

ALLEGED ON ADEQUACY OF WITNESSES

Mr. Judge:

Denis Bernardo Sanchez, holder of ID No. 24450782, by law own, with domicile in Zabala 2443 4th Street "10" CABA, with my **patrocinantes lawyers, Felipe Castro RIGLOS** T ° F ° CPACF 87 302, with 27273754933 mail address and **Bengt Martin HÖGBERG**, T ° F 130 ° 628 CPACF, with mail address 20190392385, maintaining our home proceedings at Av. Paseo Colón 1019 16 ° "D" of this city, in re "**SANCHES, DENIS BERNARDO C / MONTE VERDE SA AND OTHER S / DISMISSAL** "Expte. No 27009/2016, VS respectfully say:

I. PURPOSE

In accordance with art. 90 of the LO (Law 18,345) I come to plead on ZWARYCZ competence of witnesses and SERGIO ALEJANDRO DUARTE CARLOS HORACIO who gave their statements on March 19, 2018 and that looks fs. 980/982.

II. FUNDAMENTALS

Witness A. DANIEL SERGIO ZWARYCZ

First it should be borne in mind regarding this testimony that Mr. Sergio Alejandro Zwarycz is currently working as employees of one of the defendants in these proceedings, that is, to Monte Verde SA, which seriously to suspect that avoid making a statement that harms your employer, the risk of being punished for this, eg fired or suspended.

In another vein we may suspect that the witness noted for its long Monte Verde SA seniority and his employment status and membership feel duty loyalty to the company that is hiring the workforce over the past eighteen years.

In short, whether out of fear or a sense of loyalty, it should guard against that this witness will seek to benefit from his testimony to Monte Verde SA and Laboratorios Raffo SA Vera, as soon as you can.

But I come not to challenge his testimony in its entirety.

*-Who knows the actor, who knows MONTE VERDE SA, who knows JORGE ALBERTO Belluzzo, who knows RAFFO LABORATORIES SA, who knows the BOX ART SA which is used SA Monte Verde, which currently holds the Chief of Quality Assurance in Buenos Aires plant, **working for MONTE VERDE since 2000 ...** and below it reads: **that the deponent was employed Raffo from 1990 to 2000,***

ZWARYCZ tells us in his testimony that he was employed by RAFFO FROM 1990 to 2000 MONTE VERDE And since 2000 to date. In the same floor as RAFFO is 120 years old and historically has located the plant in Villa Martelli in the place referred to by the witness, who claims to work for MONTE GREEN, coinciding with the date of change of company, obtaining profit MONTE VERDE SA of tax in the province of San Juan. FOR THIS REASON MOST HAVE A PERSONAL WITH THE SAME **Modus Operandi** HIRING.

In the image of the LOGO RAFFO Google maps seen in the direction



AGUSTIN ALVAREZ 4145, 4147.

[https://www.google.com.ar/maps/@-34.5479626,-](https://www.google.com.ar/maps/@-34.5479626,-58.5094081,3a,44.6y,317.97h,89.9t/data=!3M6!1e1!3M4!1sYclrTyRT4h4fYEG_69YBfQ!2E0!7i13312!8i6656)

[58.5094081,3a, 44.6y, 317.97h, 89.9t / data =! 3M6! 1e1! 3M4! 1sYclrTyRT4h4fYEG_69YBf](https://www.google.com.ar/maps/@-34.5479626,-58.5094081,3a,44.6y,317.97h,89.9t/data=!3M6!1e1!3M4!1sYclrTyRT4h4fYEG_69YBfQ!2E0!7i13312!8i6656)

[Q! 2E0! 7i13312! 8i6656](https://www.google.com.ar/maps/@-34.5479626,-58.5094081,3a,44.6y,317.97h,89.9t/data=!3M6!1e1!3M4!1sYclrTyRT4h4fYEG_69YBfQ!2E0!7i13312!8i6656)

He also admits meet JORGE ALBERTO Belluso, whose own presentation is RAFFO GENERAL MANAGER LABORATORY SA. As You can be seen on record 25945/2015 captioned: "SANCHEZ DENIS S / EXTORTION "in the Court of Instruction No. 40.

