

Fibromyalgia Wars

Fibromyalgia (FM) is easy to recognize. Patients diagnosed with it have medically unexplained symptoms (MUS)¹ that are often severe and generally include widespread pain, fatigue, sleep disturbance, depressive symptoms, cognitive problems, irritable bowel syndrome, multiple somatic symptoms, and a single partially objective sign — tenderness on palpation². Representing perhaps 2% to 4% of the adult population³, patients with FM incur substantial direct and indirect medical costs, including high rates of disablement.

FM is a bitterly controversial condition. It pits patients, pharmaceutical companies, some specialty physicians, professional organizations, and governmental agencies — groups with substantial political and economic power who benefit from the acceptance of FM — against the large majority of physicians, sociologists, and medical historians in what we call the “fibromyalgia wars.”

The wars are fought over a series of questions that concern the legitimacy of the diagnosis. In the balance is access to care and disability awards for patients; careers, publications, funding, and salaries for academic physicians; profits for pharmaceutical companies; political power that influences government, research agencies, and professional organizations; and rewards for the legal system. The consequences of the dispute are societal and are best understood in terms of medicalization⁴ and social construction^{5,6}.

PATIENTS WITH FM AND THE BATTLE FOR SYMPTOM LEGITIMACY

A central concern of patients with FM and similar MUS illnesses is disbelief: that their physicians and the medical profession don't believe them^{7,8}; that physicians see their symptoms as ordinary — something that everyone has at one time or another, not serious, psychosomatic — in your head, a mental problem or the result of depression⁶⁻¹². Sensing disbelief, the commentaries of FM patients and their interactions with the medical system are filled with a sense of delegitimization, betrayal, and anger⁷.

There is a lot at stake. Real diseases are compensable and recognized by insurance companies, proof offered to family, friends, and employers that the problem is real and that it is serious¹³. Against physician doubt, patients and support groups have marshaled powerful forces: the American College of Rheumatology (ACR) criteria for FM establishes FM as “a real diagnosis”^{14,15} and the World Health Organization (WHO) provides FM ICD codes. Research on pain mechanisms and brain imaging studies demonstrate neurobiologic and imaging abnormalities¹⁶ that can be considered the basis of their problems. Further support comes from the funding of research about FM by the National Institutes of Health (NIH), and the US Food and Drug Administration's (FDA) approval of drugs for the specific treatment of FM; and by mid-2008 a MEDLINE search would result in more than 5000 citations for FM.

Support for FM is strong within professional organizations and academic centers that offer courses and symposia to physicians and the public, often with strong support from the pharmaceutical companies. FM support-group lobbying of the US Congress has led to endorsement and funding for FM research at the NIH and the Veterans Administration (VA). Lobbying at the state level resulted in at least 8 US state legislature or gubernatorial proclamations of “Fibromyalgia Awareness Day.” Most recently, ubiquitous media advertising shows happy, upper middle class women made well by the new drugs.

Not so real: medical skepticism. Physicians, however, are skeptical about FM^{2,6,11,17,18}. In a survey of 400 general practitioners in the UK, 64% thought patients with MUS had psychiatric illnesses and 84% thought they had personality problems¹⁰. Wessely and Hotopf described FM as occupying “that grey area between medicine and psychiatry that is also occupied by chronic fatigue syndrome (CFS), irritable bowel syndrome, and many others”¹⁹. The *British Medical Journal* categorized FM as “non-disease ... [part of a] spectrum disorder”¹¹. The medical historian Edward Shorter placed FM in the continuum of psychosomatic ill-

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nesses²⁰; and the *New York Times* indicated that many physicians consider FM to be a psychosomatic condition¹⁷.

