

Chapter 10

PROMOTING CONSUMER RIGHTS IN SWEDEN BY LOBBYING AND AWARENESS-RAISING ABROAD

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Increased interaction between state and civil society and a growing dissatisfaction with professional paternalism have paved the way for the rise of consumer groups of different kinds as potential drivers of democratization within the health domain (Löfgren, de Leeuw, and Leahy 2011). The numbers of health consumer and patient organizations are rising across Europe, and health consumer interests are more often being represented at a political level (Wehling, Viehöver and Koenen 2015). However, patient advocates often find it difficult to present a strong, united front that gains a hearing in national policy deliberations (Tomes and Hoffman 2011). Nevertheless, there is some evidence that health consumer organizations can influence policy and reform, especially when they work in concert with other interests (Baggott and Jones 2014). Much depends on how these organizations are affected by, and interact with, the political context in which they are situated and on the alliances they build with other policy actors. In light of the increasing significance of international relations and transnational advocacy networks for social development in general, it is important to pay attention to the political role of activist organizations as both domestic and international actors (Keck and Sikkink 1998).

The aim of this chapter is to investigate how the Consumer Association for Medicines and Health (KILEN), a small Swedish health consumer organization addressing the issues of drug dependency and consumer reporting

of adverse drug reactions, throughout the years and with varying degrees of success made use of political opportunities domestically as well as at the European and international levels to contest the dominance of Swedish corporative actors and structures. KILEN addressed controversial medical issues and was often challenged by powerful professional and political interests in Sweden at the national, regional, and local levels. KILEN tried to navigate the political landscape by using different political opportunities at various levels in order to contest the dominance of national corporative actors and structures.

At times KILEN had some support from various political stakeholders at both the central governmental level and at the county level, but it always had to fight for its existence; eventually it lost state funding in 2007 and had to dismantle the following year. A study of KILEN thus provides insights into the strategies available for domestically contentious organizations and might contribute to the discussion concerning how different levels might be strategically played depending on the specific political opportunities at hand. Feeding back to the theoretical chapter in this book, we especially pay attention to the significance of various aspects of regulatory, financial, and discursive Europeanization in this particular case (see chapter 2). In order to get an understanding of KILEN and the dynamics at play, key persons that have been involved in, collaborated with, or reported on KILEN have been interviewed. These include the two founders of KILEN (and who periodically constituted the bulk of the organization) and a few politicians, journalists, and representatives from the national and international scientific communities. We conducted nine interviews between February 2014 and October 2015. We have also studied texts from KILEN's official website, proposals and decisions from the Swedish Parliament, and proposals from the European Parliament (EP) as well as Swedish newspaper articles and medical journals that have highlighted the organization's stance and activities.

A Political Opportunity Approach

This study draws on the so-called political opportunity approach that was developed among social movement theorists in order to grasp the mechanisms and factors that facilitate or hinder movements from accomplishing their political and social goals within a specific polity (e.g., Eisinger 1973; McAdam 1996; Tarrow 1988). This approach highlights how the political context affects movements' possibilities to mobilize, influence policies, and contribute to social and political change. Synthesizing the dimensions of political opportunities that researchers on the subject have included in their

operationalization of the concept, Doug McAdam (1996, 27) has suggested the following consensual list:

1. The relative openness or closure of the institutionalized political system
2. The stability or instability of the broad set of elite alignments that typically undergird a polity
3. The presence or absence of elite allies
4. The state's capacity and propensity for repression

At the heart of the political opportunity approach is the view that exogenous factors might either enhance or delimit prospects for certain arguments or claims, particular strategies of influence, or the ability to affect mainstream institutional politics and policies (Meyer and Minkoff 2004). It focuses on how a movement's interaction with the political system and the broader political context can lead to both successes and failures for the movement, and tries to identify the concrete characteristics of the political system and/or context that provide opportunities or impose threats. In other words, it acknowledges how factors residing in the political system and the broader political context can work either in favor of or against movements that mobilize for a certain cause. The approach can be used to understand the strategies and actions of a variety of actors, which are usually social movements but can also include different types of interest groups.

