REVIEW: ADVOCACY IN PERSONALIZED MEDICINE - A DEVELOPING STRENGTH IN A COMPLEX SPACE

Author(s) names & affiliations: Iain Miller, bioMérieux; Kristin Pothier, Health Advances, and Michael Dunn, Health Advances

Abstract/Summary:

Multiple stakeholders play a role in the adoption of personalized medicine; many times in contradictory ways. A growing number of advocacy groups have emerged to unify these stakeholders in this increasingly complex marketplace. This article will identify examples of these advocacy efforts in personalized medicine today. It will discuss how far these groups have been able to go, what they are currently pursuing, and how they and others can continue to work to move personalized medicine from concept to reality.

Keywords:

Advocacy, personalized medicine, cancer, companion diagnostics, diagnostic regulation

Commercializing a targeted diagnostic is not an easy feat. The scientific grounding of the biomarker, the technical challenges of a user-friendly and robust diagnostic, and the clinical impact on patient care are just the beginning. Once the diagnostic has moved from development into commercialization, the lack of clear regulatory guidelines, targeting of the appropriate patient segments, educating clinicians, generating support for premium-pricing, and the essential need to generate near-term returns can all be overwhelming. Complicating matters further, each stakeholder in the process is interested in making sure that the diagnostic launch covers a particular, sometimes contradictory, market need.

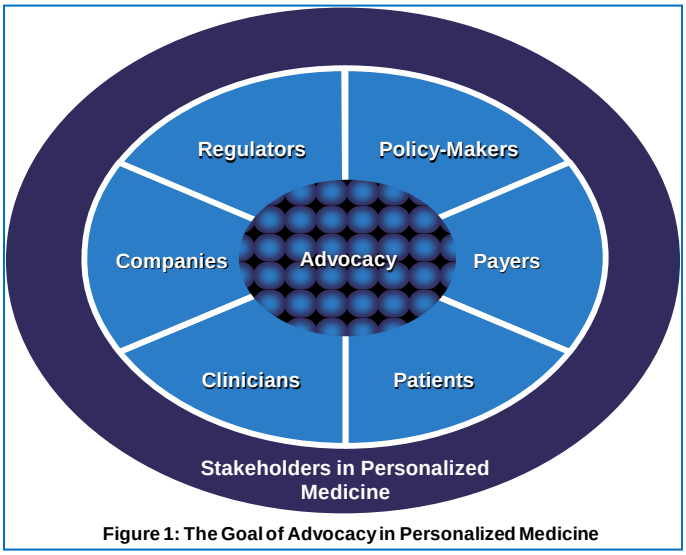

Figure 1: The Goal of Advocacy in Personalized Medicine

Multiple stakeholders exist in personalized medicine, including payers, providers, patients, policy makers, and clinicians. These stakeholders span multiple positions, institutions, and points of view. While ideally unified in a single goal of promoting personalized medicine, many stakeholders have differing opinions on how to effectively achieve this goal. At times, third parties are desired to align multiple positions or advance agendas to protect the interests of personalized medicine as a whole.

Advocacy groups are beginning to serve this function in personalized medicine. Today, these groups fall into three major categories: diverse healthcare groups, formal trade associations, and patient advocacy groups.

Diverse healthcare groups examine and promote general policies relating to personalized medicine. For example, the Personalized Medicine Coalition (PMC) [101] is a 200 member group of academic, industry, patient, provider and payer representatives. PMC has worked with the FDA and other government agencies on key policies and legislation to advance the understanding and adoption of personalized medicine. In recent years, PMC was a strong supporter of the Genetic Information Non-Discrimination Act (GINA). GINA was a necessary first-step in advancement of personalized medicine as it protects Americans from being treated unfairly because of genetic differences that may affect their health [1]. The law prevents discrimination from both health insurers