-who knows the actor, who knows what the job site of the headquarters of Villa Martelli, the headquarters of Monte Verde,

It recognizes the place but the company wants to exclude RAFFO SA in testimony I worked and worked, as the ASOTREX product declares to know, It is marketed under the name Laboratory Raffo, logo and colors of RAFFO SA

*-In the sector Sanchez, Quality Assurance, is a broad sector
It is responsible for monitoring the overall operations of the other sectors
make the manufacturing process, in that sector can Side itemize
because the deponent works in its sector, general monitoring tasks were done
the manufacturing process, documented way, who knows the industry
hierarchically he had a boss and a number of analysts. The top of Sanchez was
Silvina Bermejo, Bermejo was chief tasks sector **that as Head of Sector**
what I She was responsible for the tasks of the sector would be a job definition
on the tasks she met,*

weirdly ZWARYCZ You can not explain the tasks of the sector
Quality assurance, despite having stated that currently holds the position of
Head of Quality Assurance Ground Buenos Aires.

Audiencista When asked what were the specific functions and Chief Quality assurance, ZWARYCZ replied: "**who as head of sector is me, she was responsible for the tasks of the sector would be a definition of position on tasks she met**".

-That the deponent does not know who did the audit in the sector guarantee quality,

With this statement tries to hide his knowledge about people they Audited in its sector of quality control and audit service MAESTRANZA received, the audit carried out by me personally. As attached report appears in this file. Entitled "Audit MAESTRANZA "and whose address is in evidence on record ANMAT and exp. 43204/2015 styled "Raffo SA and other s / inf Law 16463" in the Court Federal Criminal and Correctional San Isidro No. 1 and No. 25945/2015 record, "SANCHEZ DENIS S / EXTORTION" in the Court of Instruction No. 40.

CABA can also see enlightening elements, studying e
Electronic submitted as evidence, in which the logo is seen RAFFO
SERVER RAFFO, the crossing of emails between the boss and the audited
maestranza, with a copy to the auditor, SANCHEZ DENIS.

LEGISLATION THAT SWARYCZ BASICA NO KNOWN:

<http://www.anmat.gov.ar/webanmat/Legislacion/Medicamentos/Disposicion>

2004 2819.pdf

Disp. 2819/04

8. self-inspection and QUALITY AUDITS

Self-inspection team

8.3 The company should appoint a self-inspection team

formed by experts in their respective fields and knowledgeable regarding the BPF.

They can integrate the equipment people in the company or people outside it.

Frequency of self-inspection

8.4 The frequency should be established in an operating procedure

normed. Self-inspection must be performed at least once a year.

<http://www.anmat.gov.ar/webanmat/Normativa/Normativa/Medicamentos/>

Dispo-2372-08.pd

Disp. 2372/08

CHAPTER 12

QUALITY GUARANTEE

5 Are there written procedures for self-inspections and / or quality audits

to evaluate the effectiveness and applicability of the quality system?

QUALITY AUDITS / SELF-INSPECTIONS

37 self-inspections and / or quality audits performed?

38 Quality Assurance is responsible for coordinating them?

39 Is there trained and assigned to perform

self-inspections / audits of quality?

40 The self-inspections / audits are performed with a preset plan?

41 necessary corrective measures are recommended?

41.1 Quality Assurance do you verify compliance?

Audit SUPPLIERS

45 Input suppliers Are audited and / or qualified?

46 terceristas production and quality control are they audited and / or Qualified?

47 Is there a program of audits and / or qualification of suppliers and terceristas?

48 Fulfilled?

49 records of these audits and / or qualifications are maintained?

