Correspondence

Confessions of a Disease Monger

James Phelps

I am a disease monger. I teach primary care doctors how to identify bipolar disorder. Worse yet, I take money from pharmaceutical companies for doing so. I use it to subsidize my practice so that I can treat patients with no insurance, or little money, who now account for over a third of my patients—in part because the pharmaceutical companies have drained so much money out of the health-care system. Ironic, isn't it?

My Web site PsychEducation.org (http://www.psycheducation.org) is number one on Google for searches on "bipolar II." See if you think it looks like disease mongering. Hundreds of people have written thanking me for explaining bipolar II and the concept of a bipolar spectrum, indicating that this new perspective really helps them understand their long-standing symptoms. To my immediate recall, none have complained about being led astray by an overbroad interpretation of bipolarity.

Notice that, just like Mr. Moynihan, one of the guest editors of your April 2006 series of articles on disease mongering [1], I could be mongering even now, as I too have a new book. At least I'm not trying to attract attendees to my conference. Tricky, isn't it. Has there been an oversimplification in this analysis?

(PsychEducation.org earned an Honorable Mention Moffic Award for Ethical Practice in Community Psychiatry, 2005.) ■

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Fairness Creams in South Asia—A Case of Disease Mongering?

P. Ravi Shankar, Bishnu Rath Giri, Subish Palaian

We read with interest the article by Moynihan and Henry on disease mongering [1]. The authors argued that disease mongering is the opportunistic exploitation of a widespread anxiety about frailty and of faith in scientific advance and "innovation."

In South Asia there is a widespread preference for "fair skin" and this has been exploited by the manufacturers of "fairness creams." "White" skin has a colonial connotation of power and superiority. The emergence of a "paler" global entertainment industry has served as a fillip to the marketing of an international beauty ideal [2]. Beauty pageant winners in India are all extraordinarily tall and breathtakingly slim, have light honey-colored skin, and peddle Western ideals of beauty [3]. South Asian culture has carried within itself a capacity for female objectification. Matrimonial columns and Web sites reveal the influence of a young woman's skin color on her marketability to marriage partners [3].

The craze for modern fairness creams has emerged in the last fifty years [2]. International cosmetics giants were the initial manufacturers, but these days Indian and South Asian companies are playing an important role in the skin bleaching and cosmetic markets [2,3]. Fairness creams have been estimated to account for up to 40% of the profits of the cosmetics industry [3]. Recently, a fairness cream has been launched exclusively for men [4].

Advertisements aim to produce a hierarchy of values based on the notion that "fairness" is an object of desire [2]. Being fair has been represented as an active process. Regular use of fairness creams has been claimed to halt the production of melanin and to bring out "natural" beauty.

Promoting a particular body image or behavior pattern as the preferred one and then selling medicines or products to help people attain the particular ideal may be regarded as disease mongering [5]. Fairness cream manufacturers have exploited the preference for fair skin, portrayed it as a necessary prerequisite for success, and promoted the use of their product to achieve the ideal. Controlled studies on the efficacy and safety of fairness creams are lacking.

Disease mongering companies form alliances with doctors, consumer groups, and the media to promote sales of their drugs. Fairness cream manufacturers sponsor beauty pageants and carry out an advertising blitz in the print and audiovisual media [3]. They create hype about their product. Many leading manufacturers have expanded their range to include lotions, cold creams, and soaps.

Most fairness creams are nonprescription products, and the medical profession may not be the main target of marketing professionals. However, doctors as responsible and respected members of society have an important role to play in spreading awareness about this racial distortion of body image. Fairness creams may satisfy many of the criteria of disease mongering. The issues of freedom of choice, economic impact (personal and on the society), profits, social issues, and ideal body image should be seriously debated. ■

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Disease Mongering: One of the Hidden Consequences

Kenneth Gillman

I found Moynihan and Henry's article on disease mongering [1] interesting, especially because I have previously suggested that the medical profession might consider being more proactive concerning various problematic areas in their interactions with the pharmaceutical industry by exercising their considerable power and improving the scientific quality of research [2]. There is a strong tendency for doctors to be trusting and accepting of the good intentions and honesty of others. It takes a substantial amount of evidence for doctors to adopt the contrary posture of distrust. Perhaps the profession is, understandably, at that point with pharmaceutical companies.

