Gilead has paid $178 million to doctors to promote drugs despite patient deaths

By **Dilyana Gaytandzhieva** - October 14, 2020

According to sealed court documents, Gilead has been under investigation for illegally funneling kickbacks to health care providers in the US to boost sales.

American pharmaceutical giant Gilead has paid at least $178 million to doctors and $81 million to hospitals in the US to promote and prescribe the company's drugs despite cases of deaths and severe side effects. The drug-maker funded as many as 21,833 physicians in 2019 alone, according to data about Gilead payments from 2013 to 2019.

Arms Watch has already revealed that at least 249 patients enrolled in the Gilead $3.3 billion Hepatitis C elimination project in Georgia have died, according to leaked documents. The cause of death of some patients has been reported as "unknown" in Gilead confidential reports. Other patients enrolled in the program have discontinued treatment due to serious adverse events. Some of them have died.

GILEAD	Solicited Program Reconciliation Report Form	GF-21045E (6.0)

15		Sovaldi	Death	28.04.2016	
16		Sovaldi	Death	28.04.2016	
17		Sovaldi	Death	28.04.2016	
18		Sovaldi	Death	28.04.2016	
19		Sovaldi	Death	28.04.2016	
20		Sovaldi	Death	28.04.2016	
21		Sovaldi	Death	28.04.2016	
22		Sovaldi	Death	28.04.2016	
23		Sovaldi	Death	28.04.2016	
24		Sovaldi	Death	28.04.2016	
25		Sovaldi	Death	28.04.2016	
26		Sovaldi	Death	28.04.2016	
27		Sovaldi	Death	28.04.2016	
27		Sovaldi	Death	28.04.2016	
29		Sovaldi	Death	28.04.2016	
30		Sovaldi	Death	28.04.2016	
31		Sovaldi	Death	28.04.2016	

Total number of reports:	32

CONFIDENTIAL INFORMATION
Gilead Sciences, Inc. • Foster City, CA 94404

Confidential reports reveal that at least 249 patients enrolled in a Gilead-sponsored program have died in Georgia.

GILEAD	Solicited Program Adverse Event/Special Situation Report Form	GF-21045H.03

Please complete as many details as possible and forward within one business day to:

Program Details

Name of Program: *HCV Elimination Project*	Form Completed By
Name of Organisation: *Ministry of Labour, Health and Social Affairs of Georgia*	Print Name: Giorgi Khatelishvili
Date aware of Safety Information: 30.12.15	Signature:
Country of Occurrence of Safety Information *Georgia*	Telephone Number: +995598708807
	Fax No/Email: Gkhatelishvili@moh.gov.ge

Patient Details

Age:	Initials:	Sex: Male ☐ Female ☐	DOB: (or year of birth):

Drug Details (Provide additional drugs on a separate page)

Drug Name	Dose	Route	Start Date (DD/MON/YYYY)	Stop Date (or On-going) (DD/MON/YYYY)	Reason For Taking	Lot/Batch No
Sovaldi	400mg	PO	28-05-15	25-11-15	Chronic Hep C	SFMTD
Ribavirin	200mg	PO	28-05-15	25-11-15	Chronic Hep C	SFMTD

Safety Information Details: Please provide a short summary of the adverse event(s) (AE) or other safety information (e.g. reports such as pregnancy, death, hospitalization, overdose, misuse, abuse, medication error, lack of effect, off-label use, occupational exposure, AEs associated with product complaints or AEs in an infant following exposure from breastfeeding). Please include the start and stop dates and the outcome of the event(s) or confirm if the event(s) is/are still ongoing. Please also provide any treatment given to treat the event(s), any relevant medical history and for reports of death include the date of death – continue on another page if necessary.

Death reason Unknown

Does the Reporter consider that the event(s) were possibly related to the drug? Yes ☐ No ☒	Has this safety information previously been reported to a Regulatory Authority? Yes ☐ No ☒

Reporter Details (i.e. who notified you of the above safety information?)

Is the Reporter a: Doctor ☐ Nurse ☐ Pharmacist ☐ Non-healthcare professional (e.g. patient, relative)* ☐

If the Reporter is a Healthcare Professional (HCP) and they are willing to provide us with their contact information, please record below

**If the Reporter is a Non-healthcare professional, please confirm if they are willing to provide contact information for their HCP:*

Yes ☐ (Please record HCP details below) No ☐

HCP Name:	**HCP Address**
HCP Telephone No/FAX No:	First Line:
HCP Email:	Town/City:
	County/State:
	Postcode/Zip code:

Please be aware that information provided to Gilead relating to you, may be used to comply with applicable laws and regulations. By providing us with information you are consenting to the control and processing of this personal or sensitive data by Gilead in accordance with applicable data protection laws and the Gilead privacy policy, available to you either on www.gilead.com/privacy or upon request.

