

# **Personalized medicine: from bio-politics to omic-politics?**

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## **Abstract**

Personalized medicine, the tailoring of medical treatment to the individual characteristics of each patient and classifying individuals according to their susceptibility to a particular disease or their response to specific treatments, has been described as “a major paradigm shift in biology and medicine.” This paper argues that personalized medicine is not only a new medical paradigm, it is also a manifestation of the emergence of a new field of power, the omic space – the holistic interaction between genome, proteome, metabolome, epigenome and exposome – and a new cluster of power relations, which could be called “omic-politics”. Similar to disciplinary power and the bio-politics of the population, Omic-politics represents a form of power over life. The paper analyzes the different expressions of omic-politics, focusing on how omic-politics constitutes new individual and collective subjectivities, influences practices of government and creates new forms of capital accumulation.

## **1) Introduction**

Personalized medicine, defined as medical treatment tailored to the individual characteristics of each patient together with the classification of individuals into subpopulations that differ based on the group’s susceptibility to a particular disease or response to specific treatments, has been described as “a major paradigm shift in biology and medicine” (Subramanian et al., 2001:2003). The shift from studying genes in isolation to exploring networks of genes and “defining the biochemical readouts that are specific to clinical conditions” has evolved in parallel with a process “in which DNA variations recorded in human populations will be integrated into the above paradigm, to guide a new generation of diagnostic, prognostic, and therapeutic modalities” (Subramanian et al, 2001: 2303). Personalized medicine’s promise is that “[T]herapies directed at the root cause of the disease will replace those that simply treat the symptoms of the disease” (Ginsburg and McCarthy 2001).

Building on the claims of Nikolas Rose and Melinda Cooper (Rose 2007, Cooper 2008), the present paper argues that personalized medicine is not only a new paradigm within medicine, it is also a manifestation of the emergence of a new field of power, the omic space, and a new type or cluster of power relations, which I suggest could be called omic-politics. And as a disciplinary power and similar to the bio-politics of the population, personalized medicine represents a form

of power over life (Foucault, 1978). The central role played by medical knowledge and practices in the emergence of power and the exercise of government means that paradigmatic changes within the field of medicine both influence and reflect broader changes in the characteristics of power relations and modes of government. Thus, the emergence of personalized medicine as a new medical paradigm may be considered the expression of a nascent form of power over life, i.e., omic-politics, which involves neither the individual body nor the body of the population, but the omic space.

Characterized by new technologies of power, new technologies of the self and new technologies of production, omic-politics do not replace, but coexist with the existent configurations of power: sovereignty, disciplinary power, biopolitics and what Couze Venn denominates post-biopolitical (Foucault, 1988, Venn 2009), and they are productive in different ways. First, omic-politics produces tangible diagnostic and therapeutic benefits. In addition, it generates new ways of conceiving subjectivity, new forms of shaping identities and new forms of identification (Rose, *ibid*, Gibbon and Novas 2007), and it is also amenable to the emergence of new forms of government. Furthermore, it creates new methods of capital accumulation and produces a new type of utopia.

## 2) **Bio-politics and medicine**

Foucault's conceptualizations of bio-power and bio-politics are not always coherent and consistent. In the last of his lectures compiled in "Society must be defended" and in the first of those collected in "Security, population and territory", he analyzes the emergence of a new kind of power, which he poses as different from both sovereign and disciplinary power. While the latter refers to power exercised on the individual body, an anatomo-politics of the human body, he conceived of bio-power as "bio-politics of the human race" (Foucault, 2003:243).

Because it deals with the population, bio-politics represents "power's hold over life" (*ibid*: 239); it is understood to comprise "the basic biological features of the human species" (Foucault, 2009:16). Bio-politics is "the acquisition of power over man insofar as man is a living being", i.e., man as a mass and the biological processes (birth, illness, death) that affect it (Foucault, 2003:243). In those lectures, Foucault presents power as existing in three main forms – sovereignty, disciplinary power and bio-politics – that, although they emerge at different historical conjunctures, do not replace or subordinate each other (Foucault *ibid*, *ibid*). However, in the first volume of the *History of Sexuality*, he argues that disciplinary power centered on the individual body and bio-politics of the population are two poles of the power over life (Foucault, 1978). Either way, whether they represent two of the three forms of power or two distinctive forms of power over life, disciplinary power and bio-politics are conceived as different types of power.