and employers, and was signed into federal law on May 21, 2008. PMC is now working with Congress on a reintroduction of the Genomics and Personalized Medicine Act (GPMA) [2]. First introduced by then-Senator Obama in 2007, and now being championed by representative Patrick Kennedy, the GPMA introduced several initiatives, including suggestions for Secretary of Health and Human Services (HHS) to harmonize US biobanks, improve training and counseling for genetic disorders, examine incentives for companion diagnostic test development, and conduct research on improving federal oversight and regulation of genetic tests. At the same time, PMC had 40 members complete and submit a white paper to provide recommendations on revisions to the FDA's 2005 concept paper on drug-diagnostic co-development, which outlines initial perspectives on how to prospectively co-develop a diagnostic test with a drug or biological therapy [3]. This white paper was released in December 2009 [103]. According to Amy Miller, PMC's Public Policy Director, this is expected to bring visibility to the diagnostic regulatory process, "*This will likely bring increased regulatory transparency to the development of new companion diagnostics which advocates have pushed for. Regulatory clarity will help motivate companies to expand their investment in companion diagnostics which will ultimately improve patient care.*" [Amy Miller, PMC Public Policy Director, Washington DC, USA, Pers. Comm.].Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at the FDA, has indicated that until the 2005 concept draft becomes formalized, a series of white papers should be published to allow discussion for final guidance [102]. To continue the momentum, PMC is responding to Woodcock's suggestions and is currently generating a series of additional white paper topics to be further explored.

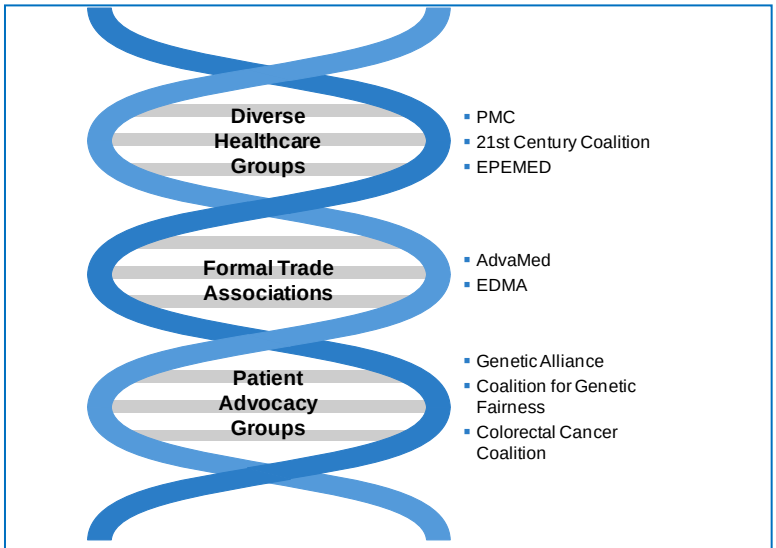

Figure 2: Examples of Advocacy Groups in Personalized Medicine.
PMC: Personalized Medicine Coalition.
EPEMED: European Personalized Medicine Diagnostics.
AdvaMed: Advanced Medical Technology Association.
EDMA: European Diagnostic Manufacturers Association.

Other diverse healthcare groups are also involved. In April 2009, The Coalition for 21st Century Medicine [104] and the Johns Hopkins University Genetics and Public Policy Center [105] joined forces to submit their recommendations for diagnostic regulations. In a joint letter to HHS Secretary Kathleen Sebelius, the groups promoted risk-based regulation of diagnostics under a new regulatory framework, subject to public review. The public review request may have been prompted due to the lack of an official public review process in introducing other guidelines such as the draft *In Vitro* Diagnostic Multivariate Index Assays (IVDMIAs) guidelines in 2006, which asserts that IVDMIAs are subject to FDA regulation as class II or class III medical devices, and the spotty adherence to any guidelines thus far. *"The FDA has published a draft guidance, but it has yet to come up with official guidelines for IVDMIAs"* says Helen Schiff [Helen Schiff, Patient Advocate, New York, USA, Pers. Comm.]. With only draft guidelines available, for both diagnostic-drug co-development and IVDMIAs, test developers are faced with an uncertain regulatory path. Schiff noted that in 2007, Agendia's MammaPrint, a personalized breast cancer recurrence risk test, was the first IVDMIA to gain clearance from the FDA. Since MammaPrint, three other tests have been cleared, Pathwork Dx's Tissue of Origin Test, XDx's AlloMap and Vermillion's OVA1 [106,107]. However, due to the lack of official guidelines, test developers may instead choose to continue marketing tests as laboratory-developed tests, one example being Genomic Health's Onco*type* DX. The Coalition for 21st Century

Medicine and the John Hopkins group also noted these diagnostic regulation discrepancies and are advocating for the establishment of a test registry [4] and strengthening of Clinical Laboratory Improvement Amendments (CLIA) oversight by the FDA to aid in stronger oversight and direction for entities launching new tests.

