vanced therapy medicinal products ("ATMPs").[9] The reflection paper was prepared by the EMA's Committee for Advanced Therapies and is open for comments until 31 July 2012.

The reflection paper clarifies the rules for the classification of medicines as advanced therapies in the context of Regulation (EC) No 1394/2007[10] and Directive 2001/83/EC. The paper provides details regarding the classification rules of these medicines as gene therapy medicinal products ("GTMP"), somatic-cell therapy medicinal products ("sCTMP"), tissue-engineered medicinal products ("TEP") or combined ATMPs.

The reflection paper specifies that, in order for a tissue-engineered product to be covered by the ATMP Regulation, it must contain viable human and/or animal cells and may contain substances such as cellular products, bio-molecules, biomaterials, chemical substances, scaffolds or matrices. In order for the product to be classified as a combined ATMP, the product must incorporate a cellular part consisting of viable or non-viable cells or tissues and of one or more medical devices, or one or more active implantable medical devices as an integral part of the product. In the case of non-viable cells or tissues, these must exercise the primary action of the combined product.

Furthermore, the reflection paper specifies the data applicants need to provide to the EMA when applying for classification of their medicine as an ATMP. The paper also addresses certain borderline cases and areas where scientific knowledge is limited or rapidly evolving, *e.g.* where human aortic endothelial cells cultured in a matrix and intended for the treatment of vascular injury are classified as an sCTMP, and not a combined ATMP.

9 The reflection paper is available on the EMA website at <http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/04/WC500126681.pdf> (last accessed on 18 July 2012).

10 Regulation (EC) No 1394/2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 324, 10.12.2007, p. 121 ('the ATMP Regulation').

Risk Communication

This section discusses issues related to risk communication across a range of publicly perceived high-risk industries (such as pharmaceuticals, nuclear, oil, etc.). It reports critically and provides analysis on risk communication as an outcome of risk research within these industries. Contributions are intended to include methods working towards the advancement of risk perception research and describe any lessons learned for successfully communicating to the public about risk.

Emerging Risk Communication Challenges Associated with Shale Gas Development

Christopher E Clarke, Darrick T.N. Evensen**, Jeffrey Jacquet*** and Richard C. Stedman*****

In recent years, there has been a push for natural gas development in shale formations in the United States (U.S)[1] and Europe[2] [3] due to factors that make extraction more economically viable, including increased demand for fuels with lower greenhouse gas emissions compared to coal and oil; new extraction technologies; and overall trends towards increased energy prices. Shale gas development entails a novel combination of technologies, including horizontal drilling from a central well pad and hydraulic fracturing (known colloquially as "fracking"), which uses large amounts of water, sand, and chemicals under high pressure to fracture the rock and release gas. While European nations debate the merits of shale

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1 United States Energy Information Administration, "What is Shale Gas and Why Is It Important?", 2012, available on the Internet at <http://www.eia.gov/energy_in_brief/about_shale_gas.cfm> (last assessed on 07 August 2012).

2 Fiona Harvey, "Gas 'Fracking' Gets Green Light", 2012, available on the Internet at <http://www.guardian.co.uk/environment/2012/apr/17/gas-fracking-gets-green-light> (last assessed on 07 August 2012).

3 Cable News Network, "Poland Has Great "Fracking" Potential with Shale Gas Reserves", 2012, available on the Internet at <http://articles.cnn.com/2012–05–28/world/world_europe_eye-on-poland-shale_1_shale-gas-fracking-natural-gas?_s=PM:EUROPE> (last assessed on 07 August 2012).

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gas development, it has already occurred across much of the U.S. over the past decade. However, it has proven increasingly controversial as national, state, and local governments work to define and quantify potential risks and benefits,[4] develop regulations,[5] and, in some cases, restrict or prohibit development.[6] [7]

Shale gas development involves a complex array of potential health, economic, social, and environmental impacts (both positive and negative) on individuals and communities.[8] The risk of adverse impacts is fundamentally uncertain, depending in part on the pace and scale of development, the governance and regulatory structure under which it occurs, and technological and geological factors.[9] We argue that understanding and effectively communicating risks associated with shale gas development can help inform ongoing policy-making about this issue. Considerable research has focused on the challenges of communicating risks and benefits of emerging and controversial technologies, both non-energy[10] and energy-related.[11] [12] In this brief report, we draw on aspects of this research, as well as our own ongoing studies, to identify key challenges – and where possible offer potential solutions – regarding risk communication in the context of shale gas development. We begin by analyzing potential functions of risk communication.