GILEAD	Solicited Program Adverse Event/Special Situation Report Form	GF-21045H.03

Please complete as many details as possible and forward within one business day to:

Program Details

Name of Program: *HCV Elimination Project*	Form Completed By
Name of Organisation: *Ministry of Labour, Health and Social Affairs of Georgia*	Print Name: Giorgi Khatelishvili
Date aware of Safety Information: 26.02.2016	Signature:
Country of Occurrence of Safety Information *Georgia*	Telephone Number: +995598708807
	Fax No/Email: Gkhatelishvili@moh.gov.ge

Patient Details

Age: 73 **Initials:** GC **Sex:** Male ☒ Female ☐ **DOB:** 09.09 (or year of birth): 1942

Drug Details (Provide additional drugs on a separate page)

Drug Name	Dose	Route	Start Date (DD/MON/YYYY)	Stop Date (or On-going) (DD/MON/YYYY)	Reason For Taking	Lot/Batch No
Sovaldi	400mg	PO	12.11.2015	03.02.2016	Chronic Hepatitis C	TPM VD
Ribavirin	200mg	PO	12.11.2015	03.02.2016	Chronic Hepatitis C	

Safety Information Details: Please provide a short summary of the adverse event(s) (AE) or other safety information (e.g. reports such as pregnancy, death, hospitalization, overdose, misuse, abuse, medication error, lack of effect, off-label use, occupational exposure, AEs associated with product complaints or AEs in an infant following exposure from breastfeeding). Please include the start and stop dates and the outcome of the event(s) or confirm if the event(s) is/are still ongoing. Please also provide any treatment given to treat the event(s), any relevant medical history and for reports of death include the date of death – continue on another page if necessary.

Death reason is unknown, was found dead in apartment

Does the Reporter consider that the event(s) were possibly related to the drug? Yes ☐ No ☒	Has this safety information previously been reported to a Regulatory Authority? Yes ☐ No ☒

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Name of Organisation: *Ministry of Labour, Health and Social Affairs of Georgia*	Print Name: Giorgi Khatelishvili
Date aware of Safety Information: 26.02.2016	Signature:
Country of Occurrence of Safety Information *Georgia*	Telephone Number: +995598708807
	Fax No/Email: Gkhatelishvili@moh.gov.ge

Patient Details

Age: 51 **Initials:** CK **Sex:** Male ☒ Female ☐ **DOB:** 02.07 (or year of birth): 1964

Drug Details (Provide additional drugs on a separate page)

Drug Name	Dose	Route	Start Date (DD/MON/YYYY)	Stop Date (or On-going) (DD/MON/YYYY)	Reason For Taking	Lot/Batch No
Sovaldi	400mg	PO	25.08.2015	19.01.2016	Chronic Hepatitis C	SFMTC
Ribavirin	200mg	PO	25.08.2015	19.01.2016	Chronic Hepatitis C	

Safety Information Details: Please provide a short summary of the adverse event(s) (AE) or other safety information (e.g. reports such as pregnancy, death, hospitalization, overdose, misuse, abuse, medication error, lack of effect, off-label use, occupational exposure, AEs associated with product complaints or AEs in an infant following exposure from breastfeeding). Please include the start and stop dates and the outcome of the event(s) or confirm if the event(s) is/are still ongoing. Please also provide any treatment given to treat the event(s), any relevant medical history and for reports of death include the date of death – continue on another page if necessary.

Discontinued the treatment due to encephalopathy and refractory ascites further died the cause of death is unknown

Does the Reporter consider that the event(s) were possibly related to the drug? Yes ☐ No ☒	Has this safety information previously been reported to a Regulatory Authority? Yes ☐ No ☒

Reporter Details (i.e. who notified you of the above safety information?)

Is the Reporter a: Doctor ☐ Nurse ☐ Pharmacist ☐ Non-healthcare professional (e.g. patient, relative)* ☐

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GILEAD	Solicited Program Adverse Event/Special Situation Report Form	GF-21045H (5.0)

Please complete as many details as possible and forward within one business day to:
Safety_FC@gilead.com

Program Details — MR ☐ PAP ☐ PSP ☐ Other ☒ - Specify :

Name of Program and Number: HCV Elimination Project	Form Completed By:
Name of Organisation: Ministry of Labour, Health and Social Affairs of the Republic of Georgia	Print Name: Giorgi Khatelishvili
Date aware of Safety Information: 26-Aug-2016	Signature:
Country of Occurrence of Safety Information Georgia	Telephone Number: +995 598 708807
Respondent reference number / case reference number:	Fax No./Email: gkhatelishvili@moh.gov.ge

Patient Details

Age: 51	**Initials:** IA	**Sex:** Male ☒ Female ☐	**DOB:** 28-11 (or year of birth): 1964

Drug Details (Provide additional drugs on a separate page)

Drug Name	Dose	Route	Start Date (DD/MON/YYYY)	Stop Date (or On-going) (DD/MON/YYYY)	Reason For Taking	Lot/Batch No.
Sof/Led	400mg/ 90mg	PO	11-04-16	12-08-16	Chronic Hep C	WBGT
Ribavirin	200mg	PO	11-04-16	12-08-16	Chronic Hep C	

Details of the Adverse Event/Safety Information: Please provide a short summary of the adverse event(s) (AE) or other safety information (e.g., reports such as pregnancy, death, hospitalization, overdose, misuse, abuse, medication error, lack of effect, off-label use, occupational exposure, AEs associated with product complaints or AEs in an infant following exposure from breastfeeding). Please include the start and stop dates and the outcome of the event(s) or confirm if the event(s) is/are still ongoing. Please also provide any treatment given to treat the event(s), any relevant medical history and for reports of death include the date of death – continue on another page if necessary.