Barsky and Borus describe FM as one of a group of “functional somatic syndromes”²¹. Persons with such syndromes “share similar phenomenologies, high rates of co-occurrence, similar epidemiologic characteristics, and higher-than-expected prevalences of psychiatric comorbidity.... Suffering...is exacerbated by a self-perpetuating, self-validating cycle in which common, endemic, somatic symptoms are incorrectly attributed to serious abnormality”²¹. Wessely and Hotopf characterize FM as lying “at the extreme end of the spectrum of polysymptomatic distress”, and indicated that it overlaps with chronic fatigue and “...virtually every other medically unexplained syndrome, including tension headache, chemical sensitivity, irritable bowel syndrome, atypical chest pain, gynecological syndromes, temporomandibular disorders, and mitral valve prolapse”¹⁹.

If FM occupies the “grey area between medicine and psychiatry that is also occupied by CFS, irritable bowel syndrome, and many others”¹⁹, it is also different from these other conditions in that extensive musculoskeletal pain (and local tenderness) is required to be admitted to the diagnosis. Musculoskeletal pain reflects the content of rheumatology practice, where FM arose. However, the distinction between FM and other MUS conditions is clearly artificial, as the pool of underlying symptoms is the same^{19,20,22,23}.

In contradistinction to the psychosomatic, socially constructed and medicalized description of FM noted above, FM proponents argue that there are central nervous system, endocrine, and genetic abnormalities that explain some or all of the findings in FM^{16,24-26}. At the 2008 ACR meeting, for example, a scientist presenting data on FM and brain imaging stated that the data proved that FM was “a real, real, real disease”²⁷. According to this approach, FM fits the biomedical model of disease; FM is real because biological abnormalities have been found. Mohammad Yunus takes it a step further on the path of a “real disease” and advocates calling FM and other MUS syndromes a “Central Sensitivity Syndrome[s] (CSS),” and would abandon “such terms as ‘medically unexplained symptoms,’ ‘somatization,’ ‘somatization disorder,’ and ‘functional somatic syndromes’” as well as “the disease-illness” and the “organic/non-organic dichotomy”²⁸. This approach argues for causality based on cross-sectional data — that the observed psychobiological abnormalities are the cause of the problem rather than the result of the problem²⁹. In addition, such suggestions^{16,24,25,28,30,31} and the tendency to equate correlation and causation imply acceptance that there is an underlying disease process that fits within the biomedical model — that FM is a disease.

Simon Wessely counters, writing of the CFS, and implicitly of FM, that “...few could now question that it is indeed an illness. It has a nosological status and is clearly associated with suffering, ill health, and disability. ...But is it a dis-

ease — that is, has a specific pathological process been identified to account for the above? ...[it] is not yet a disease because no unambiguous evidence has yet been presented that has commanded widespread acceptance by the scientific community, which remains the arbiter.”³²

Not a disease? What is it? Although the battle over FM is often fought over its status as a “real disease,” such eristics add little light. Definitions of disease are contentious, and increasingly reflect societal decisions rather than traditional biomedical designations¹¹. What is a disease at one moment may not be in the next. Consider, for example, the changing beliefs and disease status of alcoholism and homosexuality⁴. As opposed to the biomedical model of illness that has dominated most of the 20th century, David Morris describes illness (“postmodern illness”) as it occurs in our time. Postmodern illness is “fundamentally biocultural — always biological and always cultural — situated at the crossroads of biology and culture.”³³ Further, “although some maladies originate in the mind, minds operate only in the context of cultures and produce symptoms only through biologic processes. Even psychogenic pain produced in a laboratory experiment is always biological and always cultural.” “Postmodern analysis...demonstrates how human life is socially constructed and how people and institutions govern the flow of knowledge and power.”³³

We would argue that the contention around FM should be not whether or not it is real or whether abnormal central biology can be ascertained, but the extent to which cultural factors dominate the illness, the extent to which it is socially constructed and medicalized, or at the more practical level of the clinician — the extent to which psychosomatic factors predominate. Implicit in the meaning of biocultural is that the extent to which an illness is socially constructed can be modified^{5,20,34-36}. An example germane to the FM controversy is the Australian epidemic of repetitive stress injury (RSI) that virtually vanished after a simple government regulatory change³⁷.

