Patients left on the sidelines

Over 5 million Philips respirators and medical ventilators were recalled two years ago. Patients were kept in the dark for several months. They denounce a lack of transparency.

By **ANNE-SOPHIE STAMANE** and **AUDREY VAUGRENTE**

With hindsight, Joël Gilbert still hasn't digested the way Philips, the manufacturer of the machine that helps him fight his sleep apnea every night, handled the device's recall. He was simply not informed of the recall.

transmitted at the time of withdrawal, in June 2021. Neither by the manufacturer nor by the homecare provider acting as intermediary (see box p. 17). However, the alert is serious: the insulating foam used to soundproof the ventilation circuit is disintegrating, and may release com- toxic volatile compounds and fine particles

that end up deep in the lungs. At the time, the word cancer was dropped by Philips.

The photographer, now retired, was only alerted to the problem eight months later... by listening to the radio! "*I breathe with this device for several hours every night. If there's a risk, I expect my supplier, Linde France, to take the trouble to point it out to me!", he* says.

he says. In retrospect, he believes he didn't worry too much about his health, not having noticed any significant symptoms such as irritation or headaches. "*The health risk doesn't worry me. On the other hand, the omerta surrounding this affair terrifies me. Faced with Philips, no one came out in force."*

Yet, as Didier Perrin, treasurer of the Fédération des prestataires de santé à domicile (Fedepsad), points out, this is *"the biggest medical equipment recall in the world"*.

Essentially concerned are continuous positive airway pressure (CPAP) devices such as Joël Gilbert's, prescribed for sleep apnea, as well as ventilators used by people with respiratory insufficiency. In all, 5.3 million devices are affected, including 1.5 million in Europe and 379,000 in France. This is an unprecedented scale... It is incomprehensible that users were not immediately informed.

Fortunately, after a heated exchange of letters, the service provider made amends and delivered a new device to Joël. However, the Doubien resident had no intention of stopping there: he wanted to know if the respirator had caused him any harm, and moved heaven and earth to have it assessed. Neither the patients' or consumers' associations, nor his pneumologist, were able to help him. Wearily, he sends it back to the manufacturer. But he didn't give up completely, and joined the legal action launched by Me Christophe Lèguevaques (see p. 21). It should be noted that Philips has carried out tests - the seriousness of which is open to dispute - to determine the effectiveness of its products.

on devices returned by patients in order to

> It seems that Philips didn't really care about the fate of patients

their real danger.

Joël Gilbert is not the only one to deplore the opaqueness of the Philips respirator scandal, and the ignorance in which patients were kept. Patrick C., whose machine also failed, speaks spontaneously of *"withholding information, whether intentional or not, about a possible risk"*.

major health risk". He found out about it by reading *"an article on the Internet"* in early 2022.

A recall that doesn't say its name

The course of events proves them right. Right from the start of the crisis, the fate of patients seemed to be the least of the Philips management's concerns. "*The alert began on April 26, 2021, with a stock market press release to investors announcing, in the midst of other news, the provisioning of 250 million euros (an amount that has since doubled) to deal with a safety problem"*, recalls Yann Mazens, in charge of the dossier at France Assos Santé (FAS). At this point, it's hard to understand what exactly is going on. The safety notification does not appear on the manufacturer's website until much later.

several weeks later, on June 14, 2021, in the form of a >>>

ILATEURS PHILIPS

have joined forces to create a legal action

are affected by the recall in France

Joël Gilbert

Device user

to combat sleep apnea, he remains shocked by the manufacturer's attitude: *"The omerta surrounding this case terrifies me. Faced with Philips, no one has been a real problem.*

D.CESBRON/REA

>>> press release. The Dutch company is sparing itself an extensive communications campaign, and is clearly counting on-

Philips relies on journalists to do its work for it, and in particular to give instructions to users of the devices concerned. In France, the Agence nationale de sécurité du médicament (ANSM), informed by Philips, reacted a few days later and put the information online. However, in the words of Thierry Thomas, deputy director of the medical devices department in charge of the crisis, the agency today deplores a communication strategy that is *"unsatisfactory"* for the health authorities and *"catastrophic" for* patients. To the best of our knowledge, *Que Choisir* is the only mainstream media outlet to have published a detailed report on the subject, on its Quechoisir.org website.