Death reason Unknown

Does the Reporter consider that the event(s) were possibly related to the drug? Yes ☐ No ☒ Unknown ☐	Has this safety information previously been reported to a Regulatory Authority? Yes ☐ No ☒

Reporter Details (i.e. who notified you of the safety information? (For market research this is the respondent)

Is the Reporter a: Doctor ☒ Nurse ☐ Pharmacist ☐ Non-healthcare professional (e.g., patient, relative)* ☐

If the Reporter is a Healthcare Professional (HCP) please confirm if willing to provide contact information:
Yes ☐ (Please record HCP details below) No ☐ (HCP does not want to be contacted)

**If the Reporter is a Non-healthcare professional, please confirm if they are willing to provide contact information for their HCP:*
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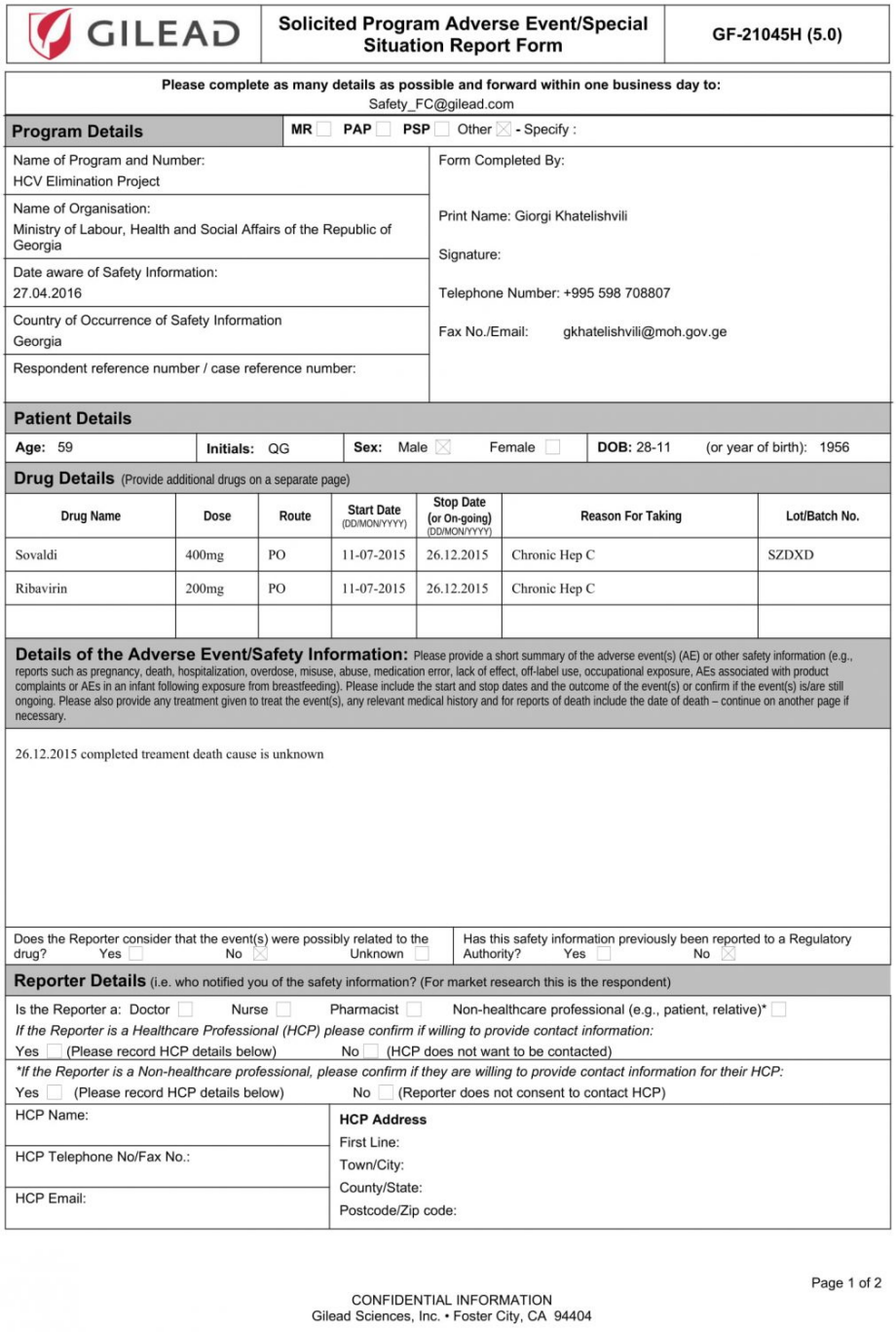
HCP Name:	**HCP Address** First Line:
HCP Telephone No/Fax No.:	Town/City:
HCP Email:	County/State: Postcode/Zip code:



