philosophy of science—any more than from science itself—sound philosophical engagement with science sharpens one’s critical senses and affords exquisite opportunities to conceive, frame, and begin to address ethical issues in bioscience. Moreover, and more importantly, perhaps, from the perspective of impact, the philosophy of biology (properly undertaken) offers the prospect of meaningful discourse with biologists: a sure way to influence the practice of science. Witness the success of the EGENIS group at Exeter.

I first introduced my systems approach to bioethics (“systems bioethics”) to the Exeter crowd in a plenary address in September 2005 at the EGENIS annual conference (Robert 2005). I subsequently published more details about this approach in 2006 (Robert et al. 2006) in the context of stem cell biology, although much of my work in bioethics over the past several years has exemplified this systems approach (e.g., Robert and Baylis 2003; Robert and Smith 2004; Robert 2006; Robert 2007; Smith and Robert 2007). The basic idea is a simple one. I begin with the assumption that knowledge of biology is integral to the ethical assessment of biology. But my focus is as much on biology as a process, as a powerful though not infallible way of knowing the world, as it is on biological facts. Accordingly, the history and philosophy of biology—the critical study of biology, its theories, concepts, methods, and meanings, over time—is an indispensable tool for any adequate bioethics. Biology, of course, is organic, dynamic and interactive (biological systems are *systems*, after all)—and so too is biology in society. Accordingly, I integrate a generic values perspective (rather than applying any specific theory of value) through a process of *moral landscaping*. This involves

surveying the landscape for values and interests, perspectives, opinions, biases, and so on, and cultivating an interdisciplinary, cross-sectoral discussion to determine, at least provisionally, which ones of these are relevant and salient, and then probing them further to assess their epistemic and political warrant. Finally, I invoke a process of *moral architecture* (Walker 1993), whereby bioethics helps in designing, building, and maintaining a literal and figurative space for reflection, deliberation, negotiation, and compromise. There may be no unique right answer about what should be done, and there may be no more agreement than agreement to disagree. But the process of engaging proactively in well-intentioned and well-informed debate—from research agenda setting, through research, development, and application (Guston and Sarewitz 2002)—nonetheless serves the very important goal of “keeping us morally accountable to each other” (Walker 1993) and is fundamental to civil society. Consilience with the O’Malley et al. (2007) project should be plainly evident.

This is a generic approach to bioethics, by which I mean its substance need not be systems biology—it applies just as well to stem cell research (Robert 2006; Robert et al. 2006) or toxicology (Smith and Robert 2007) as it does to genomics, proteomics, or systems biology. But systems biology is a nice test case for this kind of integrative approach to bioethical analysis (Robert 2007), or, as O’Malley et al. (2007) prefer, “socioethical” analysis. O’Malley et al. document the translation of the “old” problems of ELSI into “new” problems—new biological problems, but also new bioethical problems based on changes in the science and the social possibilities it engenders. It is critical to move beyond static reductionism, and to adopt an integrative approach to biological complexity and constitutive interaction (Robert 2004); moreover, it is imperative to embrace and grapple with bioethical complexity in social and political context, if we are ever adequately to engage, and maybe even resolve, tendentious bioethical debates in pluralistic civil societies. ■

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