In terms of medicine, bio-politics as the politics of life is expressed mainly in public health and in evidence based medicine, both of which are population based. From the public health

perspective, populations constitute both its subject of study and the focus of its policies and practices. As such, evidence based medicine attempts to generate “best practices” based on meta-analysis and other statistical tools specific to populations. Personalized medicine, in contrast, focuses on the individual instead of on the population, but the “individual” in personalized medicine is not the same as the “individual” who was the focus of classic clinical medicine. The practices and knowledge that have been organized into personalized medicine do not focus on the body-as-machine, on which disciplinary practices focus (and who was constituted by those practices). Rather, as a product of personalized medicine, the twenty-first century individual is conceptualized and constituted as an omic space. The emergence of a corpus of knowledge and a set of practices that conceptualize and constitute the individual as an omic space raises the question as to whether this complex of new practices and knowledge that conform personalized medicine, does not announce the emergence of a new and different kind of power over life<sup>i</sup>.

### **3) Personalized medicine and the omic space: beyond bio-politics?**

Inter-individual variation in response to treatment has been observed since the late nineteenth century. In the 1950s, certain idiosyncratic responses to treatment began to be connected with specific genes, thus giving birth to pharmacogenetics (Piquette-Miller and Grant, 2007). With the decoding of the human genome, however, genetics evolved into genomics and pharmacogenetics into pharmacogenomics, which opened the way for the development of a new field of knowledge, the omic sciences. In the wake of the development of the omic sciences, personalized medicine emerged as a new medical paradigm around the mid-2000s (Emmert Streib, 2012; Abrahams and Silver, 2009).

Most definitions of personalized medicine share the core idea that individual patient health is best managed by tailoring preventive measures and treatment to personal preferences and to particular biological—including genomic—attributes. Personalized medicine can thus be viewed as “a comprehensive, prospective approach to preventing, diagnosing, treating and monitoring disease in ways that achieve optimal individual health-care decisions” (Lesko, 2007). Indeed, the very name ‘personalized medicine’ suggests an approach to care that is based on individuals rather than groups. Personalized medicine thus implies the use of advanced, individual genomic (and other omic area) information, together with risk algorithms, to manage behavior and to develop therapies biologically tailored to the patient’s needs – an example of such therapy is customized monoclonal antibodies and vaccines – with the aim being to treat “the right patient with the right drug at the right dose at the right time”

(<http://www.fda.gov/scienceresearch/specialtopics/personalizedmedicine/default.htm>).<sup>ii</sup> The goal of personalized medicine is thus to link each individual’s molecular and clinical profiles (taking into consideration characteristics such as age, coexisting conditions, preferences and beliefs) to provide physicians a more solid base for their therapeutic decisions and enable patients to make informed and directed lifestyle decisions to promote their well-being. For example, individuals deemed at high risk for a certain disease can be recommended preventive therapy or life-style modifications by their doctors.

Personalized medicine is based on the omic sciences, the specific names of which were constructed with the suffix *-ome*. In molecular biology, the suffix *ome* is used to signify the study of a *whole* of something, i.e., proteomics refers to the study of the entire set of proteins in a particular organism. The suffix *ome* directs attention to a holistic abstraction of molecular or functional parts of a population. The essential feature of the omes is that they stress the holistic dimension of the molecular level, studying complex sets and not individual entities (Willard and Guinsburg, 2009). The “classic” omic sciences include genomics, pharmacogenomics, proteomics, metabolomics and metabonomics, epigenomics, and transcriptomics. Among them, the two most developed fields are genomics and pharmacogenomics. Genomics is the scientific study of the genome. A genome is the complete DNA sequence of an individual or the collection of genes a particular species has (Sweet and Michaelis, 2011). Genomics focus is on DNA information as a complex totality, within a holistic view of how the specific gene and the specific protein fit within the context of all other genes, other proteins and biomolecules. Genomic complexity contained in DNA based information, combined with RNA/protein/metabolite profiles (transcriptome, proteome and metabolome) and clinical data, offers the opportunity to define multidimensional risk stratifiers, to assess individual risk and to tailor treatment to the individual.

Pharmacogenomics, which arises from the confluence of genetics, biochemistry and pharmacology, is the study of the role of inherited and acquired genetic variation in the drug response (Wang et al., 2011:1144) and how that individual variation is correlated with drug responses. A fusion of pharmacogenetics with genomics<sup>iii</sup>, pharmacogenomics studies “how genetic composition affects both disease predisposition and response to therapy...” (Picquet-Miller and Grant 2007), and it is already informing drug development and testing, investigating therapies of drugs targeted to subgroups of patients according to the distinct molecular mutations that drive their diseases. Pharmacogenomics is a central link between the omic sciences, personalized medicine and the political economy of personalized medicine (since, as we will see in the fifth section, the industrial application of pharmacogenomics is one of the four main forms of personalized medicine)<sup>iv</sup>.