GILEAD

Solicited Program Adverse Event/Special Situation Report Form | **GF-21045H (5.0)**

Please complete as many details as possible and forward within one business day to:
Safety_FC@gilead.com

Program Details — MR ☐ PAP ☐ PSP ☐ Other ☒ - Specify :

Name of Program and Number: HCV Elimination Project	Form Completed By:
Name of Organisation: Ministry of Labour, Health and Social Affairs of the Republic of Georgia	Print Name: Giorgi Khatelishvili
Date aware of Safety Information: 27.04.2016	Signature:
Country of Occurrence of Safety Information Georgia	Telephone Number: +995 598 708807
Respondent reference number / case reference number:	Fax No./Email: gkhatelishvili@moh.gov.ge

Patient Details

Age: 59 | **Initials:** QG | **Sex:** Male ☒ Female ☐ | **DOB:** 28-11 (or year of birth): 1956

Drug Details (Provide additional drugs on a separate page)

Drug Name	Dose	Route	Start Date (DD/MON/YYYY)	Stop Date (or On-going) (DD/MON/YYYY)	Reason For Taking	Lot/Batch No.
Sovaldi	400mg	PO	11-07-2015	26.12.2015	Chronic Hep C	SZDXD
Ribavirin	200mg	PO	11-07-2015	26.12.2015	Chronic Hep C	

Details of the Adverse Event/Safety Information: Please provide a short summary of the adverse event(s) (AE) or other safety information (e.g., reports such as pregnancy, death, hospitalization, overdose, misuse, abuse, medication error, lack of effect, off-label use, occupational exposure, AEs associated with product complaints or AEs in an infant following exposure from breastfeeding). Please include the start and stop dates and the outcome of the event(s) or confirm if the event(s) is/are still ongoing. Please also provide any treatment given to treat the event(s), any relevant medical history and for reports of death include the date of death – continue on another page if necessary.

26.12.2015 completed treament death cause is unknown

Does the Reporter consider that the event(s) were possibly related to the drug? Yes ☐ No ☒ Unknown ☐

Has this safety information previously been reported to a Regulatory Authority? Yes ☐ No ☒

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Page 1 of 2

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Deaths of patients in treatment with the Gilead hepatitis C antiviral Harvoni have been reported in the US, Canada, and Portugal, according to data obtained from the US Federal Drug Administration (FDA).

Despite the severe side effects from these Gilead hepatitis C antivirals the pharmaceutical company has listed none of them so that patients can make their informed decision.

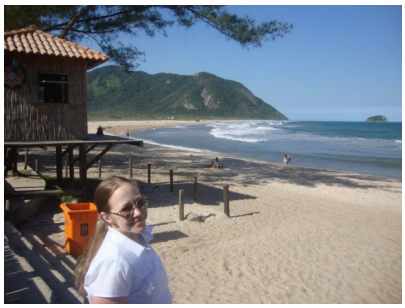
Instead, Gilead has paid kickbacks to doctors to prescribe these drugs without

patients being informed about the possible risks.

According to sealed court documents, Gilead has been under investigation for illegally funneling kickbacks to health care providers in the US to boost sales.

Arms Watch has received e-mails from patients who have suffered serious side effects while in treatment with the Gilead hepatitis C antiviral Harvoni. Below are their testimonies. Some of the patients have died. We have the permission of their relatives to publish their stories.

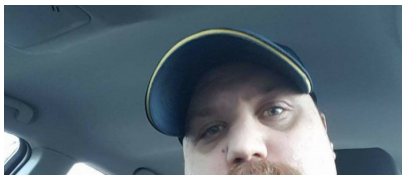
My wife died because of Hep C medicine (poison) called Harvoni: Ricardo Cunha



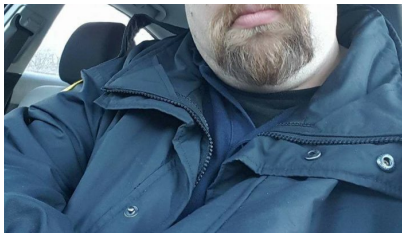
Beverly Cunha

My wife died because of Hep C medicine (poison) called Harvoni. The pharmaceutical Gilead is denying that their medicine caused her death. They are only interested in the dollars they are making from a +1000 dollar pill. My wife was prescribed 85 pills (93000 dollars). These people are killing and destroying families with their greed for profits. Be careful with GILEAD medication. Causes liver and kidney failure. Weakened bones, memory fog, nausea, diarrhea, teeth and hair loss, hearing impairment, heart problems, and much more. They have new medicine for people with HIV called Biktarvy, and for HIV prevention called Descovy, and a new medicine for Hep C called Epclusa, which also kills. I know many people who tell me that the Harvoni took ten years out of their lives. The other 3 medications are now coming out with similar warnings about liver and kidney problems. Doctors told my wife she was cured after 60 days of taking Harvoni, and again three days after finishing the last pill. The commercial on TV says they cure 96 to 99 percent of people. Kind of misleading, because most people don't expect to pass away after being cured.