A significant hidden area related to disease mongering is the inevitable increase in doctors' medico-legal insurance costs. The pharmaceutical industry has generally been quite successful in getting doctors to shoulder the blame for the negative consequences of drug treatment. They are quick to inform the profession (and patients, by covert direct-to-consumer advertising) of any evidence favourable to the promotion of their drug, but slow to update the product information, or inform doctors, about side effects, complications, or drug interactions [3]. It is dishonest to actively promote supposed advantages (to patients) whilst consciously failing to look for, or alert doctors to, the disadvantages. Furthermore, inducing patients to visit doctors and pressure them into colluding with drug company advertising is a subtle form of bullying.

Medical insurers tend to accept full responsibility on behalf of doctors without much attempt to bring others into legal actions, especially drug companies. Since both patients and doctors are being fed misinformation, it may be that a greater part of the responsibility for difficulties should be apportioned to drug companies. Perhaps both doctors and drug companies need to be reminded that only doctors are able to sign prescriptions and take the primary responsibility for the consequences. It may be time for medical organizations and authorities to impose conditions and demand more information from pharmaceutical companies if they are going to agree to sign the script. As but one of many possible examples, how many doctors realise that drug toxicity data are rarely made available and that much of the data presented to regulatory authorities are not available to ordinary doctors? I suggest that those in the profession who are in a position to influence such matters should give serious consideration to these and other similar questions and exercise their power. ■

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Defining Disease in the Information Age

Olavo B. Amaral

The series of disease mongering articles in the April 2006 issue of *PLoS Medicine* overall seem to define the term as "widening the boundaries of illness" [1] by "taking a normal function and implying that there's something wrong with it and that it should be treated" [2]. While there is undoubtedly a strong case to be made for this sort of practice by pharmaceutical companies, perhaps we should also question ourselves on what we mean by "disease boundaries."

All of the conditions touched on by the disease mongering series (e.g., bipolar disease, attention deficit hyperactivity disorder, restless legs syndrome, and sexual dysfunctions) share the fact that they represent spectra of symptoms felt by virtually everyone, but which for some people can reach a point at which they become disturbing. However, since the benefit of treating these symptoms is ultimately dependent on their significance in a patient's life, it seems doubtful that anyone but the patient can adequately define the "boundaries" of illness for these conditions.

The existence of these large "grey zones" between disease and normality (as well as the difficulty of doctors in dealing with them) might help to explain the increase in "lifestyle drug use" and self-prescription of psychiatric medication [3]. While these behaviors undoubtedly carry risks, they might well be an inevitable development in an age where information on anything (including drugs) is so widely available. Moreover, tampering with body chemistry is nothing new (alcohol, coffee, chocolate, and sunlight come to mind as examples), and it is hard to expect people will not do it because of pharmaceutical labels. Therefore, complain as we may, it is unlikely that this trend can be feasibly prevented.

Therefore, if we want to prevent disease mongering, perhaps we should start by focusing on our own concept of "disease."

Maybe it is time we start to loosen the grip on our powers to define disease and start working less as diagnosing machines and more as decision facilitators for patients. It seems quite absurd to decide on a "concept" of erectile dysfunction or depression that can define who should be treated. On the contrary, our role should be to inform patients of the benefits and risks of treatment (or nontreatment) for their particular condition. This also means being comfortable with the fact that, no matter which criteria one uses to define disease, there will always be "normal" people who will want treatment as well as "sick" people who will refuse it. And in both cases they are probably entitled to do so, without necessarily receiving a diagnosis of "normal" or "sick."

Moreover, since the trend for self-prescription is not likely to be prevented, and since the pharmaceutical industry will surely try to capitalize on it, perhaps we should also worry about making nonprofit, unbiased scientific information more available to the public. Education on health matters is an important responsibility that traditionally has been overlooked by doctors in most countries. Now, if ever, seems to be the time to change that, because if physicians do not concentrate on it, drug companies will be happy to do it for them.