ADDITION IS IMPOSSIBLE TO ONE PERSON PERFORM ALL AUDITS

-The deponent knows the ASOTREX product, the deponent at that time



devoted to that, raw materials, packaging materials and products,

http://www.raffo.com.ar/producto_/9/ASOTREX

ZWARYCZ being HEAD OF QUALITY CONTROL AND HANDLING PACKING MATERIAL PREJUDICE TO THE CONTAINER CAN NOT SELLING

*ASOTREX PRODUCT (NAME WITH LABORATORY RAFFO) THAT
**CLAIMING TO KNOW AND BE RESPONSIBLE FOR CONTROL. KNOWN
PERFECTLY THE CASE AND THE COMPANIES INVOLVED.***

*-that the deponent does not know if the place was working with Sanchez
complaints are received or irregularities or errors were detected in the products.*

As Head of Quality Assurance should know that the claims are managed by the Guarantee sector according to the Disp. 2819/04 and 2379/08 disp ... And participate often as Head of Quality Control.

DISPOSITION 2819/2004

5. CLAIMS

5.5 Any complaint concerning a defective product must be registered with all the original details and thoroughly investigated. **Person responsible for quality control should normally be involved in the review of such investigations.**

5.9 The claims records should be checked regularly for any identification of specific or recurring problems requiring attention and may justify the withdrawal of products market.

2372/2008

COMPLAINTS

53 Quality Assurance is responsible for coordinating the reception and tracking complaints received?

54 ¿ It is assigned a responsible?

55 Are there written procedures for receiving and investigating claims?

56 New users of these maintained?

57 If necessary, is analytical control is done? (QA)

58 Are there documented in the batch records decisions complaints regarding product quality deviations?

59 Are corrective action is taken when appropriate?

-The relationship between Laboratorios Raffo and Monte Verde does not know that the deponent was employed by Raffo from 1990 to 2000, working for MONTE GREEN since 2000,

The ZWARYCZ witness worked in Raffo and after MONTE VERDE in CENTENARIA same plant Villa Martelli. Authorizing the sale of the product Asotrex developed plan RAFFO and HLB PHARMA, marketed by RAFFO with MONTE VERDE materials.

-Who knows that the actor went to the Quality Control industry in this sector Sanchez requested some information, Sanchez had no task other than that in the field of quality control.

I am requesting information as affirmed in demand in research lots took to the streets without proper documentation available quality assurance and auditable by ANMAT. Or as in the above case (the stock broken glucosamine) I made micrometer thickness measurements, bags of container nylon raw materials, which were breaking on the transfer to the tercerista HLB. Research led me to request a micron gauge the of SWARICK sector then end up sending EMAILS A Polytrans, and presented as evidence in this record, reporting what happened and putting both on new controls and corrective and preventive actions the material that the company supplied.

-The sampling of primary packaging material does not remember where It performed because there was a transition in the plant where the deponent is Tortuguitas plays now, he does not remember where they were at that time.

It is false not remember the sampling, with long experience and having been Head of Quality Assurance and current Head of Quality Assurance. As all they do according to the standard 2819/04 and 2372/08 and Law 16463, in an area WHITE, AND REGISTRATION BITACORA. What did Mr. SWARICK for years, he muestreaba the primary packaging material in the warehouse and quarantine. Both areas, black. Caring nothing, exposure of the primary packaging,

and subsequent contamination of the drug. Why no records in many years sampling of material for RAFFO and MONTE VERDE.

It is the sole responsibility of Quality Control sector, which the witness he was head.

2372/2008

CHAPTER 11

QA

23 Is there SOPs describing

detailed for sampling:

23.1 raw Materials?

23.2 packaging materials ?

23.3 semifinished product?

23.4 finished product?

-Do not know if primary packaging samples were made in black areas, He does not know if primary packaging samples were made in areas such as deposit materials that handled the deposit sector, which does not know whether performed in the Quarantine, who believes that at that time the reservoir area was who He is managing those tasks.

FALSE, it IS THE RESPONSIBILITY OF PERSONAL CONTROL QUALITY WITH YOU.

-In the area of the deponent, who washed glassware was Lopinto Norma, That the deponent does not know Mrs. Mammani.

Mrs. Norma Lopinto retired in shared work period

SWARICK HAPPENED AND Phryne MAMMANI.