In Europe, **E**uropean **PE**rsonalized **ME**dicine **D**iagnostics (EPEMED) [108] was formed in June 2009 to advance personalized medicine in the public, government and private sectors. Chaired by Alain Huriez, CEO of TcLand, EPEMED consists of representatives from the diagnostic, pharmaceutical, professional services and academic communities whose initial efforts are focused on providing opinion leadership on EU policies. EPEMED intends on taking an active role in lobbying for directives related to personalized medicine, publish papers and press releases to enhance public awareness and collaborate with other personalized medicine organizations to develop educational and training initiatives. The European advocacy focus of this group is necessary because additional challenges exist for personalized medicine entry into the European market. One such challenge relates to the different clinical laboratory market structures. In the US, specialized company-run CLIA laboratories have introduced many personalized medicine tests. For example, Genomic Health's commercial development test for Onco*type* DX has so far exceeded a $100MM investment. Several other novel laboratory-developed tests carry significant development price tags in the range of $25-$50MM before launch, reflecting the investments faced by innovative tests [5]. Such companies are able to support the significant capital necessary to commercialize high-value diagnostics. In contrast, the personalized medicine adoption rate in Europe is challenged by the lack of local investment champions who are able to realize the necessary returns for widespread marketing. As a consequence there are fewer high complexity corporate laboratories or companies structured to adequately finance and develop such diagnostics. Further, regulatory barriers continue to exist, for example, it is currently forbidden by statute in France for a corporation to own more than 75 percent of the voting capital of a clinical laboratory [109]. Furthermore, reimbursement limitations associated with the larger public sector across Europe may discourage adoption of emerging complex tests, regardless of the potential for associated cost savings. Lastly, access to diagnostics is complicated by reimbursement barriers. Access to these complex diagnostics is typically limited to the private patient base comprising the minority of the population which is limiting adoption. EPEMED is diligently working to examine these challenges and developing clear directives to better advance personalized medicine in the EU.

Formal trade associations represent the second major advocacy force, focusing on revising current guidelines pertaining to personalized medicine. AdvaMed (Advanced Medical Technology Association) [110] has recently established a new division, named AdvaMed Dx. The division will be governed by an 18 member Board of Directors chaired by Beckman Coulter CEO Scott Garrett, and an eight member Executive Committee, with the broad goal of advancing the policy priorities of *in vitro* diagnostic companies in order to strengthen its advocacy impact both domestically and abroad [110].

Additionally, AdvaMed and EDMA (European Diagnostic Manufacturers Association) [111] had also established a joint theranostic taskforce composed of leading international diagnostic companies, chaired by bioMérieux. Similar to the initiative within PMC, this group is currently focused on regulatory reform and contributing to the revisions of the FDA's 2005 draft concept paper. In efforts to finalize a document, AdvaMed separately submitted its "Risk-Based Regulation of Diagnostics" proposal to the FDA in March 2009 [112]. This proposal seeks to harmonize regulation of tests with greater FDA oversight, whether tests are developed by manufacturers or clinical laboratories.

Finally, patient advocacies play a significant role in personalized medicine in a variety of healthcare settings, with focus on specific cancers or diseases and diagnostic tests to support them. Many patient advocacy groups supported GINA. Initially introduced by Congresswoman Slaughter

and Senator Snowe, the GINA initiative was strongly supported by many groups. For example, the Coalition for Genetic Fairness was founded by the Alpha-1 Association, Genetic Alliance, Hadassah, National Partnership for Women & Families, National Society of Genetic Counselors and the National Workrights Institute [113,114]. The Coalition recognized the need for a singular message among patient advocacy groups and industry; therefore they united forming an alliance, to provide another avenue to inform Congressional policy makers on the importance of genetic non-discrimination. After achieving its purpose and supporting GINA's enactment, the Coalition has since disbanded.