Many people who had taken the miracle Hep C drug were getting very aggressive cancers: Tami Aliani



My son is thirty five, had just gotten married in 2013, he has a beautiful fourteen year old son of his own, has a job he loves, he was a



William B O'Sullivan

guard at a juvenile correctional facility and absolutely loved working with the boys there.

He went to a blood drive for his job and a few weeks later got a letter in the mail telling him that he had tested positive for Hep C. He was in shock and couldn't understand how he would have gotten it. He did have a lot of tattoos so we thought he had probably gotten it from that. He wasn't a drug user so we

thought that had to be it. He went to a doctor and they did tests on him and found that he had stage 3 liver cirrhosis. That meant that he had had Hep C for many years. It takes a very long time for Hep C to destroy your liver. That is when we realized that he had to have gotten it from one of the many blood transfusions he had had as a baby. They didn't check blood for Hep C before 1990 and he was born in 1981.

His doctor reassured him that he would be ok. They had a new medicine now that had a cure rate of 98% and once he got rid of the virus, his liver would repair itself. He was so relieved!

He couldn't wait to start taking this medication. He and most people who have Hep C feel dirty and just want to get it out of their bodies. The treatment cost $93,000.00. His insurance paid for it and he was able to finish the treatment. He was supposed to be on it for 24 weeks seeing as he had cirrhosis, but he

only approved for 12 weeks. Even so, after the treatment, he was declared "cured" the Hep C was undetectable. One month after treatment, he had a scan, (the same scan he had before treatment) and everything looked great. There was no sign of cancer, or anything abnormal. He was supposed to go back for another final scan six months later but his insurance denied him. He wasn't that worried about it because he actually felt great. He said he never felt better.

Fast forward to almost two years later. He started having pain in the side of his stomach on the right side just under his ribs. He went to the doctor and they did some blood work and discovered that his cancer markers were high. They did a scan and told him that he had liver bile duct cancer. This is a cancer that

is usually only seen in very old people. He was devastated as we all were.

My son was getting sicker and sicker. His liver was starting to fail. He was turning yellow and his stomach was so bloated. He went to have some test done to get him ready for the chemo and they discovered that he had fluid in his abdomen. They had to put him on a vent so they could put him to sleep to

drain it. The drained almost 3 liters of fluid from his abdomen. They did another scan and found that the cancer had spread from his liver, to his spine, to his lymph nodes, lungs and bones. All of this in less than a month. His oncologist said he had never seen a cancer spread this fast. They admitted my son to the hospital and while he was there we discovered that many people who had taken the miracle Hep C drug, were getting very aggressive cancers. They all had only one thing in common. They all took Harvoni. My son passed July 17th 2017.

I am dying: Analidio Marreiros

My name is Analidio Marreiros I'm from Portugal, 48 years old. Before treatment I was working in U. S. I came to Portugal to do the hep c treatment, which was a mistake!

Analidio Marreiros before the treatment

After the treatment

I had hepatitis c since 2001,never got symptoms, I did surf and spearfishing all my life, I was happy until 2018,i did the tests to approve the treatment, blood tests, scan etc, my fibrosis was a F0 it was nothing, like I said, no symptoms, start the treatment in the beginning of April 2018,after 5 weeks I started to get sick, bad digestion, stomach pain, confusion, blurry vision and some small problems at the time, my treatment supposed to be 12 weeks, after 5 weeks I went to the hospital to speak with my doctor, I ask him if I can stopped the treatment because that's not normal, I felt like I gonna die at the time, she said, no, because it's my mind and Harvoni don't give that kind of symptoms, so in the next days the things started to b worst, every days in the next two months I call to the doctor to do something, after I implore a lot the

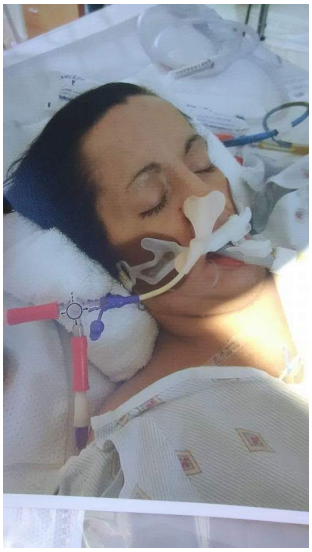
doctor make me some blood tests, and some x-rays, they make me a cobia, I did in the last two years 12 topographies and maybe 45 x-rays, I was full of radiation, but everything was OK, she told me that it is better if I go to psychiatry, I was incredible with that, but I went to there, the doctor said I have a depression and give some pills, of course I threw that away, because I just know I'm not crazy! After 12 weeks the result just come out, and no more virus, but I'm more sick than before! I struggling to right this email, in this last to months, my organs are failing , believe me, I'm almost dead and I know I'm going to die very soon, and I wish this letter would help others.