The political opportunity approach has often been used to discuss political opportunities on the national level, but it is also important to recognize the increasing role of international and supranational institutions for creating opportunities for movements to mobilize. In this context, the approach is particularly well suited for analyzing opportunities and constraints connected with regulatory Europeanization. International and supranational bodies such as the European Union (EU) might through their (recommended or binding) policies and verdicts—as well as their formal or informal pressures against, or negotiations with, their member states—create both opportunities and threats for movements (cf. Tarrow 2005). For instance, if the EU brings attention to specific political issues and recommends that its member states formulate policies to address these issues, the EU (its officials, representatives from other member states, etc.) can become an important ally for activists who are struggling against their own governments to give more attention to the issue in question. Organizations that are blocked at the national level might strategically make use of political opportunities at the European or international levels in order to obtain boomerang effects (Keck and Sikkink 1998; Beyers 2002). In alliance with

international Non-Governmental Organizations (NGOs), those organizations might exploit international norms and organizations to generate pressure for compliance on public actors. International institutions can thus offer an authoritative venue for civil society actors to challenge state behavior (Keck and Sikkink 1998; Risse, Ropp, and Sikkink 1999).

Furthermore, it is important to acknowledge that political processes and actions take place not only in the formalized political system and its institutions but also elsewhere in the polity, such as in the bureaucracy, the judiciary, the media, industry, and among the many organizations and networks that make up civil society. This broader understanding of the political context makes it relevant to expand the political opportunity approach to include how actors use and are influenced by factors such as discourses produced by the mainstream or alternative media, which relates to processes referred to as discursive Europeanization in this book (see chapter 2). Social movements and interest organizations sometimes act as norm entrepreneurs by calling attention to issues or even creating new issues by naming, interpreting, and dramatizing them (Finnemore and Sikkink 1998). Snow and Benford (1988) identify three core framing tasks for social movements, and the degree to which these tasks are attended to will determine participant mobilization. The three tasks are

1. diagnostic framing for the identification of a problem and assignment of blame;
2. prognostic framing to suggest strategies and solutions to a problem; and
3. motivational framing that serves as a call to arms or a rationale for action.

If successful, the new frames resonate with a broader public understanding and are adopted as new ways of talking about and understanding various issues (Finnemore and Sikkink 1998). Through successful framing, organizations can thus attract attention and encourage action for change (Keck and Sikkink 1998).

Last but not least, even though many of the resources that social movement organizations need to mobilize might be without direct economic costs—in particular nonpaid activist labor—economic resources still have to be secured for activities such as meetings and issue publications. The economic resources can be secured through different channels such as governmental bodies, private foundations, private persons, or the market, such as pharmaceutical companies. In this respect the EU through different types of grants has opened new opportunities for many CSOs (Sánchez-Salgado 2010). The money transfer through financial Europeanization is, however,

often in the form of short-term conditional grants that might give rise to a problematic level of dependency.

The Political Breeding Ground for Patients' Rights, Drug Safety, and Consumer Reporting

There has been a struggle over the patient's role in medical decision-making in many Western countries over the past few decades. The patients' rights movements of the 1960s questioned the authority of doctors and demanded informed consent and disclosure of medical information (Bayer et al. 2007). This development ignited an active citizenship more inclined to reflect critically on its relationship with government and other powerful bodies such as the medical profession and the pharmaceutical industry (Abraham and Lewis 2000). Physicians were now also accused of being responsible for pain and sickness induced by their treatments (Porter 1996). This course of events was partly an effect of the thalidomide tragedy of the late 1950s and early 1960s when it became clear that an antinausea drug being prescribed to pregnant women was causing serious birth defects (Carpenter 2010).

The thalidomide disaster underscored the necessity of systems to monitor the safety of medicines after they enter the market. As a consequence, government agencies were established to regulate the pharmaceutical industry in the interests of patients and public health (Davis and Abraham 2013). The World Health Organization (WHO) set up its international drug-monitoring program, and the Uppsala Monitoring Centre (UMC), an independent foundation, was established in 1978 to support the program. Through these initiatives, drug manufacturers were required by law to report to the appropriate authorities all adverse reactions to their drugs in a timely manner (Davis and Abraham 2013). Furthermore, doctors were asked to report all suspected adverse drug reactions they encounter in their clinical practice. However, it is well known that suspected adverse drug reactions are underreported, especially from health professionals (WHO 2002). The EU has also taken action. Within the EU suspected adverse drug reactions have since 2001 been reported to the European Medicines Agency and registered in the database EudraVigilance (Abraham and Lewis 2000).