It is obvious that medicine cannot abandon the concept of disease boundaries, since most of our medical knowledge and research is still based on it. Moreover, there are fields in which medical responsibility is sure to remain important in defining these boundaries (e.g., attribution of public funds, research studies, and treatment of children). But after reading so much on disease mongering, it seems to me that if we become a little more flexible in admitting that "disease boundaries" for many conditions are an oxymoron, perhaps the pharmaceutical industry will make less of a fuss in trying to convince people they are ill. My guess is that this would do everybody a favor. ■

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There Is No Such Thing as a Psychiatric Disorder/Disease/Chemical Imbalance

Fred Baughman

In her recent *PLoS Medicine* article, Christine Phillips writes: "ADHD [attention deficit hyperactivity disorder] joins dyslexia and glue ear as disorders that are considered significant primarily because of their effects on educational performance" [1]. A "disorder" is "a disturbance of function, structure, or both," and thus, the equivalent of an objective abnormality/disease [2]. In neurologically normal children, dyslexia cannot be proved to be a disorder/disease. "Glue ear," however, is otitis media, an objective abnormality/disease. Phillips continues: "In the case of ADHD, there has been a complex, often heated debate in the public domain about the verity of the illness," but proceeds, without an answer, to consider "the roles of teachers as brokers for ADHD and its treatment."

In 1948, "neuropsychiatry" was divided into "neurology," dealing with diseases, and "psychiatry," dealing with emotions and behaviors [3]. If there is a macroscopic, microscopic, or chemical abnormality, a disease is present. Nowhere in the brains or bodies of children said to have ADHD or any other psychiatric diagnosis has a disorder/disease been confirmed. Psychiatric drugs appeared in the fifties. Psychiatry and the pharmaceutical industry authored the "chemical imbalance" market strategy: they would call all things psychological "chemical imbalances" needing "chemical balancers"—pills.

At the September 29, 1970, hearing on Federal Involvement in the Use of Behavior Modification Drugs on Grammar School Children, Ronald Lipman of the United States Food and Drug Administration (FDA), argued: "hyperkinesis is a medical syndrome. It should be properly diagnosed by a medical doctor" [4].

In 1986, Nasrallah et al. [5] reported brain atrophy in adult males treated with amphetamines as children, concluding: "since all of the HK/MBD [hyperkinetic/minimal brain dysfunction] patients had been treated with psychostimulants, cortical atrophy may be a long-term adverse effect of this treatment."

At the 1998 National Institutes of Health (NIH) Consensus Development Conference on ADHD, Carey [6] stated: "The ADHD behaviors are assumed to be largely or entirely due to abnormal brain function. The DSM-IV does not say so but textbooks and journals do.... What is now most often described as ADHD...appears to be a set of normal behavioral variations."

However Swanson and Castellanos [7], having reviewed the structural magnetic resonance imaging (MRI) research, testified: "Recent investigations provide converging evidence that a refined phenotype of ADHD/HKD (hyperkinetic disorder) is characterized by reduced size in specific neuroanatomical regions of the frontal lobes and basal ganglia." I challenged Swanson, asking: "Why didn't you mention that virtually all of the ADHD subjects were on stimulant therapy—the likely cause of their brain atrophy?" [8] Swanson confessed this was so—that there had been no such studies of ADHD-untreated cohorts.

The Consensus Conference Panel concluded: "We do not have a valid test for ADHD... there are no data to indicate that ADHD is a brain malfunction" [9]. (This wording appeared in the version of the final statement of the Consensus Conference Panel distributed at the press conference in the final part of the Consensus Conference, November 18, 1998. This wording, which appeared for an indeterminate time on the NIH Web site, was subsequently removed and replaced with wording claiming "validity" for ADHD.)

In 2002, Castellanos et al. [10] published the one and only MRI study of an ADHD-untreated group. However,

because the ADHD-untreated patients were two years younger than the controls, the study was invalid, leaving stimulant treatment, not the never-validated disorder, ADHD, the likely cause of the brain atrophy.

In 2002, Daniel Weinberger, of the National Institute of Mental Health, claimed "major psychiatric diseases" are associated with "subtle but objectively characterizable changes" but could reference not a single proof (quoted in [11]).

In 2002, the Advertisement Commission of Holland [12] determined that the claim that ADHD is an inborn brain dysfunction was misleading and enjoined the Brain Foundation of the Netherlands to cease such representations.