I can't think, almost blind, head hakes, confusion, chronic pancreatitis, tomorrow I'm going to do more tests because a private doctor said to me maybe I have a kidneys failure also, I can't walk even 20 meters, can't carry a bag of carrots or potatoes, I can't even help my wife washing the dishes. I don't throw out the toxins. I am constipated all the time. I can't describe how horrible I feel. The doctors don't accept me as a patient because they think this is my mind, but is not, the blood tests are alternated in everything, all the time I do a scan, came out, with fatty liver, pancreatitis, heart arrhythmia, but they don't care! I know I am dying and I hope this letter can help you to process Gilead, because they just think about money, and destroy people's life. I hope also other people who need treatment to think about, if they want to live with hepatitis for more years or they want to die soon with the treatment. I want to get my life back, I want be normal again.

I was in coma for 20 days: Charity Cnyder

I was placed onto medication that I can prove I did not need. The medication was a trial based treatment and was the equivalent of chemotherapy without radiation. The standard treatment course was 3 months at a cost of 90k and patients only qualified if meeting a strict list of requirements. I did not qualify and was placed on a doubled treatment course at 6 months.

The medication was intense and I had a noted immune deficiency and a enlarged spleen. The medication was to be taken at the same time everyday and at the same time. Another requirement was that the entire course had to be taken like an antibiotic course. This of course would devastate my weakened system. Midway through the course, my immune system failed and my lung collapsed. Shortly later I went into respiratory and organ failure and was induced into a 20 day long coma. I was a ward to the state during my coma and still do not have the details of this despite my attempted inquiries.



Charity Cnyder in comma while in treatment with Harvoni

I was cured of my misdiagnosis 21 days after discharge which goes against the medication or treatment protocol considering I was told to finish the course despite the coma being induced by the medication in the first place. I was then basically dumped by my doctors and did one more trip back to WA (my 7th). I had suffered my second stroke during the coma and had to learn to walk and write again.

I was later diagnosed with Metabolic encephalopathy which is a neurology disorder. I was never given a discharge plan or referred to see following neurologist considering the coma and cognitive damage. I spent more than a year unable to do much or think clearly and to this day I have a lot of memory loss of that period.

In 2018 I began to look into a coma and its meaning. Until recently I have been able to attempt to pursue the issue of malpractice, negligence and medicaid fraud. I presently have yet to receive my documentation from that time period and have requested the information numerous times.

I also noted that during the 20 days in a coma I was not supposed to miss a dose of the medication according to the doctors. Therefore if it could not be crushed and I was on a ventilator for the entire duration, how did the doctors give me the pill that ultimately caused the coma?

Just recently the manufacturer for the medication trial treatment / Harvoni) was called into class action lawsuit. The reason being that there was no black label warning on the medication at the time and the medication could cause

long term effects including coma and death. At the time of the trial there was no anecdote if a person was to overdose.

I know that the doctors are covering themselves by hiding the coma. I would like to know how Medicaid was convinced by a doctor who had only seen me once that I was approved to face what I see as attempted murder. I also know that the doctors involved made a good amount off of my case and I in turn lost everything. I am suffering greatly with no support. I need help or I feel I will be a statistic to the killing fields with the medical system and its false approach in saving lives.

I'd rather die than be killed: Cathy Dreifort

I have reported to Gilead Sciences that I have 20% lung function loss after taking a 12 week treatment of Harvoni. I also may have heart damage as a result of this drug but I am still waiting on reports. I am also experiencing ringing in the ears and dizziness. A true decrease in quality of life for me after taking this drug. I know I am not the only one that is experiencing these side effects and not sure how many have reported this.

When will the FDA report these issues so that people can make an informed decision about taking this drug? I am aware of deaths of more than one person who has taken Harvoni, yet even that has not been reporting. I thought the FDA was here to protect us. And now Gilead is advertising how great their product is when there are a myriad of side effects that they are not listing.

Even though I have Hep C (not informed if it is cured or not) my life was healthy and I was active. Now am not. I wish I had never taken the drug and plan to never take another. I'd rather die than be killed.

Harvoni damaged my life: Julie Kelly

I have a list of things that happened to me from taking the medicine for 2 weeks. I told my doctor I had to get off it or I would die. During the medication I had tetonic seizures and was in the emergency room 4 times , some of my blood test came back slightly abnormal – biliruben high, chloride high, bicarbonate high, potassium low, blood pressure 190 over 92, blood gas high, but they got no definitive answer as to why I had become so very sick.

These are the lasting things it has left me with sleep apnea, anxiety increased by at least 60% panic attacks which I've never had before, burning skin especially my arms and face feel like they are boiling (comes and goes), difficulty breathing (getting a normal rhythm)- (comes and goes). I had normal blood pressure before Harvoni now it goes up not just a few points but from 120 to 170 in a matter of minuets, stomach pain after eating, weight gain (40 pounds in 1 year), rash on my chest (usually comes when the burning is happening), brain fog – comes and goes but is generalized to being duller than I was, less memory as well.