An alternative way to increase reporting of adverse drug reactions is to allow citizens—in other words, the actual users of medicines—to report directly to the authorities; this is called consumer reporting or direct patient reporting. This is what KILEN, facing much opposition, struggled to implement in Sweden, among other things through their own collection of such statistics. Consumer reporting has been described as a public shaping of medical research and research politics, where the experience of the

medicine users builds up a collective expertise of suspected adverse drug reactions (Wehling, Viehöver, and Koenen 2015). If the system works, the users/consumers might become coproducers in monitoring the postmarket safety of medicines through spontaneous reporting of adverse drug reactions to regulatory agencies (Borg et al. 2011; Vilhelmsson 2015). A great leap forward was taken in 2010 when the EP voted in favor of new pharmacovigilance legislation to ensure greater patient safety and to improve public health, which was later cleared by the European Council. Since 2012 all EU countries are obliged to establish patient/consumer reporting within their spontaneous reporting systems as a part of the new European pharmacovigilance legislation (The European Parliament and the Council of the European Union 2010; EU Legislation on Pharmacovigilance: Regulation 2010). However, it is still uncertain how well the system works, and health consumer organizations have a key role to play in ensuring that the voice of the patient is indeed heard in the policy process.

Patients' rights vary in different countries depending on the political context and on prevailing cultural and social norms (Trägårdh 2007). The Scandinavian countries are characterized by strong political ties and institutionalized links between the popular mass movements and the welfare state, and by high trust in political institutions among the population. As in other Western countries the new social movements of the 1960s and the 1970s introduced new political conflicts and more contentious forms of activism in the Scandinavian countries (Ekman Jørgensen 2008). In Sweden the so called R-movement, gathering different client organizations, was actively engaged in social policy debates and required that clients be involved in and decide on issues affecting them (Meeuwisse 2008). However, compared to similar movements in other parts of Western Europe, the actions of many of the Scandinavian movements were less confrontational. Furthermore, in Sweden patient rights, born out of CSOs and popular movements, have traditionally been more focused on social rights than on individual rights (Trägårdh 1999, 2015). Many of the organizations have also become more or less interconnected with the state through funding and engagement in public investigations. It has been argued that the traditional corporatist model, developed mainly in relation to the class cleavage, in this way has been able to channel—or co-opt—new conflicts into mainstream politics (Jamison, Eyerman, and Cramer 1990). Consequently, it has been claimed that because of a strong belief in the state and the welfare system it has been harder for CSOs on a grassroots level to push for patient rights in Sweden compared to many other Western countries (Trägårdh 2015). This perhaps also partly explains the long absence of consumer/public interest group activity regarding the regulation of medicines in Sweden (Abraham and Lewis 2000).

The responsibility for health and medical care is decentralized in Sweden and is shared by the central government, county councils, and municipalities. The regional level is especially important because the responsibility for providing health care has devolved to the politically elected county councils and, in some cases, municipal governments. But the patient's position in the Swedish health-care system is relatively weak, which has been confirmed by the quite recently established Swedish Agency for Health and Care Services Analysis (Vårdanalys), whose mission is "to strengthen the position of patients and users through analysing health care and social care services from the perspective of patients and citizens" (<http://www.vardanalys.se/Support/In-English/>). Sweden now participates in the International Health Policy Survey where patients describe their experiences of health care. The results from a survey in 2014 (Swedish Agency for Health and Care Services Analysis 2014) do not indicate a fertile ground for patients' rights in Sweden. For instance, in comparison with ten other countries, health care in Sweden and Norway appears to be less patient oriented when it comes to discussing drugs and informing patients about possible side effects of medications and why they should take the medications. Health care in Sweden also falls short in its ability to involve patients in their care and in treating each patient as a unique individual. A new law to strengthen patients' opportunities to participate in their own care process was introduced in 2015, but it is not an explicit law of rights, and the position of the patient is thus somewhat unclear (Trägårdh 2015).