In 2003, Ireland prohibited GlaxoSmithKline from claiming that the antidepressant Paxil "works by bringing serotonin levels back to normal." Wayne Goodman of the FDA acknowledged that claims that selective serotonin reuptake inhibitors correct a serotonin imbalance go "too far," but had the temerity to suggest that "this is reasonable shorthand for expressing a chemically or brain-based problem" (quoted in [13]).

At an FDA hearing on March 23, 2006, I testified: "Saying any psychiatric diagnosis 'is a brain-based problem and that the medications are normalizing function' is an anti-scientific, pro-drug lie" [14]. Yet this has become standard practice throughout medicine, for example, at the American Psychiatric Association [15], American Medical Association [16], American Academy of Child and Adolescent Psychiatry, American Academy of Pediatrics, Child Neurology Society, American Academy of Family Physicians [17], FDA [13], and virtually all US government health-care agencies.

Journal articles [6], press releases, ads [18], drug inserts, and research informed consent documents say, or infer, that psychological diagnoses are abnormalities/diseases. All patients and research participants with psychological problems are led to believe they have an abnormality/disease, biasing them in favor of medical interventions, and against nonmedical interventions (e.g., love, will power, or talk therapy), which presume, as is the case, that the individual is physically and medically normal and without need of a medical/pharmaceutical intervention.

The FDA is the agency most responsible for conveying the facts needed by the public to make risk versus benefit and informed consent decisions. Instead—by protecting industry, not the public—the FDA is a purveyor of the psychiatric "disease" and "chemical imbalance" lie. This must change. ■

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The Newest Mania: Seeing Disease Mongering Everywhere

S. Nassir Ghaemi

I feel compelled to comment on your article on bipolar disorder by my friend and colleague David Healy [1]. I respect Dr. Healy both as a historian of psychopharmacology and psychiatry and as a psychopharmacology researcher. I have been impressed by his historical scholarship over the years in bringing out the economic and social aspects of the rise of psychopharmacology. I think his specific critiques about the likely overuse of antidepressants in the West in recent years, as well as the influence of the pharmaceutical industry, have been valid in many respects. I also find the *PLoS Medicine*'s April 2006 series of articles on disease

mongering not unconvincing, especially as it relates to new potential diagnoses like adult attention deficit hyperactivity disorder. Yet I must take exception to the inclusion of bipolar disorder with such newfangled entities.

Mania and melancholia have been well described since antiquity, and the current notions about the diagnosis of bipolar disorder (even the broader notions of the "bipolar spectrum") are fully present in the writings of Esquirol and Kraepelin. It seems highly unlikely that they were markedly influenced by the pharmaceutical industry. To accept the drift of this collection of articles, one would have to suppose that Arataeus of Cappadocia was heavily influenced by pharmaceutical marketing in the 1st century a.d.

Of course, the possibility of overdiagnosis of bipolar disorder exists, often influenced by the pharmaceutical industry, but this in no way means that the diagnosis itself is invalid, nor does it counteract the much larger empirical evidence that bipolar disorder has been highly underdiagnosed (rather than the minimal empirical evidence that it is overdiagnosed) in the antidepressant era [2]. Dr. Healy seems to emphasize the issue in children, where indeed more uncertainty exists, but the overall impression of the article does not do justice to the reality that this illness has a long history of description and much more evidence of nosological validity (based on description, genetics, course, and biological data) [3] than such newcomers as adult attention deficit hyperactivity disorder and restless legs syndrome. Perhaps we should be on the lookout for the newest mania: seeing disease mongering everywhere. ■

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The Best Hysterias: Author's Response to Ghaemi

Nassir Ghaemi has helped raise the profile of this truly debilitating disorder [1], but he is wrong on the history of bipolar disorder. First, mental disease entities are a recent construct. No disease resembling bipolar disorder was described before 1854 in Paris, and the links between folie circulaire described then and modern bipolar disorder are tenuous. Second, for the Greeks, mania referred to any overactive insanity, and melancholia to any underactive state. The majority of manias were probably delirious states. The melancholias may have been anything from Parkinson disease to hypothyroidism. Third, Emil Kraepelin's manic-depressive insanity (1899) was a very different disorder to bipolar disorder, which only arose in the late 1960s. If bipolar disorder can be clearly traced back to the Greeks, the fact that American physicians so rarely made the diagnosis before 1970—when lithium was introduced in the United States—is hard to explain. Kraepelin's likely response to recent proposals that we recognize and distinguish between bipolar 1, 2, 2.5, 3, 3.5, 4, 5, and 6 and bipolar spectrum disorders would probably not be printable.