Risk Communication, Public Participation, and Shale Gas Development

Risk communication – defined as an "iterative exchange of information among individuals, groups, and institutions related to the assessment, characterization, and management of risk" [13] – performs various functions that are not necessarily mutually exclusive and may, at times, appear contradictory. Although one major function involves informing, educating, and persuading[14] (for example, pro and anti-shale gas development groups may focus on persuading people that development is or is not 'risky'),[15] we couch our commentary in the second function: involving and engaging stakeholders (ranging from policymakers to the public) in the decision-making process surrounding development. The shift in the risk communication field from 1-way, expert-to-public interaction to a more 2-way, public participatory focus is well-documented,[16] and there is a rich interdisciplinary literature on justifying, designing, implementing, and evaluating strategies for ensuring meaningful public participation in science, environmental, health, technological, and other risk domains.[17] [18] Considerable research has also focused on potential positive outcomes, including

4 New York State Department of Environmental Conservation, "Supplemental Generic Environmental Impact Statement on the Oil, Gas and Solution Mining Regulatory Program", 2011, available on the Internet at <http://www.dec.ny.gov/energy/75370.html > (last assessed on 07 August 2012).

5 Steve Hargreaves, "Obama Tightens Oil and Gas Drilling Regulations", 2012, available on the Internet at <http://money.cnn.com/2012/04/18/news/economy/drilling-regulations/index.htm> (last assessed on 07 August 2012).

6 Cable News Network, "Vermont First State to Ban Fracking", 2012, available on the Internet at <http://articles.cnn.com/2012–05–17/us/us_vermont-fracking_1_fracking-shale-natural-gas?_s=PM:US> (last accessed 07 August 2012).

7 David Castelvecchi, "France Becomes First Country to Ban Extraction of Natural Gas By Fracking", 2011, available on the Internet at <http://blogs.scientificamerican.com/observations/2011/06/30/france-becomes-first-country-to-ban-extraction-of-natural-gas-by-fracking/> (last accessed 07 August 2012).

8 Kathryn J. Brasier, Matthew R. Filteau, Diane K. McLaughlin, Jeffrey Jacquet, Richard C. Stedman, Timothy W. Kelsey, and Stephan J. Goetz, "Residents' Perceptions of Community and Environmental Impacts from Development of Natural Gas in the Marcellus Shale: A Comparison of Pennsylvania and New York Cases", 26 *Journal of Rural Social Studies* (2011), pp. 32–61.

9 Jeffrey Jacquet, "Energy Boomtowns and Natural Gas: Implications for Marcellus Shale Local Governments and Rural Communities", 2009, available on the Internet at <http://nercrd.psu.edu/publications/rdppapers/rdp43.pdf> (last accessed 07 August 2012).

10 John C. Besley, "Review: Current Research on Public perceptions of Nanotechnology", 3 *Emerging Health Threats Journal* (2010), pp. e8–e15.

11 John C. Besley, "Does Fairness Matter in the Context of Anger About Nuclear Energy Decision Making?", 32 *Risk Analysis* (2011), pp. 25–38.

12 Marjolein de Best-Waldhober, Dancker Daamen, and Andre Faaij, "Informed and Uninformed Public Opinions on CO_2 Capture and Storage Technologies in the Netherlands", 3 *International Journal of Greenhouse Gas Control* (2009), pp. 322–332.

13 Katherine A. McComas, "Defining Moments in Risk Communication Research: 1996–2005", 11 *Journal of Health Communication* (2006), pp. 75–91 *et sqq.*, at p. 76.

14 V.M. Bier., "On The State of the Art: Risk Communication to The Public", 71 *Reliability Engineering and System Safety* (2011), pp. 139–150.

15 Richard C. Haut, Tom Williams, David Burnett, and Gene Theodori, "Balancing Environmental Tradeoffs, Societal Issues, and Energy Production", 60 *Gulf Coast Association of Geological Societies Transactions* (2010), pp. 739–748.

16 Zamira Gurabardhi, Jan M. Gutteling, and Margot Kuttschreuter, "The Development of Risk Communication: An Empirical Analysis of the Literature in the Field", 25 *Science Communication (2004), pp.* 323–349.