Initial Success in Identifying a New Social Problem and Demonstrating the Need for Intervention

The Swedish Association for Help and Assistance to Drug Users was established in 1965 and worked on issues concerning drug abuse and social exclusion. KILEN was officially opened in Stockholm in 1992 and was initiated by a handful of people from the Swedish Association for Help and Assistance to Drug Users who specifically wanted to address the issues of drug dependency and consumer reporting of adverse drug reactions (Vilhelmsson 2014). They had already in the 1970s started to encounter patients who turned to them for help to break their addiction to tranquilizing, hypnotic, and analgesic medicines prescribed by physicians. The patients described adverse reactions to benzodiazepines and barbiturates, a problem that at this time in Sweden was almost unknown or unacknowledged both in the medical literature and by the national drug regulatory authority. As a consequence, a major part of the medical profession disregarded these patient experiences (UMC 2014). The initiators of KILEN began at an early stage

to map the problem, to spread information, and to establish contacts with various authorities and stakeholders like the Swedish National Board of Health and Welfare (Socialstyrelsen), the Swedish Social Insurance Agency (Försäkringskassan), and the Stockholm County Council (Stockholms läns landsting). These contacts turned out to be vital in order to secure resources and legitimacy for future operations.

The initiators of KILEN aimed at becoming a center of excellence in developing consumer knowledge on drug and health issues and sought to work across professional and national borders. They based their work on direct contact with those afflicted by the problem of adverse drug effects and other treatment injuries by providing counseling, support, and assistance. The organization also held training courses, lectures, public hearings, and hearings in the Swedish Parliament for politicians; it published reports on adverse drug reactions and harm from drugs from a user perspective (KILEN 1997, 2002, 2004, 2005); and it spread information to the general public, politicians, and professional groups. KILEN also acted as lobbyists in order to influence policy regarding consumer reporting and adverse drug reactions.

These activities could be said to be part of a deliberate information policy, where the organization asserted its right to speak through reference to the deep knowledge of patients' experiences and living conditions. Claiming a close connection among insider knowledge, documentation, information, and advocacy is not an unusual strategy for interest groups and social movements (Jeness 1995). Margaret and Kathryn Sikkink (1998, 226) refer to an activist who described it as "the human rights methodology—promoting change by reporting facts." To succeed, such a strategy requires credibility, objectivity, and trustworthiness. Otherwise the organization risks being dismissed as unserious and misinformed.

However, it was particularly the support to patients that gave KILEN its initial legitimacy. According to a researcher at the UMC, KILEN filled a void in the social safety net:

KILEN took care of groups of patients who had no one else to turn to. That benzodiazepines could create side effects and dependency in the long run had started to be highlighted in the debate. It was prescribed in FASS [the Swedish Physicians' Desk Reference, which builds on the Summary of Product Characteristics from the pharmaceutical companies] that such drugs should only be given for a maximum of one week at a time, but this was not followed. These people were therefore no one's problem—no one had responsibility for them. They came to KILEN in desperation. (Interview researcher UMC)

In the beginning KILEN gained a certain echo among Swedish politicians and authorities and even received a fair amount of funding for the services

and counseling it offered to patients. KILEN managed to raise public awareness on drug dependency and addiction and offered interventions to treat these new iatrogenic problems (UMC 2014; HAI 2005). During its first decade (1989–99), the organization received various amounts of funding from, among others, the Swedish National Board of Health and Welfare and the Stockholm County Council, and through targeted state subsidies disbursed to health authorities.

Several public figures from the political elite made speeches at the opening ceremony of KILEN, and the event was widely reported, including on Radio Sweden (Sveriges Radio). KILEN had identified a new social problem that was taken seriously and was met with sympathy from several influential politicians. At this point, KILEN clearly acted as a norm entrepreneur by calling attention to a new social problem and highlighting the issue of adverse drug reactions. They also succeeded in convincing several significant key persons with their diagnostic, prognostic, and motivational framing. In other words, they managed to get a hearing for their way to define, interpret, and point out what was needed in order to do something about the problem.

According to a politician of the Swedish Liberal Party, and also the director general of the Swedish National Board of Health and Welfare at the time, KILEN's contribution to patient reporting was also of great value: "When KILEN disappeared, the debate stalled. They were the driving force in this debate and when organizing the health care system. They have greatly contributed to providing the opportunity for patients to report side effects, earlier it was only allowed for doctors and dentists" (interview former director general of the Swedish National Board of Health and Welfare).

In the beginning KILEN had very good political contacts and their work was blessed by policymakers, both on a national and a regional level. Thus, the organization received governmental funding and in a way was protected from criticisms from the medical profession and regulatory authorities. These elite alignments were, however, unstable, and were dependent on the politicians in charge (they could for some time count on support from the Social Democratic Party, the Left Party, and the Green Party) and on short-term funding, often on a one-year basis following proposed budget claims. KILEN was sometimes strongly backed by individual politicians and senior officials in the health authorities, but some of these alliances proved to be vulnerable. This vulnerability became clear when KILEN diverted their main focus from treating patients with dependence symptoms and addiction associated with benzodiazepines and barbiturates and started to call attention to antidepressants. Suddenly some of their allies disappeared.