Because in France, if you want to be sure of reaching patients on respirators, it's imperative to turn to homecare providers - the very people who deliver the machines and are responsible for their maintenance. They are the only ones who know who is using the recalled machines. Yet nothing is done in their direction. *"If you wanted to be notified as a professional, you had to have a solid business intelligence system,"* exclaims Didier Perrin of Fedepsad. In the case of large suppliers with legal departments, the news circulated more quickly. The others were eventually warned by the unions. They are being urged to pass on the ANSM's instructions. The latter insists on the need to continue using the devices. The precise reason for their withdrawal from the market, and the associated risks, are relegated to the background, drowned out by a mass of information of little interest. At best, patients have received an attenuated signal.

When they received it! Because a large number of them were not notified, their service provider having refrained from alerting them, hampered by the impossibility of scheduling machine substi- tution due to lack of stock, and comforted in its posture by the need to keep patients in their homes.

R. MOUILLAUD/LE PROGRES-MAXPPP; PHILIPS

Philips appliances at the heart of the scandal: on the left, the DreamStation ventilator Auto CPAP; on the right, the ventilator Respironics Trilogy 100.

treatment. At the start of the scandal, everything was orchestrated so that the seriousness of the situation completely escaped the main stakeholders, the users.

Philips irresponsible

Even at institutional level, patient associations are not immediately involved in the discussions. The ANSM forgot about them at the first meeting, held on June 17, 2021, attended only by doctors from learned societies and representatives of home healthcare providers. *"Fortunately, we managed to invite ourselves to the second videoconference"*, recalls Christian Trouchot, administrator of the Fédération française des associations et amicales de malades insuffisants respiratoires (FFAAIR). Alas, not much constructive came out of these conclaves.

Philips' flippant attitude leaves its interlocutors with no grip on the course of events. It *was impossible to find out who made this foam, or what it was made of, because of business secrecy,"* complains Christian Trouchot. *Answers were evasive, or non-existent."* Depending on the source, you are obliged to *"return your equipment or, on the contrary, continue to use it"*, he adds, pointing to the inconsistency of the directives issued. The ANSM simply states

CHRONOLOGY

Two years after the announcement of the recall of millions of of ventilators and respirators by Philips, 5% of patients are still waiting for their equipment to be replaced. Only under duress that the manufacturer has agreed to change the machines.

June 18, 2021 Philips is recalling 5.3 million continuous positive airway pressure (CPAP) ventilators worldwide. In France, 379,000 machines are affected.

November 12, 2021 In the United States, an investigation by the authorities reveals that Philips was aware of the problem as early as 2015.

December 14, 2021 5% of units have been replaced. Fan replacement has not yet begun.


DreamStation
Cliquer pour fermer

the Dutch multinational's inability to change machines as promised, but seems powerless to impose a more sustained pace. The context is extremely unfavorable: China is still idling because of covid. And large-scale replacement of respirators worldwide, while meeting the needs of new patients, is seriously complicating matters.

The American health authorities are not fooled, and are taking action. Faced with Philips' lack of transparency, the Food and Drug Administration (FDA) launched an inspection, which ran from August to November 2021. Its final report criticizes the manufacturer, whose methods border on amateurish. Its risk analysis was poorly conducted, and the number of patient reports was underestimated. A 2018 internal document mentions only 17 cases. Yet, according to FDA research, at least 175,000 complaints potentially linked to foam degradation have been received, but not investigated. As for the first corrective actions, they exclude several similar models, which nonetheless suffer from the same defect.

SERVICE SUPPLIER S
A French exception

n France, one user Respirator or ventilator rents equipment, on medical prescription, from a service provider homecare provider, who has purchased devices from manufacturers such as Philips or ResMed. Either a specific model is indicated on the prescription, or the provider chooses one from stock. Once the equipment has been delivered, the provider receives a weekly lump-sum payment from the Assurance Maladie, following a request for prior approval. This organization, which relies on intermediaries, has given a particular twist to the way in which ResMed works.

to the Philips affair here at home. Providers had a major responsibility in informing patients of the recall, and did so in different ways. Left without a replacement solution by Philips, many waited until they could be offered an alternative. That's why some patients learned withdrawal by the press, several months after the alert. Some service providers claim to have bought other brands to meet demand, without being compensated. by the Dutch firm.

What's even more worrying is that the design of the devices does not take into account the state of health of the users. In the event of a problem, normal respiratory function is sufficient to evacuate any particles, according to Philips. This overlooks the fact that some of these machines are intended for people with impaired respiratory function, for example after a tracheotomy.