Other patient advocacy groups such as the Colorectal Cancer Coalition [115] are playing an important role to advance personalized medicine in the US and the EU. Such groups believe that there is a compelling rationale for testing to allow better understanding and management of both drug risk and benefit. For example, consider the development and implementation of a KRAS test co-developed by Amgen and DxS, and the role advocacy groups took to get this test incorporated into consideration for standard of care.

In 2004, ImClone Systems received both FDA and EMEA clearance for its anti-EGFR therapy, Erbitux. In 2006, two years post-Erbitux approval, the first scientific paper was published demonstrating the link between KRAS mutation status and efficacy of anti-EGFR therapies [6]. In September of that same year, Amgen's Vectibix, an anti-EGFR competitor to Erbitux, gained FDA approval. Both anti-EGFR therapies, Erbitux and Vectibix, were approved with minimal knowledge of KRAS mutation status on anti-EGFR efficacy.

By early 2007, a couple of small studies had indicated that colorectal cancer patients who had activating mutations in their KRAS gene did not respond to EGFR inhibitors [7,8]. In May, shortly after these studies were published, the EMEA declined to approve Vectibix based on its progression-free survival endpoint. With growing knowledge of the association between KRAS mutation status and anti-EGFR efficacy, EMEA required Amgen to perform a retrospective analysis of the samples used