-Who knows that in the area of quality control internal audits were conducted, It is true as is said in the demand for ANMAT available, same Self inspections that were lagging behind in their compliance. And attached as evidence this record.

Disp. 2819 / 04- 1. QUALITY ASSURANCE

(I) there is a procedure for self-inspection and / or quality audit which regularly evaluates the effectiveness and enforceability of the guarantee system quality,

1.3 manufacturer should take responsibility for the quality of products pharmaceuticals, ensuring that they are suitable for use provided meeting the requirements of authorization marketing and will not risk patients because of security, inadequate quality or effectiveness. The main administrative authorities They are responsible for compliance with this quality objective and requires active participation and commitment of all departments and all levels within the company, suppliers and distributors. For what possible to achieve the aforementioned objective quality should have a System Quality Assurance comprehensive and correctly applied, to incorporate the Good Manufacturing Practice and QA.

That is, it is not and never was oblivious to ZWARYCZ "participation" RESEARCH IN COMPLAINTS. NI WORKING IN CONTROL QUALITY AND LESS AHUN as head of quality assurance.

-That internal auditing is a regular thing, habitual, which is made between sectors, that makes the personal from one sector to another, that the internal audits firm is responsible for quality assurance and responsible sector if the According, TRUE, BUT NOT AGREE TAMBIEN.ESTO LAST DOES NOT PREVENT THE SIGNING OF THE OTHER PARTICIPANTS.

In the sector deponent when the audit was conducted compliance the signed the deponent, he does not remember if the person responsible for quality assurance signed it, does not remember if Silvina Bermejo signed it, usually the sign auditee and the auditor,

SWARICZ, SAYS FIRST, AND THEN IF NOT REMEMBER CHIEF SIGNATURE AUDITS AND AGREE THAT MAY BE ANOTHER AUDITOR AND

*AUDITED AS THE ASSERT in demand and recorded in the
AUDITS REPORTS SUBMITTED.*

*-Who knows Juan Morales, who worked long ago in Quality Assurance,
who does not know that fulfilled functions or tasks was Juan Morales, who did tasks
General quality assurance,*

*MORALES JUAN performed the same tasks I, releases online,
personnel and process controls, documentation and annual review of products,
He participated in audits as you can see his name on copies made to
record, participated in the investigation of claims and the care thereof,
as it is shown in copies of claims made to the file.*

*-Who knows that Sanchez does not continue working in the company, that the deponent
knows that the actor was detached from the company, which believes it was without cause,
restructuring, as far as the deponent learned that the deponent learned from
Public comments*

*As forever SWARICZ nourished, INFORMNDOSE OF
CORRIDOR gossips, an embarrassment to a "boss".*

*The deponent knows that the relationship between Sanchez and his companions was good,
abe by the comments of fellow Sanchez sector*

*Bermejo contradicts the testimony of which coincides with the assertions of my
person, it was an unhealthy work environment in every way.*

*-Sanchez had no good relationship, the deponent knows only for comments,
with sector deposits, central weighing the deponent does not know what the problem was
between Sanchez and deposit because they are superficial comments.*

*superficial comments that entertained while far from SWARICZ
meet minimum standards to ensure the health of consumers. So
surface as their work. A statement based on a request from attorney
surely defendants.*

*-that the deponent does not know what the problem was between Sanchez and deposit because
They are superficial comments, staff comments and central depository*

heavy, run by the same person named Paul Dullio, not remember those who worked at that time by name there, the deponent not know or remember which of them had problems with Sanchez, **that the deponent knows that Sanchez industry that made the tasks of the chief guarantees, such as enabling lines, enable assemblies, enable the control unit.**

WHAT IS TRYING TO SAY superseding supervisor PRODUCTION WHEN WAS NOT THAT inspected the WORK AND CARRIED OUT THE PRIMARY FUNCTIONS GUARANTEE QUALITY, audit, INSPECT, CHECKEAR, VERIFY, STOPPING OPERATIONS NECESSARY. **Ensuring HEALTH POPULATION.**

-that the deponent does not know how the sampling of the material was recorded primary packaging, the deponent knows that these tasks are MONTE VERDE MONTE VERDE performed for which the witness knows that these tasks were performed or for any other company.