A challenging new field that is part of the omic sciences but that extends beyond the molecular level is the study of the exposome. Coined by Christopher Wild (2005), the term exposome encompasses “every exposure to which an individual is subjected from conception to death”, taking into consideration the nature of those exposures “and their changes over time” (Wild, 2012: 24). The exposome is divided into three dimensions: internal (metabolism, body morphology, microbiome, behavioral factors such as physical activity and stress, and ageing), specific external (radiation, infectious agents, contaminants and pollutants, diet, lifestyle, occupation, medical interventions) and general external (wider social, economic and psychological influences). In Wild’s view, there is constant interaction between the omic planes at the molecular level and the exposome, and the former potentially carries the “signature” or the “fingerprints” of the latter (Wild, 2012).

Taken together, the omic disciplines provide the knowledge upon which personalized medicine draws to advance a vision of the optimal management of the individual patient's diseases or disease predisposition, thus improving health and quality of life (Personalized medicine coalition: Mission and principles). Indeed, personalized medicine is expected to radically modify the practice of medicine. But as I will attempt to show, what is described as a paradigmatic shift of the ways in which medicine understands and acts upon disease, the body, the individual and the group actually hints at a broader change that is occurring in the organization of power in society. As such, the advent of personalized medicine represents a new model of interaction between social institutions, processes of subjectification, and the political economy.

In his book "The Politics of Life Itself: Biomedicine, Power and Subjectivity in the Twenty-First Century" (Rose, 2007), Nikolas Rose also addresses the changes in bio-politics and exposes what in his view are its new characteristics. Thus bio-politics in the twenty-first century is not "delimited by the poles of illness and health, nor focused on eliminating pathology to protect the destiny of the nation. Rather, it is concerned with our growing capacities to control, manage, engineer, reshape, and modulate the very vital capacities of human beings as living creatures. It is, I suggest, a politics of 'life itself'" (Rose, 2007:3). This reshaping of politics implies new conceptions about "what human beings are, what they should do, and what they can hope for" (Rose, 2007: 5-6). Rose localizes the point of application of this novel politics of life in general at the "molecular level", where life is conceived "as a set of intelligible vital mechanisms among molecular entities that can be identified, isolated, manipulated, mobilized, recombined, in new practices of intervention..." (Rose, 2007:5-6). While I agree with Rose's placement of the politics of life at the molecular level, I also suggest that the form this molecular level has is, in fact, the omic space – the spatial, holistic interaction between genome, proteome, metabolome, epigenome, etc. (Hasegawa et al., 2006; Toyoda and Wada, 2003, 2004). Rose understands the molecular level as a set of mechanisms that function between and among individual molecular entities. However, the emergence of the omic sciences and of the novel medical paradigm inherent in personalized medicine show us that the focus of the politics of life is not an aggregate of "molecular entities". Instead, it is a novel type of space characterized by its conception as a totality formed at the intersection of different molecular (and even environmental and social) planes, each of which is also holistically conceived. Thus, rather than focus on singular molecular entities, the emphasis is on systems as totalities.

In light of our improved understanding of human biology, especially as it pertains to the decoding of the human genome, researchers have concluded that analyzing life processes in terms of "single omic elements such as genes, transcripts, proteins, genetic alleles, regulatory regions or even single nucleotides [as a] one-dimensional coordinate axis does not represent suitably interactions among multiple omic elements, which are crucial to the description of biological networks" (Toyoda and Wada, 2004:1759). The information and insights emerging from the advances of recent years in the life sciences have taught us that "[F]or a more explicit integration of non-identical interactions observed in various types of analyses, it is necessary to

describe the interacting omic elements based on a multi-dimensional coordinate system where various levels of biological knowledge, experimental findings and model-based predictions are explicitly represented and integrated” (ibid). Thus, to understand the true value of the knowledge gained through the omic sciences, we must first conceptualize the “multi-dimensional representation termed omic space and comprising comprehensive omic planes...notably the genomic, transcriptomic, proteomic, metabolomic and phenomic planes” (ibid). Instead of sets of molecular entities, therefore, the relationship between omic elements constitutes omic planes, the interactions of which, in turn, combine to form a three-dimensional omic space (Toyoda and Wada, ibid).