17 Caron Chess and Kristen Purcell, "Public Participation and the Environment: Do We Know What Works?", 33 *Environmental Science & Technology* (1999), pp. 2685–2691.

18 Gene Rowe and Lynn J. Frewer, "Public Participation Methods: A Framework for Evaluation," 25 *Science, Technology, and Human Values* (2000), pp. 3–29.

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building trust among stakeholders; strengthening the legitimacy of policy decisions;[19] [20] and developing informed perceptions of important social issues by helping stakeholders carefully evaluate scientific and technical merits, including ambiguities and uncertainties, of risk information.[21]

Public participation has featured prominently in permitting and regulating shale gas development in the U.S. It has included both unsolicited input (such as advocacy groups reaching out to elected policymakers) and solicited input in the form of public meetings on proposed regulations and environmental impact statements developed by government agencies. Haut, Williams, Burnett, and Theodori,[22] moreover, argued for "mature, meaningful dialogue among members of the general public, community leaders, representatives of oil and gas associations, regulatory agency personnel, non-governmental organization representatives, and other interested individuals" about "the potentially positive aspects and negative consequences" and "hopes, fears, and/or anxieties associated with...development." Such discourse could be facilitated by government agencies responsible for managing gas development or university researchers/educators, which often enjoy relatively high levels of public trust.[23] We now turn to challenges associated with public participation in this context.

Challenge #1: Contested Risk Information

Scholars have articulated numerous challenges to creating and implementing effective public participation strategies for controversial social issues. Such challenges range from how to best define a "stakeholder" to selecting appropriate types of participation (such as public meetings, consensus conferences, and citizen juries) to the potential for increasing stakeholder polarization.[24] We focus, however, on information about potential risks and benefits of shale gas development that lies at the heart of 'informed" participation: in particular, how such information can be as contested as the impacts themselves.[25]

As with other controversial issues, information exchange on shale gas development involves not only scientific experts and government regulators but also mobilized groups that represent various interests. These groups often communicate widely varying – and often oppositional – accounts of associated risks and benefits. In so doing, they draw on (and, in turn, reinforce the legitimacy of) various sources of scientific information, lay knowledge deriving from personal experience and beliefs, and moral values. Moreover, each side accuses the other of misleading statements, biased research, and faulty scientific data and arguments that are selectively referenced to support an existing viewpoint.[26] For example, opponents – ranging from grassroots citizen groups to national and international environmental organizations – draw on scientific studies to contend that shale gas development poses an unacceptable risk to water supplies in terms of potential contamination from the drilling process and subsequent disposal of wastewater.[27] Industry supporters, in turn, dispute the findings and methods of those studies while citing other data and claims than suggest that economic benefits outweigh environmental risk.[28] This polarization is also manifested in the ongoing debate on the greenhouse gas "footprint" of shale gas development. Differing interpretations of the same data inform the conclusion that shale gas will either mitigate or increase global emissions of greenhouse gases that drive climate change.[29]

19 Michael X. Delli-Carpini, Fay Lomax Cook, and Lawrence R. Jacobs, "Public Deliberation, Discursive Participation, and Citizen Engagement: A Review of the Empirical Literature, 7 *Annual Review of Political Science* (2004), pp. 315–344.

20 Ana Delgado, Kamilla Lein Kjolberg, and Fern Wickson, "Public Engagement Coming of Age: From Theory to Practice in STS Encounters with Nanotechnology", 20 *Public Understanding of Science* (2011), pp. 826–845.

21 Katherine A. McComas, "Even The 'Best Laid' Plans Go Wrong: Strategic Risk Communication for New and Emerging Risks", 5 *EMBO Reports* (2011), pp. S61–S65.

22 Haut, Williams, Burnett and Theodori, "Balancing Environmental Tradeoffs, Societal Issues, and Energy Production", *supra*, note 15 *et sqq.*, at p. 746.

23 Richard Stedman, Fern K. Willits, Kathryn Brasier, Matthew R. Filteau et al. *Natural Gas Development: Views of New York and Pennsylvania Residents in the Marcellus Shale Region,* (Ithaca, NY: Cornell University Community and Regional Development Institute Research and Policy Brief #39, 2011).

24 Delgado, Lein Kjolberg and Wickson, "Public Engagement Coming of Age", *supra*, note 20.

25 Deborah Shmueli, Michael Elliott, and Sanda Kaufman, "Frame Changes and the Management of Intractable Conflicts", 24 *Conflict Resolution Quarterly* (2006), pp. 207–218.