Disease mongering is not the creation of diseases de novo, as in the restless legs syndrome Dr Ghaemi cites, descriptions of which go back to antiquity. As so aptly defined by David Menkes at the Conference on Disease Mongering in Newcastle in 2006, disease mongering is where the interests of the seller of a nostrum, who sells by emphasizing the existence of and risks of some condition, in fact outweigh the likely benefits from the proposed remedy to those affected by the putative condition. It shades into hucksterism and it was associated with Harley Street long before modern pharmaceutical companies. But companies now bring an industrial efficiency to this practice, and where physicians were once a bulwark of scepticism against any trading on credulousness, they are now the most cost-effective marketing tool companies have.

Mongering applies to conditions from mild elevations of blood pressure or lipids, to bone thinning. No one argues hypertension or hypercholesterolaemia are not real or that in malignant cases these conditions do not constitute valid targets of treatment. But malignant cases are rare. In cases that are not malignant, when the likely intervention is with a toxic compound rather than a proposed alteration of lifestyle, there is or should be a boundary.

Psychiatry was once plagued by "boundary violations", where physicians exploited the dependence of their patients. All the indications are that we are now in a new era of drug-related boundary violations. There is perhaps nowhere in medicine where this is more obvious than in the case of bipolar disorders, with adults treated with bizarre cocktails and children put on some of the most lethal drugs in medicine.

Making it clear that the term "mood stabilizer" is itself an advert and that the notion of bipolar disorder can be viewed as an instance of rebranding does not deny the reality of anything. The key concerns are not reality in this sense, but rather when to treat. As the history of hysteria shows, the best pseudo-convulsions come from patients with convulsive disorders, and the most realistic somatization from patients with other real disorders. Patients conform their presentations to the interests of their doctors. Drug companies know this. Patients deserve physicians alert to such possibilities. In the current welter of bipolar presentations, one worry is that patients with severe manic-depressive disorder will lose out. Another is that research on this most difficult of disorders will be invalidated by a dilution by patients with other problems. A final worry is that when the marketing caravan moves on, manic-depressive illness will be left once more under-resourced, and researchers will have one less lever to pull as they have "had their chance". ■

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1. Ghaemi SN (2006) The newest mania: Seeing disease mongering everywhere. PLoS Med 3(7): e319. DOI: 10.1371/journal.pmed.0030319

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Questionable Advertising of Psychotropic Medications and Disease Mongering

Jeffrey R. Lacasse, Jonathan Leo

David Healy raises intriguing questions regarding the rapid increase in bipolar diagnoses and the use of "mood stabilizing" medications [1]. Although this phenomenon is multifactorial, surely consumer advertising has played a role.

A widely disseminated advertising campaign for aripiprazole (Abilify) claimed that it worked in the brain "like a thermostat to restore balance" [2]. Interestingly, the Abilify product Web sites for schizophrenia and bipolar disorder both used virtually identical explanations to describe both neuropathology and the drug's mechanism of action. Print advertisements promoting aripiprazole for bipolar disorder claimed: "When activity of key brain chemicals is too high, Abilify lowers it....When activity of key brain chemicals is too low, Abilify raises it" [3].

Since the product information insert approved by the United States Food and Drug Administration (FDA) lists the mechanism of action as "unknown" [4], this advertisement is debatable. It is further questionable whether the complexities of treating bipolar disorder (with its unknown etiology and well-known heterogeneity in response to treatment) are accurately portrayed as a reliable, mechanical thermostat. However, consumers are likely to find such advertisements compelling.

Regarding unipolar depression, we recently argued [5] that antidepressant manufacturers commonly advertise their products by claiming that depression is caused by a lack of serotonin and that selective serotonin reuptake inhibitors normalize this deficiency, a claim not congruent with the peer-reviewed literature or FDA-approved product information. We have not received any academic objections to our article, but several prominent psychiatrists have affirmed our conclusions. For instance, Wayne Goodman, Chair of the FDA Psychopharmacological Advisory Committee, admitted that the serotonergic theory of depression is a "useful metaphor"—and one that he never uses within his own psychiatric practice [6].