We would go further. A society can actively choose which illnesses are to be supported, as seen in the current rejection of support for entities like recovered memory syndrome, alien abduction syndrome³⁸, multiple chemical sensitivity syndrome⁸, and breast implant diseases. Chronic Lyme disease, which for all intents and purposes is FM/chronic fatigue, lacks sufficient societal support for longterm survival³⁹. Support for FM, too, is up for grabs; players on the societal canvas are patients, pharmaceutical companies, academic physicians (the pharmaco-academic complex), professional organizations, attorneys, and any others who stand to profit financially or in other ways from the success of FM.

Clarifying language. Disease is a biomedical term. Illness is a biocultural term that implies social construction. In the fibromyalgia wars, diagnostic words carry meaning within the biomedical model of disease. “Diagnosis,” “disease,”

and “disease mechanisms,” particularly when they are spoken by physicians, professional organization, and government, are code words for “real.” Designations that involve psychological language carry with them connotations of a condition that is not believed⁴⁰. “Unexplained medical symptoms” is perceived by patients⁴⁰ and physicians¹⁰ to mean that the symptoms are psychological in origin. “Condition,” “syndrome,” and “illness” are relatively neutral words, while “disorder” tends to the real in that it implies a disordered mechanism. When the NIH or the FDA uses the words “disease” or “diagnosis,” the words carry with them the weight of science in the biomedical representation, even if they don’t reflect scientific evidence. Watch the words that are used. They are soldiers in the fibromyalgia wars.

How did we get here? Social construction and medicalization. A socially constructed illness is one that is the result of societal factors: it need not have existed or need not be at all as it is. It is not determined by the nature of things, and it is not inevitable⁵. Medicalization is “a process in which non-medical problems become defined and treated as medical problems, usually in terms of illness and disorders [and are] described using medical language, understood through the adoption of a medical framework, or treated with a medical intervention.”⁴

Ivan Illich’s 1976 attack on medicalization in society set out some markers that are germane to understanding FM and opposition to it¹³. “In a morbid society”, he wrote, “the belief prevails that defined and diagnosed ill-health is infinitely preferable to any other form of negative label or to no label at all,” that “people want to hear the lie that physical illness relieves them of social and political responsibilities”, and that they are “innocent victim[s] of biological mechanisms...”

In addition, diagnosed ill-health provides access to disability programs and access to additional healthcare¹³.

The path that led to modern FM began in 1977 with the publication of “Two contributions to the understanding of the ‘fibrositis’ syndrome”⁴¹. Smythe and Moldofsky proposed criteria for fibrositis (later called FM) based on what they saw as its key features: nonrefreshing sleep and tender points, locations on the body that were particularly sensitive to pressure in people with the syndrome. Not only criteria, they also proposed a mechanism for FM. It was caused by sleep abnormality in all except well trained athletes^{42,43}. From these papers came the ideas that would influence FM and FM treatments for 3 decades: that it could be diagnosed by a count of tender points, and that the crucial treatments were exercise and improving sleep quality, the latter often with the help of drugs that acted centrally, such as amitriptyline.

Although FM and fatigue-like illnesses can be identified as early as the 19th century^{18,20,34,44}, and sporadic descriptions of FM⁴⁵⁻⁴⁸ can be found before the Smythe and Moldofsky paper, the major authors at the rebirth of FM in

the late 1970s and early 1980s all cite the central importance of this paper⁴¹ in personal communications with the author, one going so far as saying, “I can still see the figure in that paper,” an observation that is also true for this author.

