Public health ethics and intellectual property policy

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The articles in this issue of the Bulletin describe some of the challenges posed by notions of intellectual property in areas as diverse as genetic testing, genomic epidemiology, pharmaceuticals and vaccines. The constructive practical solutions suggested include royalty clearing houses, comprehensive research collaboration policies, and modified DNA patenting regimes. All of the articles address and respond to moral duties and potential ethical consequences of the policies they discuss, but conspicuously refrain from more explicitly describing the values and principles that underlie and motivate their reasoning. As in the article by Chokshi et al.,1 their ethical dilemmas are usually manifest as a tension between a vague moral imperative to ensure universal "access" to downstream health benefits while maintaining or developing incentives for further "innovation". While their proposals are laudable, and they do cite articles on the ethical dimensions of their work, the unique, potentially guiding voice of ethical discourse is almost silent.

Basic science research and public health practice once flanked clinical medicine at opposite extremes of the health intervention continuum. Now these emerging technologies, broadly applied, threaten to bring these two distant cousins together with the promise of enhancing our ability to detect and treat disease. While the field of clinical medical ethics is as robust as ever, and the field of public health ethics has undergone considerable development in the past decade, the ethical aspects of some applied basic sciences have been explored but have not yet spawned a genre of consistent and appropriate ethical frameworks. Clinical trials must pass rigorous research ethics boards before studies begin, and public health interventions are increasingly subjected to thorough analyses which may include explicit ethical dimensions. In the area of cutting-edge research into potentially patentable technologies, however, the

approaches to current and anticipated ethical dilemmas have been inconsistent. In some cases, there are extensive debates in the literature and the media regarding the ethical and societal impact of technologies even when their practical implementation remains very distant on the horizon. At the other extreme, new technologies and methods which have significant immediate application are often addressed in policy documents using sterile technical language without explicit referral to their underlying ethical and moral rationale. Initiatives such as the Human Genome Organization (HUGO) code of ethics² and the WHO Commission on Intellectual Property Rights, Innovation and Public Health³ provide a great deal of data and useful policy direction. However, they may not be using the most appropriate frameworks to address both the narrow and the broad ethical dilemmas which result from the knowledge generated in basic science research, and how that knowledge is to be used and shared.

As basic science consortia make the leap from "bench" to "population", skipping the "bedside", we must recognize that policies that govern this field are not only organizational and logistical necessities, but are determinants of present and future global health. Therefore, appropriately developing and implementing intellectual property policy is a public health intervention with profound ethical import. As such, it lends itself well to frameworks and concepts borrowed from the discipline that busies itself with describing and prescribing public health interventions the field of public health ethics.

While some public health ethicists have highlighted and examined key issues raised by a particular public health concern,^{4,5} others have developed ethical frameworks to guide public health practice. These varied frameworks may be based on meta-ethical political⁶ or priority-setting theories,⁷ legal grounds,^{8,9} formulaic criteria¹⁰ or the fundamental duty-relationship between those who make public health decisions and those whom the decisions affect. Many of the newer approaches resist the standard hedonic calculus of public health utilitarianism or the rigid rightsbased lens of social justice and equality that has been criticized as being foreign to many non-Western societies. Once an appropriate framework has been selected or developed, it can provide not only advice in managing the obvious ethical dilemmas, but direction in navigating logistic and bureaucratic complexities as well.

The authors of this issue's articles almost universally subscribe to the idea that the products of their research - whether genetic diagnostic technologies, genomic or DNA databases, vaccines, or even "health" in general - represent a public good. The question of how to ensure the production of public goods and their equitable distribution has a long history in the field of economics, but takes on new meaning in public health when the public good is, in the final analysis, the means to life itself. It is this question that can be systematically addressed to the public health intervention of intellectual property policy using the lens of the procedural and substantive principles of public health ethics. A substantial amount of work has been done, but the complex interplay of value-laden and controversial duty-relationships, the many unknown potential consequences, and ever advancing technology ensure that there is much work ahead. Incorporating a more explicit, systematic ethical analysis into policy documents may be a means better to clarify goals, identify common issues and — most importantly — map common solutions.

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