I was an avid work out person pre harvoni (I never imagined a day would go by that I would not be on the stair climber or jogging, my work outs are limited to only walking now, I can no longer run , jump on my trampoline or do anything very aerobic (causes my blood pressure to go very high and my breathing to go off rythem. making me gasp for air and it continues through the day

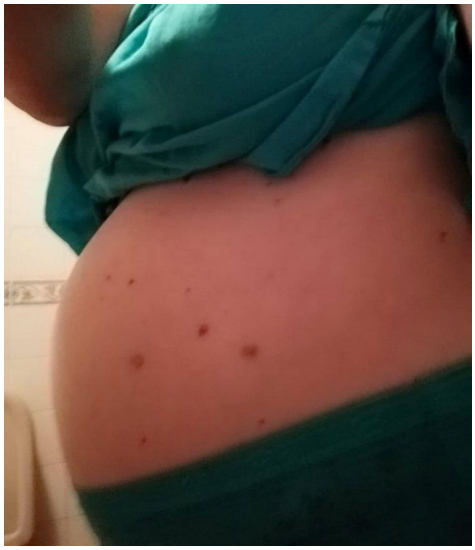
To this day I have no answers to what Harvoni did to me but it's damaged my life significantly. I would like Harvoni to pay for what they have done to me.

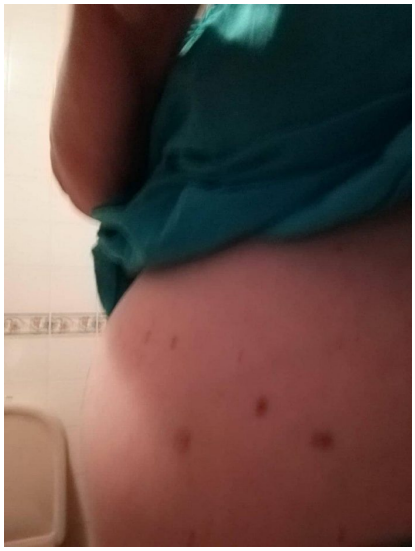
I lived a clean life and the hep C was mild with me, I had no idea I even had it. I didn't drink nor smoke for 40 years, ate organic (vegetarian), worked out every day and was at the peak of health weighing 120 when this all began – now my lifestyle is over.

All my body aches: S.M.*

Severe nausea, constipation and after a few months severe black diarrhea that lasted around 1 year, the pain began in my shoulders and came down to my arms, hands, legs and feet (all my internal organs ache), tinnitus, severe insomnia, neuropathy, muscle and nerve pain, bad leg cramps at night, chronic fatigue (severe), respiratory problems, vision problems, for 3 years I only ate salt cookies and tea, my liver is very swollen, my feet and body are deformed (swollen). I gained 20 kg after 3 years, no doctor knows the reason.

**This patient asked us not to disclose her identity for personal reasons.*





The swollen abdomen of the patient after being treated with Harvoni

I ended up with serious lifetime debilitating side effects: Emma Imperato

I am one of thousands of people that took Harvoni. It was Sept 2015. I had a blood transfusion in 1983 at Yale New Haven Hospital, was given 6pts blood from a ruptured ectopic pregnancy. I found out I had it when I was hired at Yale as a secretary it was called non A non B I was followed by doctors for years with no liver issues and a low viral load 1.2 million stayed the same for 32 years. My blood work was good. Normal liver functions slightly elevated in 2015, and no cirrhosis. My doctor felt that I should treat so I didn't get liver cancer or have problems later. I was reluctant as I didn't want side effects like people had from interferon and Ribavarin.

I ended up with serious lifetime debilitating side effects. I was sick through the 12 weeks treatment, she said headache and fatigue and nausea. I had sores in my mouth, vomiting, diarrhea, wicked migranes, burning hands and feet and numbness in my extremities, rash on palms of hands, feet and body clogged up head and ringing in my ears with all these side effects she said they will go away the further you get into treatment, they didn't. She also treated me for 12 weeks rather than 8 my viral load was low and it was gone in 2 weeks and when I asked her if I could stop she said no as the virus would come back if I didn't finish the 12 weeks, it never came back the sad part is that she had to submit my blood work to get the last bottle to Gilead and they saw my blood work and the viral load gone at 2 weeks and still filled it. I had serious brain fog, was getting lost and couldn't find my car and major confusion and I still do. My feet are still numb and painful. I missed the

bottom stair 1 month after treatment fell fractured my L1 couldn't feel my feet. I have spent the last four years of my life miserable with every side effect still with me.

I have hearing loss, severe tinnitus, 24/7 I have blurry eyesight, severe neuropathy feet calves hands forearms and it is spreading, still have rashes and red palms and soles of my feet,muscle problems brain fog, that never went away, blood abnormalties,none of these issues before Harvoni I have had multiple CT scans MRI's, spinal tap, excessive blood draws have seen so many doctors, this has been my last 4 years of my life my, aniexity never went away since treatment. My life is ruined I would have been one of those people that had issues and should have just been followed not treated. She scared me into thinking if I didn't take treatment I would die or get cancer and every side effects I had she said oh I never heard that side effect before my blood work went crazy on treatment and then she didn't know what to do with me after treatment so she turned me over to my PCP which had no clue what to do with me. I regret the the day I ever saw that doctor and listened to her. I really don't think she knew what she was doing and even more angry at myself for not listening to my own body when I was so sick on treatment. I am on a FB group as when I searched for Harvoni side effects all the problems I am having they all came up, thousands of them, all over the world, same side effects, and the Doctors pushed it on them also. I do believe some people have no choice but to take the treatment as they are in bad shape. I was not one of them.