Into the Hornet's Nest: Antidepressants, a Medical Confrontation, and the Ghost of Scientology

The new antidepressants, the selective serotonin-reuptake inhibitors (SSRIs), revolutionized the market in the 1980s. Together with the serotonin-norepinephrine reuptake inhibitor, these are often referred to as second-generation antidepressants (Healy 1997). These drugs quickly became very popular and were often seen as much safer than previous antidepressants. As long as KILEN worked with patients afflicted by drug dependency from tranquilizers and benzodiazepines, it met little resistance. Although some psychiatrists were critical of KILEN's campaigns, which they thought might cause unwarranted concern among patients, the organization had good relations with the medical profession and even collaborated with some physicians. However, when KILEN began to criticize the prescription of SSRIs and thus clearly became involved in health policy, the situation changed and they were faced with political and professional resistance. Difficulties also arose with financing. At one point the organization even had to temporarily file for bankruptcy. The most pronounced resistance came from a psychiatrist at Karolinska Institutet (a medical university in Stockholm) who in different ways tried to stop the funding of KILEN, for example by alerting funders and by participating in a live TV debate on the then newly released drug Prozac. He described the conflicting views in this way:

I expressed my worries, because I felt that they were missing the target. I also participated in a TV debate in 1995 when Prozac was released in Sweden. In addition to myself and Lena from KILEN, a priest and a representative of the Swedish Anxiety Society participated. I got into a fight with Lena. I was worried that patients would commit suicide if they stopped taking their medications. I think that the funding of KILEN temporarily ended after that. KILEN then wrote to the vice chancellor of the Karolinska Institutet and said it was un-academic behavior on my part, which they certainly were right about. But a professor of clinical pharmacology [and a member of the Swedish Parliament for the Conservatives] managed to stop the government grants through The Social Affairs Committee. He used roughly the same arguments that I had, but it then also included KILEN's stance on antidepressants. (Interview psychiatrist at Karolinska Institutet)

It has been argued that patient organizations can gain acknowledgement only insofar as their demands are compatible with certain fundamental assumptions of medical science, medical authority, and the consumption of medical goods and services (Blume 2010). KILEN challenged mainstream medical science about what constitutes drug dependency and maintained

that consumers themselves could determine adverse drug reactions. To substantiate their claims, KILEN published several reports on consumer experiences of drug dependency and reports from public hearings on drug damage, adverse events, and the increased prescribing of antidepressants (KILEN 1997, 2002, 2003, 2004). They also released a report on their website (KILEN 2005) comparing side effects and adverse drug reactions reported to their own database with those reported to the Medical Products Agency, the national medicines regulatory authority. In this way they wanted to show that consumers could distinguish between suspected adverse reactions and other symptoms just as well and sometimes even in a better way than reporting physicians.

KILEN was questioned on the grounds that its representatives lacked expertise in terms of medical and clinical training; some critics even claimed that they were followers of Scientology. (To discredit critics by labeling them as Scientologists seems to be a recurring approach to disagreements regarding mental illness and the use of psychotropic medication; see Whitaker 2011.) Among other instances this suspicion of sectarianism was raised when KILEN organized a Nordic conference on patient reporting in 1995, in association with the Icelandic drug control authority (UMC 2014). According to one of KILEN's founders, opponents within the Swedish medical profession had tried to discredit them abroad by reaching out to their Icelandic colleagues with misinformation:

It turned out that the Icelandic Psychiatric Society had written a letter to the Icelandic physicians informing them that KILEN belonged to the Church of Scientology or perhaps Christian Science, they were a little unsure. The Icelanders did not know who we were, so it was obviously these Swedish psychiatrists that had informed the Icelandic Psychiatric Society that they had to watch out for us. But one of the doctors had worked as a district medical officer in Sweden for fifteen years and had many acquaintances here. He called around to all and soon realized that no, we were not Scientologists. (Interview founder of KILEN)