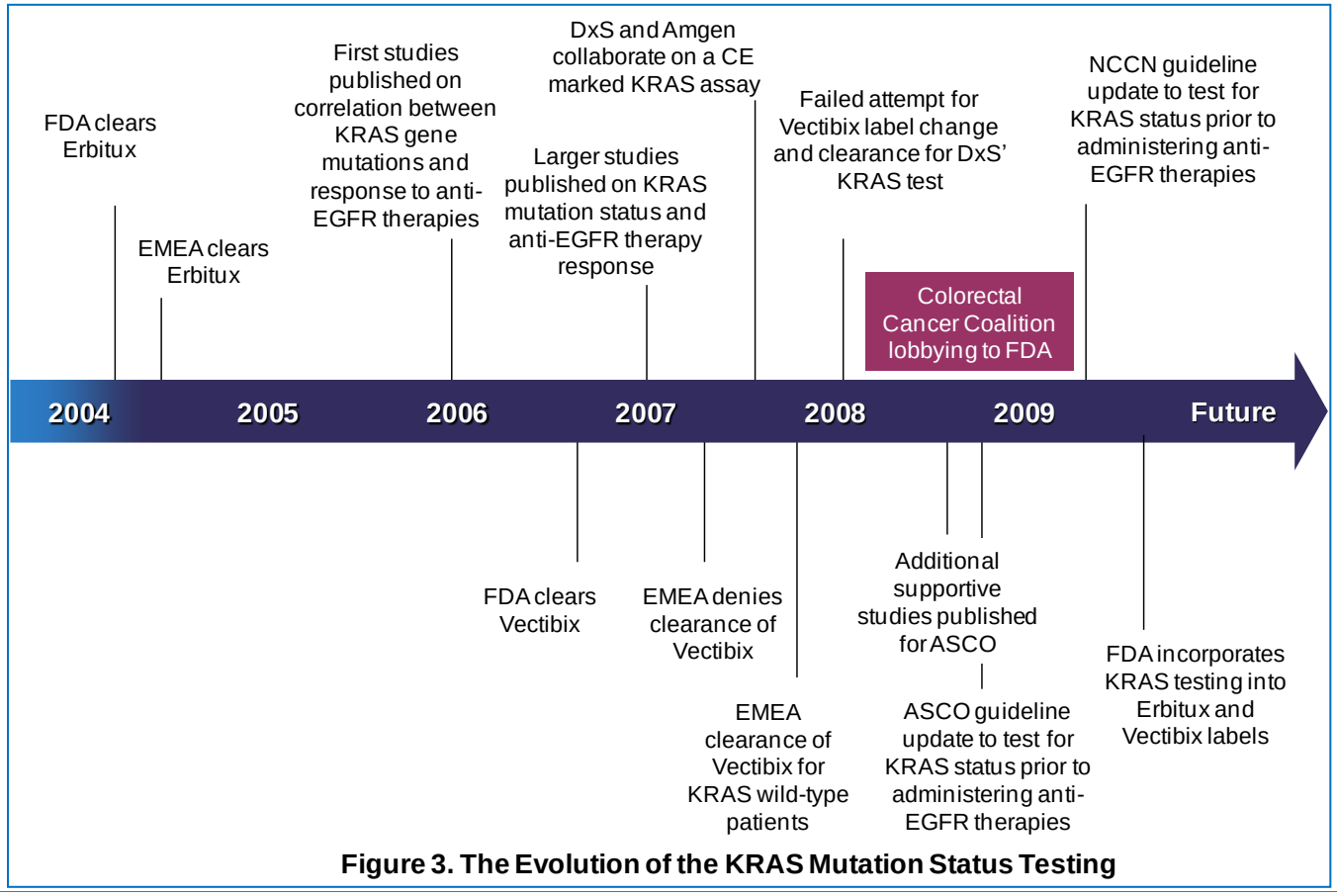

Figure 3. The Evolution of the KRAS Mutation Status Testing

to gain FDA approval for Vectibix. Amgen further validated initial studies indicating respondents to Vectibix were exclusively in the wild-type KRAS group; representing approximately 60 percent of the metastatic colorectal cancer population [9]. With this data, Vectibix received EMEA approval in December 2007 for wild-type patients only. In addition to the approval, EMEA required Amgen to assist in putting a regulatory approved test on the market. Amgen worked with DxS, a small personalized medicine company recently acquired by Qiagen, to secure EMEA approval of TheraScreen, its KRAS mutation detection kit, in December 2007.

In early 2008, Amgen and DxS met with the FDA in efforts to obtain a label update for Vectibix, and regulatory approval for DxS' TheraScreen, as a companion diagnostic test. The FDA indicated that the retrospective analysis performed for EMEA approval would not allow for a label change [116]. Shortly thereafter, more supportive studies of the KRAS mutation and lack of EGFR efficacy were presented at the 2008 American Society of Clinical Oncology (ASCO) meeting [10,11,12]. Advocacy groups, including Colorectal Cancer Coalition, then got involved and lobbied the FDA concerning the various large studies involving Erbitux [Peter Collins, VP Business Development DxS, London, UK, Pers. Comm.]. Colorectal Cancer Coalition also engaged in discussions on proper trial design and patient recruitment for publicly funded EGFR-trials funded by the National Cancer Institute (NCI), and Cancer Therapy Evaluation Program (CTEP) to ensure KRAS mutant patients were not included in studies [Nancy Roach, C3: Colorectal Cancer Coalition, Alexandria VA, USA, Pers. Comm.]. With hopes of label updates for Erbitux and Vectibix, advocates expressed their opinion that it would be unethical to recruit all comers to future studies since KRAS mutant patients would not respond to therapy. Along with industry support on regulation of *in vitro* diagnostic tests from Genentech's Citizen Petition [117] and a letter from the Colorectal Cancer Coalition in December, 2008 to the FDA's Oncology Drug Advisory Committee (ODAC) strongly urging the change of labels for KRAS mutant status, awareness escalated. ODAC had full-day discussions related to KRAS status and necessity for guideline inclusion [118].