26 Kenneth Klemow, "Marcellus Gas: Taking Advantage of a Teachable Moment", Winter 2012 *Journal of the Pennsylvania Association of Environmental Educators* (2012), pp. 1–5.

27 David M. Kargbo, Ron G. Wilhelm, and David J. Campbell, "Natural Gas Plays in the Marcellus Shale: Challenges and Potential Opportunities", 44 *Environmental Science & Technology* (2010), pp. 5679–5684.

28 Robert W. Howarth, Anthony Ingraffea, and Terry Engelder, "Natural Gas: Should Fracking Stop", 477 *Nature* (2011), pp. 271–275.

29 Kenneth M. Klemow and Ned Fetcher, "Greenhouse Gas Emissions Associated with Marcellus Shale", 2011, available on the Internet at <http://energy.wilkes.edu/PDFFiles/Reports/IEER.GHG.V3.pdf> (last accessed 07 August 2012).

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Challenge #2: Dynamic Information Needs and Risk Perceptions

Perceptions of risks associated with shale gas development, and the information people desire about those risks, are likely the product of multiple factors known to shape views on controversial science and technological issues: personal values and worldviews related to the human-environment relationship; experience with and knowledge of fossil fuel extraction; patterns of issue-related interaction with others; and information from mass media.[30] [31] As such, an important element of risk communication research and public participatory efforts involves exploring how stakeholders perceive risk and the factors that drive these perceptions, which can provide insight into salient information needs. A challenge, however, is that these needs, like the perceptions that drive them, are dynamic.

Shale gas development represents an industrial land use change that directly impacts large regions of the U.S. Identifying how perceptions of risk vary by individual, community, or region is challenging. Extant research on energy "boomtowns", which describes objective and subjective social, economic, and environmental effects arising from rapid population growth in communities in close proximity to energy development,[32] has provided a framework for addressing some of these challenges, while other researchers – including the present authors – have studied stakeholder perceptions of shale gas development impacts (both ongoing and proposed) in several U.S. states.[33] For example, Jacquet[34] surveyed Northern Pennsylvania landowners on their perceptions of local natural gas and large-scale wind farm development and found that proximity to the actual development had little role in influencing levels of support or opposition; by contrast, preexisting environmental attitudes were associated with increased perception of risk related to environmental indicators such as scenic beauty, water quality, and recreational opportunity as well as community indicators such as trust of/among community members. Types of perceived risks from wind and gas were similar, although the magnitudes of perceived risk events were higher for natural gas development. Moreover, perceptions of risk were attenuated among respondents who felt that the act of leasing their land for development provided an opportunity to participate in the decision-making process (i.e. negotiating additional environmental protections for one's land). These findings illustrate the importance of contextualizing natural gas development among the many types of emergent, large scale energy development opportunities. They also suggest that associated risks may overlap and can be cumulative in nature.

Stedman et al.[35] moreover, conducted a comparative survey among residents of Pennsylvania (where shale gas development has been ongoing for a decade or more) and New York (where a defacto moratorium remains in place pending a comprehensive review of environmental impacts). New York residents were much more likely to perceive risks from natural gas development than Pennsylvanians, hold more negative views of the gas industry in general, and be more involved in public participation (i.e. signing petitions and attending meetings) around such development. They were also more likely to trust university researchers and environmental groups and less likely to trust the gas industry. Also, perceived knowledge did not differ across states, even with the longer history of development in Pennsylvania, suggesting the positive and negative impacts, and their communication, has been far from clear. Finally, respondents in both states received information about shale gas development from newspapers almost twice as often as any other information source (including interpersonal communication).

The observed differences in risk perception between New York and Pennsylvania residents led the authors to consider whether media coverage may vary systematically across the two states, thus providing a potentially different information environment with which to help inform risk judgments. Ongoing media content analysis of shale gas development coverage from 2007–2011 in two major regional newspapers in northern Pennsylvania and two in southern New York has revealed that despite their close spatial prox-

30 Dan M. Kahan, Donald Braman, Paul Slovic, John Gastil and Geoffrey Cohen, "Cultural Cognition of the Risks and Benefits of Nanotechnology", 4 *Nature Nanotechnology* (2008), pp. 87–90.