These accusations also hampered media relations, and the problem of representation (Epstein 2011) became an issue for KILEN. Due to the rumored association with Scientology, some media outlets did not take KILEN seriously. It has been argued that this type of guilt by association might taint the reputation of independent consumer organizations and question their role as the legitimate voice of patients and consumers (Jones 2008). Social movement organizations often rely on the media for mobilization of political support and legitimization (or validation) in the mainstream discourse, and the quality and nature of the media coverage strongly influence how they are perceived in the public eye (Gamson and Wolfsfeld 1993). To get the message out the movement or the organization has to successfully pinpoint

what the problems are, what is causing them, and how they can best be solved. This requires not only contacts and knowledge of how the media works but also an understanding of how the message ought to be packaged and timed. KILEN received some media attention in the beginning, but it did not have an active media strategy and failed to create fruitful cooperation with the media. Some science and medical journalists never really understood who or what KILEN represented and what agenda they were advancing, and therefore held them at arm's length, which was expressed by a science journalist at one of Sweden's largest morning newspapers: "KILEN only had little coverage in the newspapers and was met with skepticism. I never got a clear picture of what the organization stood for. They were somewhat solitary and therefore had problems with credibility when they made their media actions. I didn't really understand why they were so engaged in criticizing psychotropic drugs, and I kept them at a distance" (interview Swedish science journalist).

KILEN Goes Abroad in Search of Support and Allies

The Swedish Medical Products Agency was not keen on establishing consumer reporting of suspected side effects and adverse drug reactions. One argument put forward was that patients were not able to distinguish between adverse reactions and symptoms of their disease. Another common claim was that consumer reports would create only background noise that somehow would distort the overall analysis (UMC 2014). At the time, consumer reports were often dismissed as being anecdotal or nonscientific (Herxheimer and Mintzes 2004). According to a pharmacovigilance expert who sympathized with KILEN, those arguments were not sustainable: "The argument that patients cannot determine and recognize the symptoms caused by drugs or underlying factors and distinguish between them is basically not true. Patients are not stupid. They recognize recurring symptoms when they take medications. It was often argued that the data they fill in are incomplete—that they don't know what's important. But several studies show that patient reports are no more poorly documented than others" (interview Swedish pharmacovigilance expert). After a while it became quite obvious to KILEN that there was a lack of political opportunities in the Swedish context because of the unfavorable political climate and the opposition from influential actors. They therefore established contacts and collaborations with key partners (individuals and organizations) abroad in order to reach an international arena and to continue their political advocacy. They thus tried to bypass the national level by compensating at the European level (as well as at the Nordic and international levels) in hopes

of a boomerang effect. As argued by Keck and Sikkink (1998), domestic activist organizations increasingly seek international support or allies to try to bring pressure locally or nationally from the outside.

The EU, together with the WHO, played an important role in pushing KILEN's agenda for further acknowledgement. Consumer reporting had already attracted some attention at the European and international levels, where there was ongoing discussion about the problem of physicians under-reporting adverse drug reactions (BEUC 2008; HAI 2005; van Grootheest, de Graaf, and de Jong-van den Berg 2003; WHO 2002, 2006). The European and international arenas offered KILEN several new important allies. Sweden's membership in the EU in 1995 also opened new opportunities for financial support for various projects.

Through its work, KILEN had become convinced that drug dependency was not an isolated Swedish phenomenon. They therefore arranged a number of Nordic conferences concerning drug dependency and patient reporting in the 1990s: Stockholm, Sweden 1994; Reykjavik, Iceland 1995; Mogenstrup, Denmark 1997; and Tromsø, Norway 1998. These conferences gathered control authorities, scientists, medical professionals, and patients. At the second Nordic conference in 1995, organized by KILEN and the Icelandic drug control authority, a joint statement was issued saying that patients' knowledge and experience of drug-related problems ought to be collected systematically and assessed equally valuable as adverse reaction reports from professionals. The conference gave the representatives for KILEN the task of trying to find the ways and means to achieve this goal.

KILEN applied for, and was granted, financial support by the European Commission (EC) to develop a Nordic database on consumer reports.¹ This funding turned out to be pivotal: without this financial help KILEN would not have been able to establish the consumer database or engage in international networking. KILEN was later also funded by EU grants for an international EU project to collect and code consumer reports in Denmark and Moldavia (UMC 2006). Hence, KILEN clearly benefitted from financial Europeanization.