Although the Coalition never received a formal response to this letter, advocates were confident label updates were imminent [C3: Colorectal Cancer Coalition, Washington, DC, USA, Pers. Comm.]. Advocates waited patiently during what seemed to be a lengthy delay in label updates given significant data supporting the link between EGFR-response rates and KRAS mutation status. This delay may have been in part due to controversy surrounding the label and whether a specific branded test should be assigned to EGFR-inhibitors or whether the label should be less specific and include a gene or pathway mutation status. In the end, following the Coalition's letter and guideline inclusion from ASCO and the National Comprehensive Cancer Network (NCCN), the FDA incorporated the need for KRAS testing into Vectibix and Erbitux labels in July 2009*. KRAS testing is now available from both private and public corporations across the US. The label updates and guideline inclusion is an important step forward as highlighted by ImClone Systems Executive Vice President and Chief Medical Officer, Eric Rowinsky, "*This revision is being included in the labeling of EGFR monoclonal antibody inhibitors with metastatic colorectal cancer indications in the US and is the result of a collaborative dialogue between the FDA, the industry, and the public about the role of the KRAS biomarker in metastatic colorectal cancer patients being considered for therapy."* [119]

In addition to a label change that directly benefits patients; the KRAS scenario has catalyzed awareness and interest in the field which will facilitate the future development of personalized medicine tests. This outcome was a clear win for all personalized medicine stakeholders, and an example of how lobbying efforts from a variety of societies can play a role in the process of governmental regulation in the diagnostic standard of care. As stakeholders continue to lobby for acceptance of personalized medicine, stakeholders will need continued support from biomedical science companies in efforts to develop the necessary tests.

As seen with the National Breast Cancer Coalition (NBCC) [120] for breast cancer and its support for HER2 testing [121], advocacy can have an incredible impact on awareness and positive pressure on governmental organizations to implement guidelines. However, challenges for these groups exist. While several of the personalized medicine advocacy groups have a strong membership base, others are nascent and small in scale. Additionally, the field is complex, and competes for attention in the US with current healthcare reform efforts focused on the uninsured, comparative effectiveness measures and control of cost escalation. Important goals, such as better value realization for diagnostic tests, can mistakenly seem to offer the prospect of increased cost of care; an argument not yet easily dismissed due to the few economic models detailing current personalized medicine scenarios [5,13,14].

Furthermore, the larger and more diverse advocacy organizations can suffer from the sometimes conflicting agendas of their membership. PMC, for example, while an effective organization, must strive to balance the diverse agendas of its 200-member base. Also, differences can be seen in the agendas of various advocacy organizations on the same issue. For example, The Coalition for 21st Century Medicine and John Hopkin's letter to Secretary Sebelius contrasts slightly with the AdvaMed agenda. While both groups agree on a risk-based approach for FDA oversight, AdvaMed favors direct FDA oversight of diagnostic regulation while the Coalition's letter to Secretary Sebelius suggests more stringent CLIA oversight. Such differing views from advocates may further stall any regulatory development. By contrast, the efforts by the National Partnership for Women and Families, the American Academy of Pediatrics, Hadeassah and the Genetic Alliance among others to form the Coalition for Genetic Fairness proved successful in passing GINA. This latter example demonstrates the importance of groups uniting to advocate one unified message. Executive Director of National Lung Cancer Partnership, Regina Vidaver has also expressed, *"One of the major problems we have as advocates is that we cannot agree on a singular message, everyone has their own agenda."* [Regina Vidaver, Executive Director, National Lung Cancer Partnership, Wisconsin, USA, Pers. Comm.] This statement further highlights the importance of a cohesive message across advocacy groups.

Future Perspective

Although challenges exist, this review of the impact of advocacy in the personalized medicine marketplace reveals significant signs of progress:

- Passage of the GINA in 2008, in part due to the unified efforts of Coalition for Genetic Fairness after 13 years of congressional debate, should stimulate personalized medicine research and development
- The successful KRAS story highlights the impact of patient advocacy groups such as the Colorectal Cancer Coalition, and the positive outcomes which can ensue when pharmaceutical and diagnostic companies work together with regulators
- The FDA's anticipated update of its companion diagnostic guidelines, after multiple comments from industry and advocacy groups, will potentially bring much-needed regulatory transparency to the development of new tests

While these initiatives are significant, their successful implementation requires the continued involvement of the many but diverse constituencies that have a stake in the success of personalized medicine. Personalized medicine has the potential to benefit all parties in this era of healthcare reform, and with additional exposure, coordination, and time, advocacy groups can play a driving role in the delivery of personalized medicine to those in need. Constituents in this complex space are encouraged to participate.