So why did FM arise and become established at this time? How did the pool of medically unexplained symptoms that are endemic in the population become organized into FM and sustained? Medical historians and sociologists agree that many factors must fall into place at once. Hacking’s social construction description requires the interaction of a matrix of participants, ideas, and *zeitgeist*⁵, similar to what is called the “therapeutic domain” by Hazemeijer and Rasker³⁵. The participants include the patient, the patient’s family and coworkers, support groups, government agencies, medical professionals, attorneys, insurers, pharmaceutical companies, research physicians, and other patients. When the mixture and time is right, symptoms aggregate and become redefined into illnesses. For patients, FM offered a legitimization of what otherwise was seen by many as psychosomatic symptoms. FM was also a convenient diagnosis for physicians because it allowed them to avoid dealing with psychosomatic issues, particularly in an era in rheumatology when psychological issues were not ordinarily addressed in articles and textbooks, and not taught in rheumatology fellowship programs. Still, none of this could have happened without the Smythe-Moldofsky definition and the scientific hypothesis as to etiology. Here at last was an explanation for common symptoms. Here was some potentially exciting science.

Hadler and Greenhalgh argue cogently that pharmaceutical company support and the approval of FM criteria by the ACR were instrumental in the widespread adoption of the syndrome⁶. Industry support allowed the idea to propagate, and ACR endorsement gave it academic respectability. Without these, FM might have languished as just one more transient description of chronic pain, or been abandoned as previous characterizations of fibrositis had been⁶. So it all came about in a period of a few years, in a social setting ready for it, and with the necessary, but not inevitable, contribution of Pharma and the ACR criteria. In its second decade would come the knowledge that FM was similar to CFS and other MUS conditions, something that was generally not appreciated by the authors of this period, and in the decade that followed that “fatigue and myalgia syndromes are arbitrarily created syndromes that lie at the extreme end of the spectrum of polysymptomatic distress.”¹⁹ Less than 10 years after the publication of the 1990 ACR criteria for FM, pharmaceutical company support of treatment studies began. Seventeen years after the publication of the criteria, pharmaceutical company dominance was everywhere, from professional meetings and education to direct-to-patient advertising.

Socially constructed illnesses can also be defined in terms of medicalization in which ordinary, universal symp-

Pharmaceutical industry. FDA approval of specific FM treatments — pregabalin (Lyrica) and duloxetine (Cymbalta) — has been a boon to pharmaceutical companies, and additional treatments are on the way. Because treatment for FM, however conceived, is unsatisfactory^{2,53}, every patient is a candidate for these new and expensive therapies. According to the *New York Times*, in November, 2007, there were 800,000 prescriptions per month written for pregabalin. FM Marketing Research reports that “With their extensive sales and marketing resources, Pfizer, Lilly and Forest will be instrumental in driving the growth in patient potential through extensive clinical education seminars and marketing campaigns. Estimated at \$367 million in 2006 in the US and EU⁵, the FM market is forecast to grow to \$1.7 billion by 2016.”⁵⁴ “Lyrica revenues in third-quarter 2008

Medical practitioners. Many practitioners are involved in FM treatment, some because patients with pain seek medical

- Treating the wrong illness
- Expanding the base of fibromyalgia patients
- Expanding unnecessary, marginally effective treatment
- Increasing medical costs and treatments
- Increasing disability
- Corrupting scientific research
- Corrupting the dissemination of scientific information
- Changing psychosomatic illness into compensable disease
- Confusing correlation with causation

care and some because practitioners advertise FM treatment. As a rough measure of practitioner involvement, we counted Google hits in September 9, 2008, using “fibromyalgia AND type of health practitioner” as the search term. FM treatment has attracted orthopedists (1,070,000 hits), rheumatologists (243,000), physiatrists (70,000), physical therapists (779,000), psychologists (831,000), chiropractors (747,000), nutritionists (390,000), homeopaths (462,000), and pain clinics (43,600). Given the limited effectiveness of current therapies, these numbers should give pause. What do all of these practitioners do?

Support groups. The success of the FM movement owes much to ubiquitous and well organized patient support groups. The National Fibromyalgia Association (NFA) website names over 300 allied support groups that have registered with it, and a Google search on “fibromyalgia AND support group” results in 445,000 hits. Support groups, some with public relations departments, have had exceptional success in lobbying and influencing legislation. Adding “legislation” to the above search term results in 28,200 hits. In addition to “public awareness” proclamations, the real successes of FM lobbying have come by inducing Congress to require the NIH to support FM research and to publicly buy into the FM disease concept.