5 doctors I am seeing believe its from Harvoni, it has messed up immune system and damaged my body and my nervous system. I just finished at USF specialist I have sensory peripheral neuropathy, this cannot be a coincidence that we all have the same side effects, this is truly heartbreaking. I was a happy healthy bubbly person, this has destroyed my life. I am 60. I was dancing 3 days a week and active. Now I can barely get out of my bed, my life is ruined, and so many others, this drug was fast tracked and I was stupid enough to take it.

I am extremely upset they are actually giving this poison to children. Its all about the money they don't care I did find on FAERS the side effects people reported. I also called Gilead after treatment. I did find financial disclosures and realize that all of the investigators were either paid by Gilead, got grants from them or were employees how is that possible they had financial ties. I also found side effects on a clinical review page and they only put 4 at 5%

and rest they didn't put but listed on their page at 3% and below. If I would have had a chance to review that information prior to treatment and I could have made a better decision to actually not take treatment and be followed like I was prior to destroying my life. I am in pain every day.

31% of reported cases resulted in death: Institute for Safe Medication Practices

The Institute for Safe Medication Practices (ISMP), a US-based independent watchdog organization devoted entirely to preventing medication errors, has already reported serious safety issues related to the same Gilead drugs Harvoni and Sovaldi as those donated to Georgia. The independent watchdog has provided the following review of drug safety issues reflected in adverse drug events reported to the US Food and Drug Administration (FDA):

Reactivation of hepatitis B. In October 2016, FDA identified the first new major safety problem linked to the nine new direct-acting antiviral drugs for hepatitis C. For patients who currently or previously had an infection with the hepatitis B virus, the direct-acting antivirals can cause reactivation of the virus and result in serious liver problems or death. The FDA report described 24 cases of hepatitis B reactivation, including 3 cases of acute liver failure leading to 2 deaths and 1 liver transplant. The reactivation of hepatitis B was not detected in clinical testing done prior to approval because such patients were excluded in the studies. This risk potentially can be managed by pretreatment virologic testing for hepatitis B, as the FDA now recommends.

Liver injury and failure. Searching beyond the FDA's cited cases above to review the most recent 12 months of data up to Q2 2016 in the FDA cing system (FAERS), we identified 524 reported cases of liver failure associated with the drugs, and another 1,058 reports of severe liver injury that had apparently not progressed to liver failure. The 524 reported cases of liver failure included all the approved direct-acting antivirals as either primary or secondary suspect drugs (Table 1), often in combination with each other or with ribavirin. Almost half of the cases reported encephalopathy, the hallmark symptom of liver failure. Overall, 165 (31.5%) had died at the time of the report. While the complications of hepatitis C rather than the suspect drug might have contributed to some cases, 90% of the reports were submitted by healthcare professionals, who would be more likely to understand the natural progression of the disease.

Generic name	Brand name	PS	SS	Total (%)
paritaprevir combinations	**TECHNIVIE, VIEKIRA PAK, VIEKIRA XR**	120	61	181 (34.5)
sofosbuvir	**SOVALDI**	91	80	171 (32.6)
ledipasvir-sofosbuvir	**HARVONI**	116	5	121 (23.1)
daclatasvir	**DAKLINZA**	74	25	99 (18.9)
simeprevir	**OLYSIO**	16	21	37 (7.1)
elbasvir-grazoprevir	**ZEPATIER**	1	0	1 (0.2)

***EPCLUSA** (sofosbuvir, velpatasvir) is not included as it was first approved at the end of Q2 2016.

Source: QuarterWatch™ (2016 Quarter 2 Data) Liver Failure with Hepatitis C Drugs, Institute for Safe Medication Practices (ISMP)

Gilead clinical trial on 3-year old children

Gilead has started a clinical trial on the safety of its Hepatitis C drugs (Sovaldi, Harvoni, Eclupsa) involving children aged 3 years and older, according to information from the US clinical trials registry. The duration of the trial is ten years – from 2015 to 2025. The primary objective is to determine the long-term safety of anti-HCV regimens in the pediatric population. The estimated enrollment is 500 participants from 50 study locations in the US, Australia, Belgium, Germany, Italy, New Zealand, Poland and Russia. The results of this Gilead-sponsored study on children have not been published yet.

Many of the researchers promoting the safety of these Gilead drugs receive funds, hold stocks in the company or are Gilead employees which is a direct conflict of interests.

I am an independent journalist and I do not work for governments or corporations. If you have more information, please send a message to dilyana@armswatch.com. If you want to support my work, please go to the Donation page or Become Volunteer. Thank you!

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Dilyana Gaytandzhieva is a Bulgarian investigative journalist, Middle East correspondent and Arms Watch founder. Over the last years she has published a series of revealing

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