

# Collision or convergence?

## *Beliefs and politics in neuroscience discovery, ethics, and intervention*

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**Discovery and interventions for neurological disorders have a unique capacity to galvanize public opinion over issues of access, human rights, decision making, and the definition of disease. Here we highlight five cases where beliefs and politics prevailed over evidence and ethics. We examine lessons from them about the communication of risk and the power of public influence on science, society, and policy.**

### Democratizing decision making

In the aim of democratizing the process by which health policy is formed, scholars and policy makers have begun to converge on the importance of including the voice of the public in agenda-setting and prioritization [1]. Strategies to create constructive public deliberation have focused on facilitating informed, effective, and legitimate participation and taken heed of the ways in which the process of developing evidence-based policy can go awry. Understanding the capacity of stakeholder capture in influencing public policy, a process in which groups exert undue influence over public participation given specific expertise and vested interests, is crucial to efforts to navigate the complex process through which public opinion influences policy. None of these efforts could be more important than those that relate to emerging health policy domains for neurological disease, which pose serious risk to both physical well-being and personal identity [2].

Many scholars have identified public trust in science as a vital component of the policy influence of stakeholder and patient groups, and have expounded on the policy implications at both the individual and societal level when trust is breached [3]. For example, in 1999, the death of gene therapy patient Jesse Gelsinger led to a loss of both public and government trust, with long-lasting implications on the field. In 2007, the revelation that Dr Hwang Woo-suk fabricated data from stem cell and human cloning research followed a similar trajectory for that field. The rapid pace of progress and emergence of new medical, biotechnologies and neurotechnologies continually test the boundaries of

trust, as a lack of public understanding of scientific progress can easily be exploited or misdirected.

In a comparative review of five cases chosen for their enduring or contemporary nature, involving stem cells and neurodegenerative disease, blood flow intervention for multiple sclerosis (MS), vaccines and autism, vegetative states and the right to life, and the Gulf War syndrome (GWS; [Box 1](#)), we highlight this phenomenon in detail.

### Core challenges

Neurological disease represents one of the most significant global sources of disability and its prevalence continues to grow as populations become older worldwide. Disorders associated with pathologies of the nervous system are often unique in their capacity to provoke strong emotional responses from patient groups due to issues related to social perception and treatment. The tendency for public opinion to influence government action on health policy decisions related to neurological disease is a common and rising phenomenon. The cases we highlight here variously illustrate how calculations of health risk and consent, considerations of health privacy, and decision making alongside the involvement of caregivers create a perfect storm for public disenchantment with the scientific progress and the consequences of under- or over-government intervention ([Table 1](#)). Separately and together, the cases also raise questions about values, autonomy, justice, and trust in biomedicine against a backdrop of other clear successes, and they illustrate the harms of communication failure or shortfall.

### *Values, autonomy, justice, and trust*

Respect for autonomy and justice represent primary values underlying the five cases. Achieving the best interest of a patient, as in the case of Terri Schiavo, has long been a fundamental principle for healthcare regulators and practitioners. Similarly, promoting autonomy and freedom of choice to accept or decline vaccination or to pursue the remediation of MS following the theory of chronic cerebrospinal vascular insufficiency (CCSVI) is another. Upholding the right of access to health resources, as highlighted in the case of soldiers returning from the Gulf War, closes the healthcare ethics loop. In areas of medical uncertainty, however, balance in decision making is especially difficult to strike. The loss of hope and threat to identity associated with incurable neurological conditions further inflame public opinion. On this tightrope are also differences in stakeholder tolerance for risk, with patients and advocacy groups

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**Box 1. A comparative review of five cases**

**Stamina Foundation – stem cell therapy now:** unproven, self-described stem cell therapy for central nervous system diseases is offered by a private nonmedical organization in Italy. The provider is shut down due to noncompliance with clinical good manufacturing practice (GMP) regulation. Supporters mount a legal challenge on grounds of compassionate therapy. A popular tabloid television show features distressed parents and ill children, and catapults Stamina to the forefront of public discourse with outspoken celebrities alongside. The case draws sharp criticism from scientific communities nationally and worldwide [10] with a marginal correcting effect.

**Multiple sclerosis – the call for correcting cerebrovascular insufficiency:** an Italian radiologist proposes a controversial explanation and intervention for MS based on blood flow that brings unprecedented disease-liberating hope to sufferers worldwide. The study has significant methodological limitations, is met with skepticism from academic communities, yet still gains high profile exposure. Patient advocacy groups rally behind trials of the new procedure and pressure health officials to act and provide resources with unprecedented response. The race to demonstrate treatment efficacy is on and the momentum fuels both media hunger for promising news and public confusion.