For more information on the advocacy groups mentioned in this article, please contact the following:

Advocacy Groups	Email	Website
AdvaMed	info@advamed.org	http://www.advamed.org/MemberPortal/
Coalition for Genetic Fairness	Andria Cornell: acornell@geneticalliance.org	http://www.geneticfairness.org/
Colorectal Cancer Coalition	info@fightcolorectalcancer.org	http://fightcolorectalcancer.org/
EDMA	edma@edma-ivd.be	http://www.edma-ivd.be/
EPEMED	contact@epemed.org	www.epemed.com
Genetic Alliance	info@geneticalliance.org	http://www.geneticalliance.org/
PMC	Edward Abrahams, Executive Director : eabrahams@PersonalizedMedicineCoalition.org	http://www.personalizedmedicinecoalition.org
21st Century Coalition	jeyer@deweysquare.com	http://www.twentyfirstcenturymedicine.org/

Table 1. Contact Information for Example Advocacy Groups.

References:

[1]H.R. 493 [110th]: Genetic Information Non-discrimination Act of 2008.

[2] S.976: Genomics and Personalized Medicine Act of 2007.

[3] Wong C. PMC Member Newsletter 3 (Summer 2009).

[4] Javitt G, Katsanis S, Scott J, Hudson K. Developing the Blueprint for a Genetic Testing Registry. *Public Health Genomics.* Jun (2009). [Epub ahead of print].

[5] Gustavsen and Pothier, How to Earn the Economic Payback Diagnostic Companies Deserve. *In Vivo* 3, 70 (2009).*

[6] Lièvre A, Bachet JB, Le Corre D *et al*.: KRAS Mutation Status Is Predictive of Response to Cetuximab Therapy in Colorectal Cancer. *Cancer Res.* 66(8), 3992-3995 (2006). **

[7] Benvenuti S, Sartore-Bianchi A, Di Nicolantonio F *et al.*: Oncogenic Activation of the RAS/RAF Signaling Pathway Impairs the Response of Metastatic Colorectal Cancers to Anti-Epidermal Growth Factor Receptor Antibody Therapies. *Cancer Res.* 67(6), 2643-2648 (2007).**

[8] Di Fiore F, Blanchard F, Charbonnier F *et al.*: Clinical relevance of KRAS mutation detection in metastatic colorectal cancer treated by Cetuximab plus chemotherapy. *Br. J. Cancer.* 96(8) 1166-1169 (2007). **

[9] Amado RG, Wolf M, Peeters M *et al.* Wild-Type KRAS Is Required for Panitumumab Efficacy in Patients With Metastatic Colorectal Cancer. Presented at: *14th European Cancer Conference*. Barcelona, Spain, 23 September-27 September 2007.**

[10] Bokemeyer C, Bondarenko I, Hartmann JT, *et al*. KRAS Status and efficacy of first-line treatment of patients with metastatic colorectal cancer (mCRC) with FOLFOX with or without cetuximab: The OPUS experience. Presented at: *American Society of Clinical Oncology*. Chicago, IL, USA 30 May-2 June 2008. **

[11] Van Cutsem E, Lang I, D'haens G *et al*. KRAS status and efficacy in the first-line treatment of patients with metastatic colorectal cancer (mCRC) treated with FOLFIRI with or without cetuximab: The CRYSTAL experience. Presented at: *American Society of Clinical Oncology*. Chicago, IL, USA 30 May-2 June 2008.**

[12] Tejpar S, Peeters M, Humblet Y *et al*. Relationship of efficacy with KRAS status (wild type versus mutant) in patients with irinotecan-refractory metastatic colorectal cancer (mCRC), treated with irinotecan (q2w) and escalating doses of cetuximab (q1w): The EVEREST experience (preliminary data). Presented at: *American Society of Clinical Oncology*. Chicago, IL, USA 30 May-2 June 2008.**

[13] Garrison, L.P. Will Pharmacogenomics Disrupt the U.S. Health Care System? No. *Public Health Genomics.* 12:185-190 (2009).