Therefore, the locus of emergence and the aim of the new politics of life is not the molecular level in general, but the omic space, the multi-dimensional integration of the different omic elements. Thus, we can argue that the advent of the omic space means that we should understand the modifications in the politics of life as the emergence as a new type of power, omic-politics. As Dean poses it, Foucault’s analyses enabled power to be conceptualized as appearing in different zones or clusters of power relations (Dean, 2002). In this sense, personalized medicine as the dominant medical practice in the omic space is an expression of a new type of power relations, omic-politics. To highlight the differences between sovereign power and bio-politics, Foucault wrote that sovereign power assumed the right “to take life or let live”, while bio-power, in contrast, gives life and lets die (Foucault, 2003: 247). To point out the differences between omic politics and other forms of power, we could paraphrase Foucault and claim that omic politics modifies life to postpone death.

Thinking in terms of omic politics means understanding power as existing within, or applied over, the omic space. Omic politics could be understood as power emerging and exercised at the genome/epigenome/proteome/metabolome level together with power emerging from and exercised over the information networks that form the connections between the different omic planes; and the practices of power that take place, and constitute the exposome (Wild, 2005). If for Foucault bio-politics means power applied over (and constituting) the population, and the individual is conceived as being part of that population, then omic politics includes a redefinition of the notion of “person”, in which the individual is conceived as the integration of several omic planes. Taken together, those planes constitute a “global molecular view” of the individual and, of his/her interaction with the natural and social environments. Thus, omic politics represents a new approach to combining totalizing and individuating effects. Firstly, the omic sciences are grounded in a total perspective. Secondly, through concepts such as exposome and socio-exposome, not only is the individual conceived of as a totality (the omic space), but also as part of a broader totality (the exposome) that includes and transcends the population. However, omic-politics also individuate, since this new intersection and interaction of totalities defines each of us as singular, as different from our fellow human beings, as persons, as focus and aim of the diagnostic and therapeutic practices that constitute personalized medicine. As such, is an example of omic politics, the dawn of which relates to the development of new forms of

knowledge, new technologies of power, new technologies of the self and new technologies of production that differ from those Foucault described as characterizing modern governmentality.

From a scientific perspective, not only is personalized medicine a trans-disciplinary practice (including the omic sciences and also informatics, statistics, public health, health care management, health economy, law, bio-ethics) (Ozdemir et al., 2009), but it also takes place at and integrates the different levels from the omic to the global . Personalized medicine combines diagnosis, therapy, surveillance, risk-assessment, management of conduct, the production of discourses of law and ethics, forms of state regulation, “global health diplomacy” and new forms of capital accumulation and distribution. Moreover, its supporters (as made explicit, for example, in an article published in *Current Pharmacogenomics and Personalized Medicine*) are completely aware that personalized medicine is limited neither to the omic space as the most “primordial” molecular level nor to the individual person. Personalized medicine also implies a global dimension, “vigilant and trans-disciplinary horizon scanning...with strong international outreach to expertise available in different global regions” (Ozdemir 2009 1-2).

The diagnostic procedures of personalized medicine include the integration of information obtained through genomics, proteomics and metabolomics with more “classical” diagnostic techniques. Although currently, new therapeutics are based mostly on pharmacogenomics, in the near future treatments also based on the other omic disciplines will be developed. Indeed, part of the appeal of personalized medicine comprises the new combinations it forges between the different levels of the traditional medical practice, aptly expressed by the neologism *theragnostics*, a combination of therapeutics and diagnostics<sup>v</sup>. In addition, it generates new forms of economic activities (the production by the pharmaceutical industry of “theragnostic” kits that combine a treatment associated with a diagnostic procedure) and regulations (the requirement that certain treatments be prescribed only following the specific diagnostic procedure that is part of the kit).

Among the central aims of personalized medicine are individually tailored disease prevention and just-in-time treatments. But as monitoring and medical surveillance are necessary to achieve these aims, a central element of personalized medicine will be “a portable integrated medical record system, a lifelong electronic health record” (Beitelshees and Veenstra, 2011:1252). As part of the trans-disciplinary profile that characterizes personalized medicine, information systems are being developed to allow for the integration and management of huge quantities of information. For example the Pharmacogenomics Research Network is facilitating the incorporation of pharmacogenomic information in the medical record, and the Electronic Medical Records and Genomics Network, a National Institutes of Health (NIH)-funded consortium, seeks to integrate clinical data from electronic medical records with results from genomic studies (Beitelshees and Veenstra). As envisioned by personalized medicine supporters “[I]n the future we may all carry a “gene chip assay report” that contains our unique genetic profile that would be consulted before drugs are prescribed” (Phillips et al 2001:2278). The place of surveillance within personalized medicine is not limited to individual surveillance, but

includes also combinations of population surveillance with surveillance at the omic level, as expressed in the idea of “pharmacogenovigilance”, defined as “pharmacovigilance activities informed and guided by accompanying pharmacogenomics analyses” (Sardas, 2010:1).<sup>vi</sup>