**Measles, mumps, and rubella (MMR) – the debate that does not abate:** a British physician publishes papers suggesting a link between the MMR vaccine and autism. It goes largely unnoticed until it is featured in a television press conference. Emboldened by famous supporters, fears about vaccines spread rapidly throughout the UK

and North America, and childhood vaccination rates drop. Decades of research fail to support causal link. Nonetheless, measles, which was once largely eradicated in the developed world, re-emerges. The widespread and dangerous misconception about vaccines endures as one of most damaging medical fallacies of the century.

**Persistent vegetative state (PVS) – right to die meets the political right:** a chilling debate, fueled by politics and emotion, over an individual's right to die is brought to the foreground by the case of 26-year-old Terri Schiavo, a patient in PVS following hypoxic-ischemic brain damage. In the absence of hope of recovery, her surrogate decision maker wishes to withdraw life support. Other family members vehemently object based on video images of responsiveness that is interpreted to be voluntary. The unscientific evidence weighs heavily into the discussion about life sustaining interventions that comes to involve both legal and political stakeholders.

**Gulf War syndrome (GWS) – biological and social constructions of illness:** reports emerge about a unique multi-symptom illness involving chronic headaches, deficits of memory and concentration, persistent fatigue, mood disturbances, and widespread pain in soldiers returning from the Iraq war. Termed Gulf War syndrome, the condition appears to be distinct from the class of post-traumatic stress disorders. Academic debate ensues over whether GWS is a single unique pathological entity with a neurological origin or a social construction fueled by rising levels of stigma and frustration with war fighters struggling to reintegrate into society [11]. The latter notion is promulgated by the press.

often placing far greater importance on rapid access to treatments rather than on their demonstrated safety or efficacy [4]. The examples of CCSVI and Stamina Foundation further illustrate high degrees of frustration when regulatory processes [5] are privileged over individual will. Similarly, the continued public rejection of vaccination represents the rejection of the notion that health policy should trump autonomy. And, certainly, few better cases than that of GWS illustrate how access to care can be compromised when the line between objective medical measures are challenged by suspicion, uncertainty, and misunderstanding.

How does trust factor into this equation? Unmet expectations are the greatest challenge to this complex phenomenon and, in biomedicine, hype and premature promises of benefit are the underlying culprits [6]. Fruitless suppositions lead to impressions of deception, inaction, and indecision that all conspire to compromise trust. Instances in which regulatory officials bow to public pressure in the face of scientific advice serve to satisfy public demand and provide near-term political gains, but they undermine the process by which evidence-based health policy is informed. If public engagement and education are not sufficiently addressed, then calls for caution and restraint in the progress of medical therapies will go unheard.

*Communication of uncertainty*

The myriad challenges surrounding public understanding of scientific progress are ever-evolving with the dynamic content and pace of biomedicine, and significant advances in models of neuroscience communication, knowledge translation, and public education [7] have been made in an effort to keep apace. Nonetheless, a dated Information Deficit Model that describes how medical controversies stem from limited public understanding is still held as

the prevailing view by scientists and policy makers. Science communication and education initiatives designed to fill a void in public understanding have been shown to fall short [8], and are instead being increasingly replaced with a more interactive public engagement approach that emphasizes the facilitation of a dialog in which the plurality of viewpoints are heard and can inform research priorities and science policy [7]. Success has been achieved in some fields, but there remains a strong need to normalize these new engagement models across scientific domains. It has been stated that the scientific community's 'license to practice' can no longer be assumed and, rather, must emerge through processes that include public engagement and discourse. Following this, determination of scientific quality can only be achieved through the representation of the plurality of social perspectives, where lay publics are a part of a broader community that enact 'extended peer review' [9]. Whether even the most harmonized efforts could have mitigated the public response to any of the cases we featured here, given the presence and extra layers of political and financial conflict, however, is an open question.