31 Besley, "Review: Current Research on Public perceptions of Nanotechnology", *supra*, note 10.

32 Jacquet, "Energy Boomtowns and Natural Gas", *supra*, note 9.

33 Brasier, Filteau, McLaughlin *et al.*, "Residents' Perceptions of Community and Environmental Impacts from Development of Natural Gas in the Marcellus Shale", *supra*, note 8.

34 Jeffrey B. Jacquet, *Landowner Attitudes and Perceptions of Impact from Wind and Natural Gas Development in Northern Pennsylvania: Implications for Energy Landscapes in Rural America,*(Unpublished Doctoral Dissertation (Ithaca, NY: Cornell University, 2012).

35 Stedman, Willits, Brasier, Filteau et al. *Natural Gas Development, supra*, note 23.

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imity, articles in the New York newspapers focused much more on environmental impacts, including effects on drinking water, streams/rivers, and overall water quality. By contrast, Pennsylvania newspapers focused more on economic impacts, including effects on jobs, tax revenue, impacts on local business, and landowner wealth from gas leases. The valence of coverage was much more positive in Pennsylvania and more negative in the New York newspapers.

While these studies provide valuable insight into perceptions of risk and benefit associated with shale gas development, and associated communication, we see a need for additional research in two areas: (1) longer-term, longitudinal research on how these perceptions may evolve through different phases of development and (2) understanding factors that shape media coverage of shale gas development impacts. In terms of the first area, a common truism in the boomtown literature is that energy development, especially related to oil and gas, are susceptible to boom-bust cycles due to factors such as volatile commodity prices, demand for the resource, well production rates, and other factors. Different impacts can gain prominence in public, policymaker, and media arenas depending on the pace of development and the occurrence of particular events (positive and/or negative) such as population growth, job creation, housing shortages, or water contamination. Longitudinal studies of shale gas development conducted to date provide early insights into potential worsening or improvement of perceived effects.[36]

Other research not specific to shale gas development elucidates how individuals and communities may adapt to positive and negative impacts. For example, some research suggests that as communities experiencing energy development become more "pluralistic" in terms of population, age distribution, political leanings, education, and other indicators as new people move into an area, there can be problems associated with the ability or willingness to integrate these newcomers, including social tension and community dissatisfaction.[37] At the same time, there is also evidence of community resilience in the face of such issues.[38] We believe this line of inquiry can likewise be applied to perceptions of economic, environmental, and other impacts associated with shale gas development over time.

In terms of the second area, mass media play a crucial role as sources of risk information about health[39] and environmental risk issues[40] and as resources for mobilizing individuals to participate in political and policy-making processes.[41] An important question related to coverage of shale gas development impacts is whether, as communities potentially change as a result of such development, so too potentially does information about benefits and risks to which people are exposed. For example, the conflict-consensus model suggests that information about risk issues may be reported differently depending on the power structures in communities within which media reside.[42] Less pluralistic communities tend to have fewer interest groups that compete for decision-making power and, as a result, often reach policy decisions through consensus. In this setting, news media serves as the platform for consensus-building, focusing less on the presence of a given risk as opposed to solutions to managing it. More pluralistic communities, by contrast, have more diverse power structure that more easily facilitate debate and conflict, and news media may therefore focus more on risk, especially if stakeholders do not agree on the nature of risk or how it should be managed.[43] This research raises an important question of interest to those studying impacts of shale gas development. If communities become more pluralistic as a result of such development, in terms of population growth, political ideology, educational diversity, relevant interest groups, and other indicators, does the balance

36 Gene L. Theodori, "Paradoxical Perceptions of Problems Associated with Unconventional Natural Gas Development", 24 *Southern Rural Sociology* (2009), pp. 97–117.

37 Brasier, Filteau, McLaughlin *et al.*, "Residents' Perceptions of Community and Environmental Impacts from Development of Natural Gas in the Marcellus Shale", *supra*, note 8.

38 Ralph B. Brown, Shawn F. Dorius, and Richard S. Krannich, "The Boom-Bust-Recovery Cycle: Dynamics of Change in Community Satisfaction and Social Integration in Delta, Utah", 70 *Rural Sociology* (2005), pp. 28–49.

39 Darrick Evensen and Christopher Clarke, "Efficacy Information in Media Coverage of Infectious Disease Risks: An Ill Predicament?", 34 *Science Communication* (2012), pp. 392–418.