Surveillance and the modeling of conduct sare technologies of power central to personalized medicine. The use of informatics technologies to interpret and integrate the results of the different tests, diagnostic procedures and individual data (combining information on morbidity, medications, age, gender and lifestyle such as occupation and smoking) generates a risk assessment for each individual. The information about the individual omic space is integrated with epidemiological data and the person’s clinical history to identify unique characteristics of each individual, calculate the individual’s rates and patterns of risk and to create “customized health strategies” (Burke and Psaty, 2007:1683). Individuals deemed at high risk of disease can be targeted for preventive therapy or lifestyle modifications, and they can then be screened periodically “using protein-based markers and or molecular imaging, for preclinical disease detection.” (Burke and Psaty, 2007:1683). Personalized health strategies will not only entail tailoring treatment to the individual patient, they will also help guide the individual who is working to improve his/her omic space through self-surveillance, lifestyle changes and behavioral modifications as viable risk management mechanisms (Burke and Psaty, 2007:1683; Royal society33).

The inclusion of the exposome within the omic space is already driving the development of new methods and practices of surveillance. Tools and methodologies that have been developed in the last few years hold promise for producing information about the intersection between some of the environmental exposures that an individual may come into contact with over the course of his or her lifetime, the individual’s behavior and modifications at the molecular level of the omic space. Kellyn Betts mentions an unpublished pilot study in Barcelona that tested the suitability of cell phones for tracking one’s exposure to environmental pollutants. Tracked by cell phones and other wearable devices, students’ movements were overlaid on models developed by the city’s energy agency and others to predict air pollution levels (Betts, 2012). Other new tools include the Wockets, a device that provides continual data on the type, intensity, duration, and location of the wearer’s upper- and lower-body physical activity for months at a time and measurements of psychosocial stress and social interaction via electronic diaries and mobile phone video technologies (Wild, 2012). These existing devices will eventually be combined with technologies for monitoring the relationship between exposure and omic profiles using blood plasma, cells from inside one’s cheek or nostril, or – as in a project taking place at Boston University – looking at gene-expression profiles in the human airway as signatures of internal exposure to relate the ‘specific external’ domain of the exposome to changes in the genome, proteome or metabolome (Betts 2012, Wild 2012).

In this framework, personalized medicine does not only manage risk, it also modifies our conceptualization of risk and risk assessment. The development of new techniques such as proteomic diagnostics will transform traditionally static risk assessment “...towards a more



dynamic, ongoing diagnostic testing *within* the same individual, to obtain a longitudinal “repeated measures” *functional risk* signature” (Ozdemir et al., 2009:2). The advent of personalized medicine “suggests a re-definition of what it means to be ‘a patient’ and how the life-world of the ‘being-at-risk’ is... structured.” (Scott et al. 2005:1870) Surveillance, risk assessment and what Foucault called “the conduct of conducts” will all become parts of an ongoing process, the result of which will be not only better treatments and better health indicators, but also “novel concepts and mechanisms for regulatory oversight” (Ozdemir et al., 2009:2) and the emergence of a new form of subjectivity, of new discourses of law and ethics, and of new methods of capital accumulation and a new political economy.

Indeed, the name “personalized medicine” is indicative of the influence of its approach on, and of the relevance of the omic sciences and the constitution of the omic space to, our conceptualization of the very idea of the person. The concept *person* is a “historically and culturally situated concept” (Evnine, 2008:8), taking place within (and for some constituted by) a network of economic, legal, political cultural, and moral institutions and practices (Evnine, 2008, Howard 2007). The concept of person has evolved, as Marcel Mauss has shown, “[F]rom a simple masquerade to the mask, from a ‘role’ (personnage) to a ‘person’ (personne), to a name, to an individual; from the latter to a being possessing metaphysical and moral value; from a moral consciousness to a sacred being; from the latter to a fundamental form of thought and action...”(Mauss 22). Over the entire course of this evolutionary process, the body remains central to the concept of the individual person (Fowls). For the realists, a person is identified with the *homo sapiens* as a biological kind, and thus the bodily dimension indeed defines the person (Evnine, 2008). But even for nominalists or social constructionists, for whom the concept of person is a historically and culturally situated concept, associated with a set of necessary and sufficient conditions<sup>vii</sup>, the concept of person is linked to some form of life, is "enabled by biological facts pertaining to human beings" and thus it is embodied (Evnine, 2008:8).