But what this report reveals above all is that the deterioration of the insulating foam is not a recent problem. As early as 2015, several patients complained to Philips about this malfunction. A year later, a dia-

The diagnosis is even made: the foam has a *"bad"* >>> appearance.

February 9, 2022 Agence nationale de sécurité du médicament (ANSM) forces Philips to replace all machines by the end of the year.

March 10, 2022 In the United States, the FDA orders Philips to inform patients of the device recall.

June 8, 2022 ANSM experts criticize Philips' management of the crisis and point to an error in the identification of substances resulting from foam degradation.

June 20, 2022 In France, an investigation has been opened for endangering the lives ofothers, aggravated deception and administration of harmful substances.

April 5, 2023 Italian court rules against Philips to replace all machines before the end of the month.

April 14, 2023 ANSM puts Philips to replace the machines and took the matter to court.

Philips is a Dutch company, its head office is in Amsterdam.

E. PLEVIER/REUTERS

>>> *resistance to humidity in combination with high temperature"*. Other types of foam are being tested and more resistant alternatives identified. But no changes are ordered. An internal investigation is carried out in 2019. However, there are no plans to correct this design flaw before 2020.

The ANSM is slow to react energetically

The contrast with the French situation is striking. The FDA investigates and contradicts Philips on its communications, while the ANSM is dependent on the manufacturer's actions. It can't even get Philips to talk about withdrawal: it's a *"safety notification"* that concerns France, whereas the Americans call a spade a spade. When the stakeholders (ANSM, patients, service providers, doctors, manufacturers) meet, Philips representatives don't speak French, read texts prepared in advance and demand a delay before answering questions in writing. "*You get the impression that the ANSM is putting users face to face with Philips and counting the blows"*, says Yann Mazens, who attended these meetings.

It wasn't until February 2022 that the ANSM put its foot down. In a health police decision, it ordered Philips to replace all the devices by the end of 2022. This first major action against the company failed. The company contested the timetable and appealed, aware that it could not meet the deadline. Two months later, in April 2022, progress was tenuous indeed: the substitution rate was painfully low at 20%, according to data from a Philips emissary. By summer, only 37% of equipment had been exchanged. The health police measure issued against the manufacturer required 75% to be reached by this date. But, as promised, Philips assures that all patients concerned will receive a new respirator.

Replacing defective units is a laborious task

by the end of 2022, in line with ANSM requirements. At the end of December, the company proudly boasted 98% for machines dedicated to sleep apnea.

Unfortunately, providers report a percentage of 70.7%, well below target. And that's not to mention the "life support" dis- positives, which patients can't do without. Philips has shipped none. Replacements are made from existing stocks. Although the company claims that there is a time lag between dispatch from its warehouses and actual delivery to the user, this explanation doesn't hold water. What's more, the overall figures conceal a less-than-glorious reality: to compensate for Phi- lips' failure, many service providers had to purchase machines from other brands, using their own funds, in order to satisfy a demand for replacements that accelerated after the media coverage of the affair in early 2022.

In the United States, too, Philips is misleading: on its website, it announces the distribution of 2.4 million replacement devices and repair kits... even though the latter are only used internally by the manufacturer to repair defective respirators and ventilators! These figures do not reflect the solutions offered to patients.

Deafening silence

The ANSM is determined not to let this happen again. In June 2022, it convened a Temporary Scientific Committee (CST), made up of patient associations, representatives of healthcare professionals, toxicology experts and independent epider- miologists. At the meeting, attended by Phi-

lips participates by videoconference, CST reveals how >>>

INSULATING FOAM
Toxicity in question

Philips and lung specialists are reassuring us that there is a risk of cancer. But the available research does not allow us to give a definitive ruling.

The failure of insulating foam, composed of polyurethane, in respirators and ventilators
Did Philips put users' health at risk? Patients continued to use the recalled machines, sometimes for several months,
until they are replaced. They therefore legitimately wonder about the long-term effects of this exposure. One thing is certain: Philips' initial risk assessment was flawed. The company began by explaining
that several volatile organic compounds (VOCs) are found in the air breathed in by patients. These include dimethyldiazene (or azomethane), which, when combined with oxygen, transforms into a neurotoxic molecule.
and carcinogen, azoxymethane. However, as of July 2021, Philips points out that this dangerous by-product was not detected during research. In fact, the company misread the results. It wasn't dimethyldiazene that was detected, but acetone. These two substances have a very similar spectrum, and those responsible for the analysis did not question their interpretation. It wasn't until June 2022, before the Temporary Scientific Committee (CST) set up by the French National Agency for the Safety of Medicines (ANSM), that the expert appointed by the latter raised the issue. He subsequently obtained confirmation that the initial diagnosis was indeed false.