40 Philip S. Hart and Anthony Leiserowitz, "Finding the Teachable Moment: An Analysis of Information-Seeking Behavior on Global Warming related Websites during the Release of The Day After Tomorrow", 3 *Environmental Communication: A Journal of Nature and Culture (2009), pp.* 355–366.

41 Jack M. McLeod, Dietram A. Scheufele, and Patricia Moy, "Community, Communication, and Participation: The Role of Mass Media and Interpersonal Discussion in Local Political Participation", 16 *Political Communication* (1999), pp. 315–336.

42 Philip J. Tichenor, George A. Donohue, and Clarence N. Olien, *Community Conflict and the Press* (Beverly Hills, CA: Sage).

43 Robert J. Griffin and Sharon Dunwoody, "Community Structure and Science Framing of News about Environmental Risks", 18 *Science Communication* (1997), pp. 362–384.

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of attention afforded to potential positive and negative impacts on the part of news media potentially change? Are certain impacts more or less likely to be covered? Does this model hold for local newspapers that may heavily rely not on locally-written stories but rather those from centralized sources like the Associated Press? (How) do journalists view the role of community structure in shaping coverage of shale gas development (the authors are beginning to investigate this area via journalist interviews)? There is ample room for research on these questions.

Challenge #3: Communicating the "Big Picture" of Natural Gas Development

As previously mentioned, public participation seeks to encourage stakeholders to make informed decisions about an issue based on consideration of diverse viewpoints about risk and benefit. Shale gas development features not only a diverse array of potential impacts and deeply contested views on risk information and communication at the local level; it also engages important large-scale societal issues such as energy supply, geopolitical relations, and climate change. We have observed, and research suggests, that people often become acutely aware of perceived benefits and risks of energy development both before and after it begins. The perception of risks acts as a filter through which benefits are perceived, and vice-versa.[44] However, people may be generally less apt to consider short versus long-term tradeoffs or balance local versus global concerns. For example, oftentimes enthusiasm over potential positive economic impacts at the onset of energy development is tempered by concerns related to provision of public services to community newcomers, the longevity of jobs across different phases of development, and other issues.[45] Risk analysts have struggled with these issues as well, as researchers and practitioners have found it difficult to weigh – in their assessments – global cost/benefit against local concerns (for example, global climate change implications of shale gas development versus the potential for adversely affected water quality in local areas).

A nascent literature on communicating risk-benefit tradeoffs of energy development has emerged around carbon capture and storage[46] and solar and wind energy.[47] Based on the notion that, as part of public participatory opportunities, citizens must "acquire the information needed to deal effectively with... the nuances and complexities of risk situations,"[48] this work focuses on the provision of objective, "balanced" information on risk and benefit so as to facilitate informed decision-making on policy preferences. We see a clear opportunity to apply such research to better understand perceptions of impacts associated with shale gas development on the part of the public and other stakeholders. We are also aware, however, that "balanced" information may not necessarily be self-evident. For example, research highlights people's tendencies to view a balanced message (in particular, those in mass media) as biased against their own point of view; this phenomenon is especially pronounced among those with already strong views toward that issue.[49] As highlighted earlier, pro-development and anti-development advocates have often ridiculed scientific studies that express conclusions that run contrary to their viewpoints as improperly done, wrongfully interpreted by the "other side," and/or biased by funding sources.[50] [51] Whether there are effective means to encourage people to consider risks and benefits as objectively as possible – or whether such a goal is even advisable – is a provocative question for future inquiry.

44 Ali Siddiq and Paul Slovic, "A Psychological Study of the Inverse Relationship Between Perceived Risk and Perceived Benefit", 14 *Risk Analysis* (1994), pp. 1085–1096.

45 John S. Gilmore, "Boom Towns May Hinder Energy Resource Development", 191 *Science* (1976), pp. 535–540.

46 de Best-Waldhober, Daamen and Faaij, "Informed and Uninformed Public Opinions on CO_2 Capture and Storage Technologies in the Netherlands", *supra*, note 12.

47 Lauren A. Fleishman, Wandi Bruine De Bruin, and M. Granger Morgan, "Informed Public Preferences for Electricity Portfolios with CCS and Other Low-Carbon Technologies", 30 *Risk Analysis* (2010), pp. 1399–1410.