Thus we can conclude that a deep transformation in our ways of understanding, conceptualizing and knowing the body modifies our concept of the person (and the legal-institutional context that defines it). This is the kind of transformation that the omic sciences bring with it and that personalized medicine expresses as a combination of knowledge, practices and institutions. Within the context of the omic sciences, it is the omic space that defines us as persons. Personhood, or individuality, is defined as “the biological qualities that distinguish one person from another. These include variations in bodily or cellular structure or function and in homeostasis and adaptation. These are all properties mediated by proteins, which themselves express the individuality of the genes that specify them. Thus, the root of individuality expressed in these terms is genetic.” (Valle, 2004:375). In this view, individuality is conceived today also in terms of single nucleotide polymorphisms, insertion/deletion differences, allelic variation in gene expression, alternative splicing and its variations, and epigenetics (Valle, 2004). Therefore, the ‘person of the patient’ is defined by their genetic and biological characteristics and their statistical association with certain known risks and outcomes (Tutton, 2012).

Omic power produces not only new subjectivities (or at least new ways of conceptualizing subjectivity), it also creates new collective identities. The study of genetic variation – especially the great variation at the proteome and metabolome levels – has the potential to undermine traditional group identities such as ethnicity, race or nationality, since they point to similarities at the different omic levels that cut across categories such as ethnic group or race, and to differences at the omic level within those same groups (Rothstein and Epps, 2001). Genomic profiling can establish new communities of belonging that cut across traditional social groups. In his discussion about pharmacogenetics and the social construction of identity, Foster argues that “[B]iomedical innovations in particular, however, have the potential for making previously covert or insignificant physical characteristics both observable and meaningful and, hence, for forming *new* social groups around those characteristics (Foster, 2003). Thus, the omic field is the grounds for the emergence of new subject positions that interact with existing ones. Forster himself, for example, suggests in another paper that one benefit of research in the field of genomics will be the ability to group people according to a common extended pedigree rather than according to ethnicity and/or race (Foster et al., 2001). These new collective identities eventually become political subjects, as shown in Vololona Rabehearisoa’s study of people suffering from muscular dystrophy (Rabehearisoa, 2006).

The omic field also generates modifications of the discourses of bio-ethics and law. The flow of new knowledge, new technologies and new therapies must “take into account, for example, how data translates into knowledge and the socio-ethical factors that can facilitate, hinder or bias this knowledge translation process, “it ...requires integration with the recent empirical turn in philosophical bioethics towards evidence-based ethics.” (Ozdemir, 2009:8)

Since the development of the omic field is still in its infancy, we are not able to thoroughly appreciate its influence on the discourses of bio-ethics and law. However, we already know that bio-ethicists discuss the need to re-design one of bio-ethics central topics, informed consent. One of the characteristics of research in the omic field is the difficulty to assess the near-future consequences (and possible uses) of genetic material obtained for current research, since “research questions themselves may rapidly change with the advancement of technical knowledge” (Mascalzoni et al., 2008). Omic research modifies the research conditions that suit the conventional conception of informed consent. Even with all the possible good will, in omic studies it is difficult to protect the rights of participants vis-à-vis who owns the data (since the same sample, will in a near future contain new data), who will have further access to the data, or issues concerning privacy or financial benefits<sup>viii</sup>. Thus, the concept of informed consent is being reconsidered as the relevant stakeholders realize that it should not be thought of as a “finite time step, but as an ongoing process” that should be implemented in stepwise form (Mascalzoni et al., 2008).

The emergence of the omic space will require a whole set of techniques and practices that will redefine the role of the state insofar as it deals not only with individuals or populations, but with the intersection of the molecular level and the socio-exposome. Because this field is so new, it is

difficult to foresee how this set of techniques will be configured. However, the already developing field of omic and exposome surveillance, the redefinition of risk and the emergence of a new political economy of life, all hint at an ongoing reconfiguration of the “art of government”

The growth in our knowledge about the omic space is transforming the currently accepted conceptualizations of intellectual property, liability or legal elaborations of the boundaries between nature and culture (Marchant 2007). These changes in the legal sphere take place not only at the level of the nation state, but also at the global level, insofar as personalized medicine requires the development of global health diplomacy, a hybrid field that combines international policy making and legislation in health care and biomedicine (Ozdemir et al., 2009:6).

Finally, the development of the omic sciences in general and of personalized medicine in particular represent a significant step forward in the growth of the bio-economy, which, as Melinda Cooper states (Cooper 2008), effaces the boundaries between labor and life, the market and living tissue when combined with neo-liberalism.