The deterioration of reliable scientific sources. If most physicians are skeptical about FM, “that grey area between medicine and psychiatry,”¹⁹ one might expect to see some of this uncertainty described by expert medical sources. But this has not been the case. There has been a general distortion in the communication of scientific and health data that results in presentation of the positive attitude, FM-is-a-disease point of view. “Medline Plus,” which is a “service of the US National Library of Medicine and the National Institutes of Health” that provides “Trusted Health Information for You,” addresses FM at <http://www.nlm.nih.gov/medlineplus/fibromyalgia.html>. On this website one may learn from a recommended link of the 13 foods you should eliminate to make your FM better (“FM Diet: Eating for a Better Quality of Life”). The site links to the American College of Rheumatology, which instructs patients to join a support group, provides sappy homilies (“Look forward”), and manages to show a third of the FM tender points in the wrong locations⁶⁰. An NIH Medline Plus website tutorial states, “Fibromyalgia is a common condition that *causes pain* and fatigue in the muscles, joints, ligaments and tendons [*italics mine*].”⁶¹

One might expect the FDA to stick to data in their “Living with Fibromyalgia, Drugs Approved to Manage Pain” website⁵⁸. But it doesn’t. The site provides supportive patient stories, selected information about FM, a description of FDA-approved treatments, and the statement by Dr. Jeff Siegel, the clinical team leader in FDA’s Division of Anesthesia, Analgesia, and Rheumatology Products, that “One of the challenges is that FM hasn’t always been

recognized as a specific illness.”⁵⁸ It also provides links to the National Fibromyalgia Association and the Fibromyalgia Network (support groups). One also finds enthusiastic endorsements of FM and grossly inaccurate articles concerning FM and its treatment in the publications and on the websites of the ACR and the Arthritis Foundation (“Fibromyalgia patients are our constituency”). The ACR website indicates that FM “causes widespread muscle pain and tenderness...”⁶⁰. The pharmaceutical industry provides substantial support through advertising and symposia to the ACR and the European League Against Rheumatism.

What one doesn’t find at any of the sites of important medical organizations and information sources is the slightest degree of skepticism with respect to the central controversies that surround FM: its existence and content, its status as an unexplained medical syndrome, the role of cultural factors, the marginal effectiveness of treatment, the quality of FM research, the poor outcomes of treatment, and the potential harm of the FM label. Through political pressure and industry funding, the public responsibility to provide accurate scientific information and interpretation has become corrupted.

Academia and FM. In the popular press, academic research is seen as objective, a defense against industry influence and biased research. However, a large majority of academic physicians who write and lecture about FM receive funding and platforms from pharmaceutical companies. Industry hires research groups and academic physicians to prepare articles on FM. In addition, when an illness is accepted through political pressure and in the *zeitgeist*, funding becomes available at the NIH. University researchers, almost all of whom depend on grants for their survival, then compete for the available funds. There is always something to study, and often by the same pool of researchers. In the review process, “experts are chosen based on their perceived expertise and qualifications. Unfortunately, this sampling scheme is particularly subject to bias because the extreme experts have a vested interest in the current paradigms”⁶². Little that was not known in advance has come from this research, but its main result has been to continue to support the “fibromyalgia is a disease” research concept that was formed by political pressure.

Disability and the legal industry. Pharmaceutical companies and practitioners are not the only ones who benefit by FM. A search in Google using the terms “lawyer fibromyalgia” produced 838,000 hits. According to the US Social Security Administration, “individuals with impairments that fulfill the American College of Rheumatology criteria for FMS [will be found] to have a medically determinable impairment.” However, the ability to obtain a Social Security Administration disability award depends strongly on the use of an attorney. FM has also given rise to a controversial construction, “post-traumatic fibromyalgia,” that is largely pro-

secuted by attorneys. In this construct, persons suffering injuries that may be very mild or quite severe who develop FM assert, often successfully, that the injury caused FM and that FM is disabling and incurable⁶³.