Through its international work KILEN managed to establish valuable contacts and found support among several authoritative international organizations and institutes around the world, including the WHO, Health Action International (HAI), the Dag Hammarskjöld Foundation, the BEUC, the UMC, the group around the French journal *Prescrire* (UMC 2014), and several major national consumer organizations. This kind of networking gave KILEN an international reputation and leverage that they could also use in the Swedish context. The First International Conference on Consumer Reports on Medicines was held in Sigtuna in 2000 and was organized by KILEN in collaboration with many public and civil society

actors.² Participants included experts from the medical and pharmaceutical professions, drug regulatory authorities, consumers, and representatives of the WHO.

The conference in Sigtuna was later perceived as an important event in getting the idea of consumer reporting publicly known and more widely accepted (Herxheimer, Crombag, and Alves 2010). It resulted in the adoption of the consensus document “Consumer Reports on Medicines: Policy and Practice” (Finer et al. 2000), which was widely disseminated and had a significant impact. Another major step forward was when the representatives for KILEN received an invitation from the WHO to contribute to the twenty-fourth annual meeting of the WHO Programme for International Drug Monitoring held in New Zealand in 2001. According to a WHO program expert, KILEN was a key player that greatly influenced the views on consumer reporting:

The symposium in Sigtuna in 2000 was groundbreaking! They had invited experts from around the world who were the driving forces in the discussions. And this wasn't an isolated event. KILEN was among those who stood on the barricades for consumer reporting and participated very actively. They have for example been part of the WHO's annual pharmacovigilance program, and they presented about consumer reporting when representatives from numerous countries gathered in New Zealand in 2001. They have greatly influenced public opinion on patient reporting. Why should only doctors report? It became difficult to defend yourself against their arguments. (Interview WHO program expert)

One might here speak of discursive Europeanization, because KILEN seems to have been an important norm entrepreneur in changing the discourse of how patients' experiences were seen and acknowledged in Europe. By framing consumer reporting of adverse drug reactions as a civil rights issue and a question of solidarity, it was no longer only a matter for the medical establishment. KILEN was also recognized in the scientific literature as an important contributor of patient reporting (Blenkinsopp et al. 2007; van Geffen et al. 2007). Through their own database and by building collaborative networks among scientists, KILEN influenced the research agenda in identifying consumer reporting as a significant research gap or undone science. KILEN also to some extent managed to shape knowledge production on medical issues through adding data from consumers (cf. Wehling, Viehöver, and Koenen 2015).

KILEN's norm entrepreneurship can also be seen as part of a strategic action to exploit opportunity structures. In the international arena, KILEN could seek political alliances and lobby for policy changes in collaboration with other interest groups, such as with The Medicines in Europe Forum, the BEUC, and HAI. The Medicines in Europe Forum was launched in

2002 to increase awareness among the public and policymakers of developments in pharmaceutical policy from a patient perspective. As a result of the activities of these umbrella organizations and patient associations, all EU member states were obliged in 2012 to implement the new pharmacovigilance legislation and thereby enable consumers to directly report adverse drug reactions to their drug regulatory agencies (EU Legislation on Pharmacovigilance: Regulation 2010). KILEN was one of the signatories to the Forum and thus also contributed to regulatory Europeanization (EPHA 2003). These events at the European level also clearly affected domestic affairs in Sweden. According to one of the founders of KILEN, nothing would have happened in Sweden without this external pressure: “I would go so far as to say that it is thanks to us that we have patient reporting at all, because when we started to pursue this matter it was seen as nonsense by the Medical Products Agency” (interview founder of KILEN).

A Challenging Voice Falls Silent

Despite success at European and international levels, KILEN continued to meet resistance at home. In order to survive economically KILEN was dependent on—and exploited—the shifting political power nationally, regionally, and locally. Because it worked on a controversial issue—in opposition to the pharmaceutical industry and powerful professional interests—it could never count on steadfast political support. This made the organization financially vulnerable and made it hard for it to make long-term plans. KILEN had a few allies among influential politicians and could cope as long as these defenders backed up their claims, but once they lost their political positions the organization was seriously weakened.

KILEN was unexpectedly forced into bankruptcy when a new center-right government took office in Sweden in 2006 and the Swedish Parliament in March 2007 decided not to allow continued government grants (Nihlén, Ericson, and Lindholm 2007; Westin 2007). According to the founders of KILEN, no explanation was ever given from the Ministry of Health and Social Affairs to justify the dismantling of KILEN as a consumer institute even though such demands were raised from several organizations and individuals, both nationally and internationally.