[14] Carlson, R.J. The Disruptive Nature of Personalized Medicine Technologies: Implications for the Health Care System. *Public Health Genomics.* 12:180-184 (2009).

* While DxS' TheraScreen was used to gain both label changes, it is not commercially available in the US at this time.

Websites

[101] PMC www.personalizedmedicine.org

[102] Press release asking for white paper publications on drug/diagnostic co-development http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=130

[103] PMC white paper press release http://www.genomeweb.com/dxpgx/pmc-issues-white-paper-help-fda-update-outdated-rxdx-co-development-concept-pape

[104] The Coalition for 21st Century Medicine twentyfirstcenturymedicine.org

[105] Johns Hopkins University Genetics and Public Policy Center dnapolicy.org

[106] IVDMIA test clearance http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtlt_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtlt&cntvwrPtlt%7BactionForm.contentReference%7D=committees%2Ftechnology%2Fivdmia.html&_state=maximized&_pageLabel=cntvwr

[107] IVDMIA OVA1 test clearance http://www.genomeweb.com/dxpgx/vermillionquests-ova1-ovarian-cancer-risk-test-cleared-fda-ivdmia

[108] EPEMED www.epemed.org

[109] Article L6214-3, French Public Health Code http://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=E5624ABDE00D8F4674173F353F800C29.tpdjo08v_3?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006691255&dateTexte=20091215&categorieLien=cid

[110] AdvaMed www.advamed.org/MemberPortal/

[111] EDMA www.edma.ivd-be/

[112] AdvaMed's Risk-Based Proposal http://www.dnapolicy.org/news.enews.article.nocategory.php?action=detail&newsletter_id=41&article_id=198.

[113] Coalition for Genetic Fairness http://www.geneticfairness.org/about.html

[114] Genetic Alliance leads formation of Coalition for Genetic Fairness http://www.geneticalliance.org/ws_display.asp?filter=policy.leg.nondiscrim

[115] Colorectal Cancer Coalition www.fightcolorectalcancer.org

[116] Press Release indicating FDA's decline of retrospective Vectibix data http://www.fiercebiotech.com/story/fda-advisers-skeptical-retrospective-genetic-analysis/2008-12-17

[117] Genentech Citizen Petition http://www.genomeweb.com/genentech-files-citizen-petition-urging-fda-regulate-all-lab-developed-tests

[118] ODAC proceedings http://www.fda.gov/ohrms/dockets/ac/cder08.html#OncologicDrugs

[119] ImClone Press Release http://www.businesswire.com/portal/site/bms/?ndmViewId=news_view&newsId=20090720005482&newsLang=en

[120] National Breast Cancer Coalition (NBCC) http://www.stopbreastcancer.org/

[121] NBCC support for HER2 testing http://www.stopbreastcancer.org/index.php?option=com_content&task=view&id=341

Reference Annotations:

* Article outlines commercial challenge facing test development

** Articles and proceedings outline importance of K-Ras marker to select patients for large molecular anti-EGFR therapy

Executive Summary

- **Multiple stakeholders play a role in the development, commercialization, and adoption of personalized medicine.**
- **Advocacy groups have emerged to unify these stakeholders in this increasingly complex marketplace.**
- **These groups, made up of diverse healthcare groups, formal diagnostic trade associations, and patient advocacy groups, each focus on promoting specific initiatives within personalized medicine.**
- **Although these groups have made great strides on improving awareness and putting positive pressure on governmental organizations to implement personalized medicine guidelines, major challenges remain.**
- **With additional exposure, coordination, and time, advocacy groups can continue to play a driving role in the delivery of personalized medicine to those in need.**

About the Authors:

Iain Miller, PhD, is the Senior Director of Oncology Strategy and Theranostics at bioMérieux (Iain.Miller@na.biomerieux.com). Kristin Pothier is a Vice President and Michael Dunn is a Senior Analyst at Health Advances, a healthcare strategy firm (kcpothier@healthadvances.com).

Financial and Competing Interests Disclosure:

The authors have no relevant financial or other competing interests relating to this manuscript.