*The other side of the coin*

Public advocacy and stakeholder influence do not by definition negatively affect the development of health policy for conditions that affect the central nervous system. Amid those that have been unconstructive are others where patient advocacy successfully guided policy decisions to the benefit of public health. Access to experimental HIV/AIDS treatments in the 1980s, and the influence of Mothers Against Drunk Driving (MADD) on drug and alcohol policy are among a few. In Canada, both public and academic support contributed to preventing the closure of Insite, North America's first supervised drug injection facility that

**Table 1. Comparative analysis**

	Stamina Foundation		Chronic cerebrospinal venous insufficiency (CCSVI)		MMR vaccine in autism		Case of Terri Schiavo		Gulf War syndrome	
Key theme	Regulatory policies for compassionate therapies		Scientific validity of venous insufficiency for MS		Adverse effects of vaccines		Withdrawal of life support		Biological and social construction of disease	
<b>Case details</b>										
<b>Time relevance</b>	2013 to present		2009 to present		1998 to present		1990 to present		1991 to present	
<b>Time to policy impact</b>	3 months		24 months		24–36 months		N/A (used as legal precedent)		Ongoing	
<b>Diseases and intervention</b>	Parkinson’s, Alzheimer’s, muscle-wasting disorders, progressive congenital neurological deficits and others		MS		MMR vaccination, enterocolitis, autism		Vegetative state		Central nervous system syndromes	
<b>Terminal condition</b>	Yes		No		No (autism)		No		No	
<b>Initial sample size</b>	32 (no study)		65 ([12])		12 ([13])		1		At least 167 500 [14]	
<b>Estimated impact</b>	32		Estimated 2.5 million		Measles cases from 56 (1998) to 1370 (2008) [15]		Countless		670 000	
<b>Analysis of media coverage</b>	None published		Yes		Yes		Yes		None published	
<b>Funding</b>	Government-funded clinical trial and hospital care		Government-funded clinical trials		Government-funded research programs and institutes		N/A		Government-funded patient support programs and research	
<b>Regional origin</b>	Italy		Canada		UK		USA		USA	
<b>Stakeholder capture</b>	<b>For</b>	<b>Against</b>	<b>For</b>	<b>Against</b>	<b>For</b>	<b>Against</b>	<b>For</b>	<b>Against</b>	<b>For</b>	<b>Against</b>
	Stamina Foundation, Italian Health Ministry, Political right	Academics, Italian Medicines Agency Regulators, Science journals, Political left	Inventor, Media, MS patients, Government	Research sponsors, Professional health associations, Media, Government	Primary investigators, affected parents, media	Medical associations, academics, media, public health advocates	Surrogate decision maker, academics, medical professionals, political left	Patient’s family, religious conservatives, political right	USA Department of Veteran Affairs, media, veterans	Academics
<b>Ethical legal and societal considerations</b>										
<b>Key ethical and regulatory issues</b>	Waiver of regulatory process Right to hope		Efficacy		Safety		Right to life Right to die		Medical legitimacy	
<b>Informed consent</b>	Yes		Yes		No		No		No	
<b>Health risk</b>	Yes		Yes		Yes		No		No	
<b>Health privacy</b>	No		No		No		Yes		No	
<b>Decision making</b>	Yes		Yes		No		Yes		No	
<b>Justice and rights</b>	Yes		Yes		Yes		Yes		Yes	
<b>Caregiver involvement</b>	Yes		Yes		Yes		Yes		Yes	

has served over 8000 people since 2003. Despite evidence supporting its cost-effectiveness and benefit to fatal overdose rate in the area, the facility was at risk for closure by an unsupportive federal government. Sustained advocacy from both academic and patient communities drove continued media coverage and public support of the facility, enfeebling government efforts to withdraw financial backing and legal privilege for operation. These particular cases illustrate how well-formed relationships between stakeholders from the public and patient communities, academics, and health professionals can be aligned towards the common goal of beneficence and reduction of harm.

### Concluding remarks

Court action involving the Stamina Foundation is ongoing today. Advocates of CCSVI for MS are holding on to a last but unraveling thread of hope. The anti-vaccination campaign retains a small yet vocal stronghold that continues to be heard. Terri Schiavo is dead, but the lessons learned from her suffering and those around her live on. War fighters are deployed to restore peace abroad, and many return to anything but a peaceful health setting in which to revive normal healthy lives.

Where do we go from here? The neuroscience community has a duty to explicitly recognize and address the powerful emotive capacity of neurological disease to galvanize stakeholders. The community must take heed of the importance of collective understanding surrounding experimental therapies as they emerge and inspire action that promotes understanding. Targeted communication strategies using the tools of knowledge translation [7], social media, and deliberative decision making will lead to better framed messages that co-originate with patient groups affected by neurological disorders, advance accurate reporting on regulatory principles for clinical trials, and mitigate controversies that are both

sensitive and fundamental at an individual and societal level.

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