THREE UNEQUAL STUDIES

Patients are not reassured, however. In the United States, a testimonial seems to confirm their concerns. Almost at the same time,
the foam manufacturer claims to the American courts that it is not specifically intended for
for sanitary use. So how can you be sure there's no risk?
Philips has conducted its own studies, but none have been made public. A nationwide study might have helped to dispel any doubts, but this is impossible. The basics national data do not mention manufacturers, and provider data are not of good quality. So we have to turn to the few published works on the subject. But they are all flawed,
starting with the lack of distance, which makes it impossible to observe
cases of cancer. "*They didn't show any excess risk. That doesn't mean the risk doesn't exist. But if it does,
it is too small, in relation to the number of people monitored, to be detected*", explains Prof. Renaud Tamisier,
Vice-President of the French Society for Research and Medicine
of sleep (SFRMS). In addition,
The three main studies adopted very different protocols.
One compares all manufacturers, while the others pit Philips against the rest of the market.

The insulating foam used in Philips appliances disintegrates under high temperatures. the effect of humidity and heat.

Faced with such uncertain data, ANSM experts feel that it is not possible to make a decision.

A DOUBT PERSISTANT

"Methodologically, we couldn't see how we could do any better and, above all, we wanted to get it done quickly. answers," retorts Prof. Jesus Gonzalez, President of the Société
de pneumologie de langue française (SPLF). The lung specialists may talk a good game, but they're not convincing patients. Faced with users at a round-table discussion organized at the end of May by
Fédération française des associations et amicales de malades insuffisants respiratoires (FFAAIR - French federation of associations and friends of patients with respiratory insufficiencies), the practitioner has noted this mistrust. "*Doubt has set in, and I think it's here to stay*", he says. A number of respirator users spoke out, expressing their fears, particularly with regard to other manufacturers. On this point, the work available does not allow us to be sure.
to make a decision: they simply compared the risk between appliances of different brands, but never
in the face of untreated people. ◆

>>> The firm's management of the file is hazardous. Relevance of studies, lack of transparency, nature of the measurements, knowledge of the material used... the many grey areas maintained by the manufacturer are highlighted. A lunar scene leaves a lasting impression on the participants. Najet Yagoubi, professor of physics and chemistry at the univer-

sité Paris-Saclay, asks the Philips representative if the defective foam was intended for medical use. An interminable silence reigned in the room... so much so that Thierry Thomas, from ANSM, who was in charge of the exchanges, thought the internet connection had been cut off. Rephrased, the question remains unanswered. Only the American justice system has shed light on this point (see p. 19). In the light of these debates, and the written justifications that followed, the toxicology experts concluded that there was insufficient evidence: the safety of the foam had not been proven.

While the ANSM and patient associations were incivious, the learned societies adopted a much calmer tone. In September 2022, several of them even called for the alert to be lifted, as the risk of cancer seemed to have been ruled out. Their position was clear: the dan- ger caused by stopping treatment outweighed any possible peril much later. Professor Renaud Tamisier, Vice-President of the French Sleep Research and Medicine Society (SFRMS), explains to his patients that

"*Over several years of exposure, six more months probably won't have much more influence. Much has been said about the risk of cancer, but the cardiovascular risk associated with the absence of treatment is much greater*".

The grey areas maintained by the manufacturer have been highlighted

Questionable links of interest

No one disputes the fact that interrupting treatment carries risks. However, to prevent patients from making this choice, some decide not to tell them everything. In a fine example of medical paternalism, the website of the Société de pneumologie de langue française (SPLF) reproduces information from the ANSM, but without mentioning the risk of cancer. Its president, Pr Jesus Gonzalez, refers to a risk *"which we no longer believe in",* and asks us to turn the page. In the face of this highly assertive discourse, some patients are questioning the financial links between Philips and these professionals.