The presentation of metaphorical explanations as scientific consensus in consumer advertising has not been publicly addressed by the relevant professional associations. In fact, we observe that a cooperative relationship exists between industry and medical facilities, even highly esteemed ones: the Mayo Clinic Web site on depression, sponsored by Wyeth Pharmaceuticals (makers of venlafaxine) explains the treatment of depression via the serotonin metaphor [7].

Such bioreductionistic and highly arguable advertisements for psychiatric treatments imply much about the disorder they are licensed for. As Dr. Healy suggests, consumers who view such advertisements are likely to characterize their problems in a manner congruent with industry promotion and to request well-advertised pharmaceuticals as treatment. At a bare minimum, increased medicalization will result; in some cases, disease mongering may indeed be an appropriate characterization.

Such consumer advertising is only possible in the absence of vigorous government regulation [8] or outcry from professional associations. We hypothesize that their combined silence significantly contributes to the process of disease mongering. ■

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Taiwan's Potential to Assist Developing Countries to Combat Infectious Diseases

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The article on influenza in tropical regions by Viboud and colleagues outlines an alarming global burden of influenza,

with an estimated one million annual deaths worldwide [1]. We would like to give an example of the immense potential of Taiwan to assist developing world communities in fighting against emerging infectious diseases in the near future.

Taiwan (area 36,000 km^2; population 23 million), officially known as the Republic of China, is located on the Tropic of Cancer. Taiwan lost its United Nation membership in 1971 to its rival, the People's Republic of China, but maintains official diplomatic relations with 25 countries and de facto relations with many nations. Taiwan has one of the highest levels of life expectancy in Asia, and it has eradicated infectious diseases such as the bubonic plague in 1948, smallpox in 1955, rabies in 1959, malaria in 1965, and polio in 2000. Taiwan became the first country in the world to implement a hepatitis B immunization program. Taiwan also initiated active vaccination programs against diptheria, pertussis, and tetanus in 1955, Japanese encephalitis in 1969, measles in 1978, hepatitis B in 1984, rubella in 1986, hepatitis A in 1995, and influenza in 1998. Valuable lessons may be learned from Taiwan's experience in public health and its response to disease outbreaks and crises.

Taiwan provides a modern, world-class health-care system to its people [2]. According to Taiwan Department of Health's statistics, the average life expectancy in 1951 was 53.38 years, and it increased to 73.35 years for men and 79.05 years for women in 2003. The Centre for Disease Control in Taiwan was established in 1999 to consolidate disease control resources. When an epidemic of enterovirus took the lives of 78 people in 1998, Taiwan responded by setting up disease surveillance [3].

To fight influenza, Taiwan embarked on a free influenza immunization program aiming to increase the coverage rate to 80% for those above the age of 65. There has been an increase in immunization of the elderly from 59.9% in 2002 to 68.4% in 2003, with medical care providers and disease control staff immunization up to 91.3%. Taiwan is committed to retaining vaccination production capability in the event of an emergency. The government is supporting a plan for the domestic production of influenza vaccines over the next few years as a part of Taiwan's readiness for an avian flu epidemic.

Taiwan is committed to work with the global medical community by contributing its resources and expertise. Unfortunately, it is not a member of the World Health Organization (WHO). It has therefore been excluded from the Global Outbreak Alert and Response Network (GOARN). During the time of the enterovirus outbreak, Taiwan did not get any assistance from the WHO but managed to combat the outbreak. The avian flu scare of 1997 was controlled in Hong Kong because of timely action, aided by the WHO. If Taiwan is to respond effectively to similar outbreaks of global epidemics in the future, it will certainly need the cooperation of the WHO. Although the WHO is a non-political agency, because of pressure from the People's Republic of China, which considers Taiwan as a renegade province, Taiwan has been marginalized. Regardless of this, Taiwan has contributed over US$180 million since 1995 in medical and humanitarian aid to 95 countries, and it plans to make further donations. Therefore, excluding Taiwan from the WHO's GOARN is counterproductive from both medical and ethical standpoints.

Taiwan, through its own efforts, has managed to improve public health remarkably, despite having no assistance from the WHO. It certainly has the potential to assist developing nations in the fight against emerging disease outbreaks, so other countries can seek Taiwan's expertise to fight against infectious diseases in the near future. ■

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