Should we diagnose FM? Should patients be labeled? The scientific and societal issues we have cited above seem problematic when a physician faces a patient who has FM complaints. Talk of social construction and medicalization is not much help here. Why not just diagnose FM and explain the reasoning and treatment associated with it? Huibers and Wessely sum up the arguments in favor of diagnosis⁶⁴. Diagnosis is “an intervention in itself, a breakthrough that brings an end to the burden of uncertainty and de-legitimization and that determines the course of action to follow. Diagnosis generates comfort, relief, acceptance, credibility and legitimacy and...can provide a refuge that preserves self-esteem and...offers a socially accepted reason for failure to cope, especially if all miseries can be pinned on that disease”⁶⁴. And diagnosis also provides entry to health services, welfare benefits, workers’ compensation claims, and pensions⁸.

The argument against labeling has been made by Hadler^{6,65} and summarized and added to by Huibers and Wessely: labeling leads the patient to “believe she has a serious disease, leading to symptom focusing that becomes self-validating and self-reinforcing and that renders worse outcomes, a self-fulfilling prophesy. Diagnosis leads to transgression into the sick role, the act of becoming a patient even if complaints do not call for it, the development of an illness identity and the experience of victimization. The dangers of labeling have raised some voices to abandon diagnostic labels such as CFS altogether”⁶⁴.

We would make one other argument against diagnosing FM. In the years since modern FM was identified, there has been no evidence that patients are better off now than they were at the start. The pool of FM symptoms has not changed in the years before and after FM, nor is there less evidence of suffering. In fact, there may be more evidence of harm, as more and more symptoms are identified and knowledge of them is spread. We would add that labeling contributes to medicalization and the overall societal burden of the FM concept (Table 1).

Can we help the patient without spreading FM? One might say to the patient something like this. “You have a kind of pain problem that we commonly see but that doctors do not understand well. There is a lot we can do to help you.” If necessary, we can add, “Some people call this problem FM. FM is the name we give to the problem, but it is not what causes the problem.” In addition, sometimes patients ask the physician, “Do I have fibromyalgia?”. The answer might be, “Some doctors call your problems FM. FM is the name we give to such problems, not the cause of the problems.”

Where should we go from here? Although most research has

been aimed at patients diagnosed with one of the named MUS disorders, epidemiologic and clinical studies have shown that the key features of these syndromes exist as a continuum in the general population and in clinical patients⁶⁶⁻⁶⁸. We have suggested that the number of painful body locations and the severity of fatigue are the key features of patients diagnosed with FM⁶⁹, and others have confirmed the importance of widespread pain⁷⁰⁻⁷³. When the extent of body pain (the number of reported painful regions)⁷⁴ and a visual analog scale for fatigue are combined into a single scale, such a scale is associated linearly with all measures of demographic disadvantage, and physical and mental distress⁶⁹. Such a scale appears to be a measure of the intensity of FM-like symptoms in all persons (“fibromyalginess”). One of the most frequent errors in FM research is to compare FM patients with “healthy” controls, thereby comparing 2 ends of human experience, but ignoring the humans in between. We suspect that the results of central nervous system imaging studies would show a continuum of results, and that the FM–healthy control dichotomy would look far less convincing with this approach.

In summary, FM diagnosis offers short-term legitimacy and social benefit to patients, but at the cost of creating and expanding illness. The influence of pharmaceutical companies has resulted in expansion of the number of patients diagnosed with FM and exposed to new treatments. Pharmaceutical companies, the pharmaceutical-academic complex, attorneys, and patient support groups have strong interests in continuing FM. But their influence has distorted scientific and public information and institutions.

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FREDERICK WOLFE, MD,
National Data Bank for Rheumatic Diseases,
Arthritis Research Center Foundation,
1035 N. Emporia, Suite 230,
Wichita, Kansas 67214, USA

Address reprint requests to Dr. Wolfe. E-mail: fwolfe@arthritis-research.org

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