#### **4) The political economy of personalized medicine**

In her book “Life as Surplus” Melinda Cooper maintains “[T]he biotech revolution...is the result of a whole series of legislative and regulatory measures designed to relocate economic production at the genetic, microbial and cellular level, so that life becomes, literally, annexed within capitalist processes of accumulation, life is put to work at the cellular level...” and that “the whole space of reproduction becomes potentially available for commodification...” (Cooper, 2008). I would extend her claim, arguing that in addition to the space of reproduction becoming available for commodification, so, too, does the omic space as a whole. The omic space offers almost infinite opportunities for the accumulation and realization of capital. Among these opportunities, the omic space functions as an analogy of financial markets. Just as in the neo-liberal model, financial markets combine promises of future gains (or losses) with the management of risk (options, emergent markers), here bio-business combines promises of future gains (potential use of portions of the genome) with the management or risk of future disease. Accumulation of capital also includes the effects of the new ways of defining illness and risk, the flow and circulation of omic information, and the use of that information to develop preventive measures, new diagnostic and therapeutic instruments, and new forms of surveillance. The economic activity related to the emergence of personalized medicine exemplifies the how, in the omic space, life produces value.

The new economy linked to the omic sciences and to personalized medicine comprises four main areas – the industrial application of pharmacogenomics, the capitalization on patents on omic information and knowledge, the establishment of biobanks, and the development of the informatics infrastructure – each of which is addressed in detail below.

The traditional approach to drug development, or the blockbuster model, is in crisis, evidenced by the relatively small number of new drugs that have been developed in recent years. The omic sciences, especially pharmacogenomics, may contribute to the creation of a smarter drug development process grounded in a new business model for the pharmaceutical industry based on accelerated drug discovery and development, risk reduction, regulatory drug approval and product differentiation. The capitalization on omic knowledge (in the form of patents, diagnostic kits, etc.) is based on the emergence of small bio-tech companies and entrepreneurs and the alliance of these two groups with big pharma companies. The goal of this collaboration is to capitalize on patents on omic information and knowledge. Thus consortia have been formed by the world's largest pharmaceutical firms, such as Wellcome, Bayer, Pfizer, SmithKline Beecham and Novartis, to discover and map the most common type of genetic variation, single nucleotide polymorphisms. Somewhere between 10 and 20% of the R&D budgets of big pharmaceutical companies are now directed toward genomics (\$4-8 billion a year) (Rothstein, 2003).

The phenomenon of bio-banking goes hand-in-hand with pharmacogenomics and the exploitation of omic knowledge. The term bio-bank refers to an organized collection of [mostly human] biological material and associated information stored for research purposes (Winickoff and Winickoff 2003). One of the cornerstones of personalized medicine, bio-banks are evolving into important centers of “genetic and genomic discovery, information brokering, and providers of genetics-based services to health care enterprises.” Research indicates that the global demand for human tissue and for associated human tissue research services in 2009 was estimated to be approximately \$700 million. Moreover, the bio-banking marketplace has been growing between 20% and 30% annually, with some 180 commercial bio-banks currently operating in the United States. In this respect, the bio-bank is probably the best example of the way in which life – biological material – is involved in the process of capital accumulation. Although it is true that in classical capitalism life was already involved in the process of capital accumulation, it was a process mediated by the worker's activity (Virno, 2004). In modern bio-banks, in contrast, there is no such mediation. Value is not even related to the number of specimens in the inventory, but to the circulation of information: “the real measure of success for a bio-bank is not the volume of samples in inventory, but the number of outgoing samples and research projects supported” (Vaught, et al., 2011: 29), since “[T]he real value addition occurs when bio-specimens are linked with the clinical, pathological, histopathology, treatment response, and disease outcome data” (ibid).

Central to the development of the new economy is the informatics infrastructure, because the omic space itself depends on the integration of the vast amounts of data generated by the different omic sciences and the future-oriented character of personalized medicine critically depends on information technology. The area of informatics is divided into two sectors, the first of which is the development of the general informatics systems that will be able to manage and deal with the huge amounts of data that will be produced (storing, analysis, integration, risk assessment, distribution, and coordination). Included in such systems are bio-medical informatics

and technologies that will manage “massive amounts of raw healthcare data of all types (genomic, proteomic, patient, image, population), evolving into structured knowledge representations, distilled identification of fundamental biological mechanisms and significant disease factors, ultimately leading to improved healthcare decision support capabilities” (Sarachan et al. 2003). The directors of the FDA and the NIH expressed it as “building a national highway system for personalized medicine, with substantial investments in infrastructure and standards (Hamburg and Collins 2010:304). The second informatics sector, “consumer health informatics”, has been defined as a branch of medical informatics that “analyzes consumers' needs for information, studies and implements methods of making information accessible to consumers, and models and integrates consumers' preferences into medical information systems” (in Gibbons et al. 2009).