48 Clifford W. Scherer, Katherine A. McComas, Napoleon Juanillo, and Lisa Pelstring, "Promoting Informed Decision-Making: The Role of Message Structure", 10 *Risk: Health, Safety, & Environment* (1999), pp. 209–220 *et sqq.*, at p. 209.

49 Albert C. Gunther and Kathleen Schmitt, "Mapping Boundaries of the Hostile Media Effect", 54 *Journal of Communication* (2004), pp. 55–70.

50 John Campbell, "In Hydrofracking Debate, Can Science Be Bought?", 2012, available on the Intneret at <http://www.courier-journal.com/article/CB/20120414/NEWS01/204140318> (last accessed on 07 August 2012).

51 Kenneth M. Klemow, Dale A. Bruns, and Brian Oram, "Institute for Energy and Environmental Research for Northeastern Pennsylvania (IERR)/Wilkes University Commentary on Osborn et al. (2011) article: *Methane Contamination of Drinking Water Accompanying Gas Well Drilling and Hydraulic Fracturing,* Published in Proceedings of the National Academy of Science (vol 108, pages 8172–8176)", 2012, available on the Internet at <http://energy.wilkes.edu/PDFFiles/IEER%20Commentary/IEER.Osborn.Commentary.pdf> (last accessed 07 August 2012).

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Conclusion

Impacts associated with shale gas development and policy decisions in the U.S. and Europe about whether to allow for such development remain important and controversial issues. Effective risk communication is a crucial element of ongoing policy discourse. In this brief report, we highlighted relevant perspectives on risk communication in the context of shale gas development, focusing on opportunities and barriers to public participation in the decision-making process. We drew on ongoing research to help identify emerging communication challenges, offer solutions, and identify future research needs. We recognize the intense passion with which pro-development and anti-development advocates work to have their voices heard in what is becoming a national and international energy policy debate. As such, we do not naively expect all sides come to consensus on whether it should or should not be allowed. What we do hope for, and apply our research toward, is facilitating greater awareness of short-term and long-term impacts and tradeoffs as well as more nuanced communication efforts that better engage two way communication and a diversity of evidentiary claims.

Trade, Investment and Risk

This section highlights the interface between international trade and investment law and municipal and international risk regulation. It is meant to cover cases and other legal developments in WTO law (SPS, TBT and TRIPS Agreements and the general exceptions in both GATT 1994 and GATS), bilateral investment treaty arbitration and other free trade agreements such as NAFTA. Pertinent developments in international standardization bodies recognized by the SPS and TBT Agreement are also covered. Risk regulation refers broadly to regulation of health, environmental, financial or security risks.
Of recurrent interest in this area are questions of whether precautionary policies can be justified, the extent to which policy can and should influence risk regulation and the standard of review with which international judicial and quasi-judicial bodies assess scientific evidence.

Re-tuning Tuna? Appellate Body Report in *US – Tuna II*

*Lukasz Gruszczynski**

Under the TBT Agreement, a labelling requirement can be qualified as a technical regulation, and not as a standard, even if it does not constitute a precondition for placing a product for sale on the relevant market. Examination of "no less favourable treatment" under Article 2.1 requires determining whether a measure modifies the conditions of competition in the relevant market to the detriment of imported like products, and whether such detrimental impact stems exclusively from a legitimate regulatory distinction rather than reflecting discrimination against the group of imported like products. The evaluation of whether a measure is more trade-restrictive than necessary under Article 2.2 involves a process of balancing different factors, such as the contribution of the measure to the pursued objective, its trade restrictiveness, and risks arising from non-fulfilment. In order for a particular rule to qualify as an international standard for the purpose of Article 2.4, it is necessary to determine whether it has been adopted by a body which has recognized activities in the field of standardization and whose membership is open to the relevant bodies of at least all WTO Members. As far as the last element is concerned, the process for joining such a body by interested WTO Members should be automatic and any required consent from participating Members should be only a pure formality.

I. Introduction

The Agreement on Technical Barriers to Trade ("TBT Agreement") has remained an unappreciated piece of WTO law for a long time. Although WTO Members have actively participated in the activities of the TBT Committee and frequently referred to the agreement in their requests for consultations,[1] concerns arising

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1 According to the WTO webpage, the TBT Agreement was cited in 43 requests for consultations <http://wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A22#selected_agreement> (last accessed on 16 July 2012).

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