Since its establishment, KILEN met heavy domestic resistance from governmental agencies like the drug regulatory agency but also from many physicians and right-wing politicians. The Swedish Medical Association welcomed the shutdown of KILEN and strongly criticized the former Social Democratic government for having, after pressure from the Green Party and the Left Party, supported KILEN with state funding for several years. In the

weekly Swedish health journal *Dagens Medicin*, the president of the Swedish Medical Association argued that KILEN had lobbied against the “best available psychiatric evidence” and had criticized psychotropic drugs in an unbalanced way, and also that KILEN’s actions were based on emotions rather than on science (Helte 2006, 8). A Swedish pharmacovigilance expert also identified the emotional dimension of KILEN—noticeable especially in the first few years and exploited by opponents—as a problem: “They could become desperate and angry and go to the media with accusations—they were emotional. The authorities and government officials could therefore say that they were hysterical. Later, they learned and became more matter-of-fact” (interview Swedish pharmacovigilance expert).

But the same person also pointed to a patronizing sentiment in Swedish culture that hampered the possibility for KILEN to get a hearing for its demands regarding patient reporting: “Sweden has refused to give in and was probably last in the world to introduce patient reporting; it was not until the EU directive that it was introduced. It’s sad. There has been a patronizing attitude in Sweden—that this is something that only doctors understand, because the doctors are the ones who make diagnoses. An arrogant attitude. Today we know that this is wrong” (interview Swedish pharmacovigilance expert). After the closing down of KILEN, its founders still had support from the Swedish Green Party that in several parliamentary bills (without success) maintained that it was a mistake to cut the state funding to the organization. In the bills it was argued that KILEN defended important consumer rights against the financial interests of pharmaceutical companies (Nihlén, Ericson, Lindholm 2007). One Green Party politician stated that KILEN was perceived as threatening the system, and that it eventually lost its political support because no politicians dared to openly oppose powerful interests: “To criticize such fundamental societal interests and authorities, primarily the National Board of Health and Welfare, but also the Medical Products Agency and the medical profession, is almost like committing suicide in Sweden today. My understanding is that very few politicians dared to talk about KILEN” (interview Swedish Green Party politician).

Conclusion

This case study suggests that the political opportunity structure in Sweden might be unfavorable for a civil society organization (CSO) that is challenging the medical establishment. There is a well-developed system for financial support for CSOs of various kinds, but our study shows that problems can occur if the organization has ambitions that can be perceived as political

and threatening to powerful interests in society. KILEN managed to call attention to a new social problem, and as long as the organization mainly worked with direct services to individual patients afflicted by adverse drug effects, it enjoyed support from several influential politicians and senior officials in the health authorities. But when KILEN started to question the pharmaceutical industry and medical practices it was hit by political and professional resistance and withdrawn funds. The growth of professionalism in medicine in Sweden has gone hand in hand with the development of the state's prosperity in the welfare state, and there are close links between these institutions (Carlhed 2013). Medical doctors also enjoy high status and trust among the public and are rarely questioned. Hence, the patient's position in the Swedish health-care system is relatively weak. These factors in the Swedish political opportunity structure probably limited KILEN's ability to affect mainstream institutional politics and policy. The fact that the organization never managed to establish a good relationship with the media did not improve matters.

When the domestic political arena seemed more or less blocked, KILEN chose to build alliances with a number of authoritative key partners abroad and could also benefit from the greater interest in patients' rights and consumer reporting at the European and international policy levels. It was largely thanks to the financial support from the EC that KILEN could establish a consumer database and actively engage in international networking, which in turn eventually made it possible to influence the discourse and policy on drug safety at both the European and Swedish levels. The organization was forced to shut down in Sweden but had by then contributed to new EU legislation on pharmacovigilance that also affected the patients' position in Sweden. Thus, in the end KILEN's strategy of using political opportunities at European and international levels was fruitful.

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Notes

1. KILEN also received some financial support from the Swedish National Board of Health and Welfare and the Swedish National Institute of Public Health (Nilsson 2002).
2. SIDA, the Swedish National Board of Health and Welfare, the Dag Hammarskjöld Foundation, HAI, People's Health Assembly, UMC, the Swedish Consumers Association, and the Sigtuna Foundation.

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