In sum, personalized medicine and the emergence of the omic space pave the way for new methods of capital accumulation based on specific knowledge and on the valorization of life itself.

## 5) Conclusion

While the processes and trends discussed above are very recent, complicating an assessment of their relative endurance over time, they do support the claim that the emergence and development of personalized medicine as a new paradigm within the practice of medicine can be understood as an expression of a new type of power over life, omic-politics. In line with Foucault's conceptualization of governmentality, omic politics is both individualizing and totalizing, and in fact the concept blurs the boundaries between the two. Personalized medicine is an expression of omic politics aimed to individualize medical practice by focusing on the omic space as a totality that involves not only a new conceptualization of the individual person, but also the complex system of information flow. It is power not, or at least not only, in its repressive sense, but as a capacity to act (Revel, 2009). It is not an up-to-date form of medicalization (Finkler et al. 2003). Personalized medicine as omic power is not only repressive (even though the centrality of surveillance involves the possibility of repression). Firstly, it may empower patients, making them active participants in the diagnostic and therapeutic process. Secondly, the concepts of exposome and socio-exposome constitute fields in which the power of corporations or the neo-liberal model can be challenged by showing their deleterious effects on health. But most of all, personalized medicine as omic power is not only repressive because it is first and foremost a productive power. Personalized medicine as omic power is productive in four main senses. First, because it produces new forms of individual and collective subjectivities. As shown above, personalized medicine and the omic sciences redefine our idea of person and ground the emergence of new forms of collective subjects and the ethics and regulative discourses dealing with these new subjectivities. Secondly, personalized medicine is productive since it produces tangible diagnostic and therapeutic benefits. The development of personalized medicine and the omic science will play a role in decreasing the number of adverse drug reactions (currently the fifth leading cause of death in the US). It will also allow for the development of new and more

effective treatment, leading to a higher probability of desired outcomes with treatment, lower probability of side effects, development of preventive strategies, more focused therapies and improved health. Thirdly, omic power is productive in economic terms, generating new forms of capital accumulation, new commodities, and the flux of new types of capital. Finally, personalized medicine as omic power produces a new form of utopia, which replaces modern social utopias with a utopian dream in which “corporeality is transfigured into an active utopian project ... ‘let my body endure’”(Chrysantou 2002:469).

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<sup>i</sup> For a different interpretation of the influence of genomics and bio-informatics on biopolitics see Eugene Thacker (2005).

<sup>ii</sup> It should be noted, however, that even though the aim and the rhetoric of personalized medicine is the individual patient, in fact much of its concrete practice is the transition from the universal level to that of sub-populations (Tutton R. Tutton / *Social Science & Medicine* 75 (2012) 1721e1728: 1726)

<sup>iii</sup> Pharmacogenetics focuses on drug response as a function of genetic differences among individuals.

<sup>iv</sup> Proteomics is the study of the expression and function of proteins on a global level. Proteomics characterizes the information flow within the cell and the organism, a flow mediated through and by protein pathways and networks (Liotta et al, 2001:2211). Metabolomics is the study of global metabolite profiles in cells, tissues and organisms (Metabolomics takes its place 2004), while metabonomics emphasizes the systemic changes of complex metabolic systems through time (Azuaje, Biomarker discovery: omic data analysis for personalized medicine). Epigenomics is

the study of the comprehensive set of factors that affect the genome function without the accompanying changes in the genome itself (for example, changes in DNA methylation) (Genomics and personalized medicine).

<sup>v</sup> Theragnostics associates a diagnostic test that identifies patients most likely to be helped or harmed by a new medication and targeted drug therapy based on the test results.

<sup>vi</sup> Pharmacovigilance may be defined as the detection, assessment, understanding and prevention of the adverse effect of medications.

<sup>vii</sup> Daniel Dennett, for example, lists six. Something is a person only if it is rational; it is the subject of psychological, mental, or intentional states; it is treated in a certain (personal) way by others; it reciprocates this attitude; it is capable of verbal communication; it is conscious in some special way (perhaps by being self-conscious) (Evnine, 2008:7)

<sup>viii</sup> As the Nuffield Report states, “we recognize that one important feature of genetic data is that they may reveal information that is unrelated to the illness in question, or indeed to any disease, and that this additional information may not be known about at the time the genetic sample is taken. This makes obtaining informed consent to the test difficult.”(Nuffield report)