In fact, over the past five years, several specialists approached by the ANSM have received money from the manufacturer. Philips has paid €4,060 to Pr Frédéric Gagnadoux, who is conducting the only French study on the subject, in 2019 and 2020. The pulmonologist also took part in a webinar organized by the brand in June 2020. The SPLF, for its part, received €85,300 in 2018 and 2019. As for Jesus Gonzalez, he tells us that he trained physiotherapists on behalf of Philips between 2005 and 2015. He fails to mention, however, that the manufacturer granted him €2,570 in 2018.

These links of interest are not insignificant. Whether consciously or unconsciously, these stakeholders use Philips' language: users' maintenance of respirators is said to have encouraged the destruction of foam; its main competitor is said to be fuelling the crisis... As a result, patients are misinformed. "*According to this*

I've heard that the material in question deteriorates especially when cleaned with ozone", says one patient. In reality, it's not the ozone that's to blame. It's the hot, humid environment in which the foam is kept that poses the problem, and the FDA, the American health authority, points this out in a letter sent to Philips as early as May 2022.

Is doubt being deliberately maintained? In any case, patients talk about their difficulties in trusting Philips, other manufacturers and medical specialists. As if to prove them right, refurbished products are themselves the subject of recall campaigns. In January, the manufacturer announced that the replacement foam on the Trilogy 100 and 200 fans had come loose and was in danger of blocking the air intake. At the end of May, it was the Trilogy EV300 and Evo O2 fans that malfunctioned. Normally used in hospitals, they were made available to service providers on an exceptional basis. And in early June, three models used in hospitals or at home were recalled due to a filter problem. This series of recalls within a recall leaves the unpleasant impression that in two years,

Philips has learned nothing from this crisis. ◆

JUSTICE

Victims go on the attack

Following the worldwide recall of Philips respirators and ventilators, victims and a patient association have put together their case to take the Dutch firm to court, and are gearing up for a long legal battle.

The first victory was won on January 19 by the Fédération française des associations et amicales de malades insuffisants respiratoires (FFAAIR), whose members are undoubtedly the most affected by the Philips affair. The association called for the company provides internal documents on the release of volatile organic compounds (VOCs) and sound-absorbing foam particles during operation respirators. She won cause. However, the judge rejected his request for information on the exact composition of the foam.

TWO LEGAL ASPECTS

On the patient side, two main fronts - civil and criminal - are currently open. In both cases, it's a question of an action the "joint" approach, i.e. the victims bring together their files on an Internet platform. In return for a flat fee, they are defended by a common lawyer, Christophe Lèguevaques. He prefers to proceed in this way, rather than by through a group action, as its current procedures seem ill-suited to a rapid outcome.

The existence of this initiative does not, of course, prevent patients from acting outside this framework. And to initiate with their own lawyer. In civil cases, the aim is to obtain recognition of *"the prejudice moral anxiety resulting from a lack of information, and to obtain compensation for each victim,"* explains lawyer Christophe Lèguevaques.

Here he is playing a card that he had already successfully played in the Levothyrox case, where the The Merck laboratory was heavily penalized. Criminal charges have been brought against Philips on three counts: deception, endangering the life of others and administering a harmful substance.

Logically, the Public Health Division of the Paris Judicial Court followed suit and opened a preliminary investigation in June 2022, a year after Philips first sounded the alarm. If a trial is to take place, it will be necessary, as is often the case in health-related cases of this type, to establish a link between the two.

Maître Christophe Lèguevaques is defending the patients who have decided to take Philips to court.

causality between the treatment - in this case, the use of a damaged breathing aid - and a physical injury: cancer, irritation, breathing difficulties, etc., at people already suffering from serious health problems. In the absence of pathology characteristic of exposure to the substance in question, it is likely to be difficult to succeed. The deception charge raises hopes more results. It's enough to have used the faulty equipment, and to have been exposed. Bodily injury is not required to constitute the offence.

ANSM ALSO SUES THE FIRM

The French National Agency for the Safety of Medicines (ANSM) has also taken legal action. Invoking article 40 of the French Penal Code, the health authority referred the matter to the public prosecutor, on the grounds that Philips had failed to comply with the decision. obliging him to replace all machines affected by the notification before December 31, 2022. In the same vein, in Italy, a judgment required the manufacturer to take back and exchange all incriminated equipment by April 30, 2023, failing which a fine of €20,000 per day of delay. It must be said that 70,000 of the 100,000 transalpine respirator owners remained no news from Philips... Delays in repairing faulty equipment was even greater than in our own country. ◆