FALSE, It is responsible SAMPLING AND IN YOUR SEAT Binnacle special area for this activity. What It Seemed APPLYING THE LAW, WITH CONTROL RESPONSIBILITY QUALITY.

- He does not know if Morales was working for another company ZWARYCZ NOT MEAN THAT DARES TO MORALES JUAN, toiled MONTE VERDE SA AND RAFFO SA

-Monteverde is the company that marketed the product ASOTREX up Witness-knows where **FALSE It is MARKETED IN JOINTLY BY ENTERPRISE GROUP HOLDERS MONTE VERDE, COMMERCIAL NAME ASOTREX RAFFO LABORATORIES SA. OCCURRED IN PART IN RAFFO SA. VILLA MARTELLI PLANT AND THE REST BETWEEN HLB PHARMA AND MONTE VERDE SA.**

B. Testimony of DUARTE CARLOS HORACIO

First it should be borne in mind regarding this testimony that Mr. Carlos Horacio Duarte is currently working as employees one of the co-defendants in these proceedings, that is, to Monte Verde SA, which makes seriously suspect will avoid making a statement that harms your employer, the risk of being punished for this, eg fired or suspended.

In another vein we may suspect that the witness noted for its long Monte Verde SA antique feel belonging and duty of loyalty to the company it is occupationally hiring the last 18 years.

In short, whether out of fear or a sense of loyalty, it should guard against that this witness will seek to benefit from his testimony to Monte Verde SA and Laboratorios Raffo SA Vera, as soon as you can.

But I come not to challenge his testimony in its entirety.

-MONTE VERDE working for since 2000.

This statement coincides with the date of creation of the company and completion of plant construction MONTE VERDE SA and start your benefit tax Province of SAN JUAN.

-that the actor knows because he worked at the headquarters of Villa Martelli, at the headquarters MONTE VERDE,

It is true in part, tends to hide the fact that there are works for RAFFO SA, which the sector Sanchez had a normal relationship,

Contradicting versions that had conflicts with other sectors.

-that the deponent knows not say if the actor conducted audits some time that the deponent does not have much knowledge in depth.

The witness is unqualified personnel in pharmaceutical production, provides services production support, therefore unknown operations and further legislation and documentation which does not have access.

-who he does not know who made them, in the field of quality control does not know who performed the audit.

The witness does not know the operative drug manufacturing.

-Who knows the sector Sanchez had phones, the deponent knows because all sectors have phones, which the actor does not know who Sector called not know if they called clients.

The witness known operations and legislation.

-Who knows that at the headquarters of Villa Martelli no product claims were received, that the deponent knows that there is a sector that receives complaints, which is the industry believes which Pharmacovigilance, who works at the headquarters of Munro.

The above it's false in part and can confuse the sector pharmacovigilance It was created especially for drugs lists intensive monitoring and new adverse effects, no effect and repeated effects, **in order to gather data, not to respond to the patient and investigating failures quality, replenishing units.** Pharmacovigilance was created by arrangement international and national membership for ex Resolution No. 706/93 MS and AS. Do not replaces the responsibility of Quality Assurance or Quality Control that of each laboratory. **Pharmacovigilance is an international action together with the responsibility of each processor.** So you need not be FLOOR PRODUCTIVE, STORED DATA FOR THESE DATA ARE TRANSLATED With time standards, recommendations.

-That the deponent does not know what it was doing when claims were made by products. That the deponent does not know whether irregularities or errors were detected in the product ASOTREX.

I would not necessarily know, except for unauthorized comments.

-Silvina Sallese working in the same sector as the actor, the deponent She knows she was not remember exactly the tasks he was doing, but was in that sector. Who knows Juan Morales, who performed the tasks, if not bad remembers Denis, above Denis

CONFIRMA lo que afirme en la demanda, que JUAN MORALES realizaba tareas similares a las mías, entre las que se encontraban AUDITORIAS Y AUTOINSPECCIONES.

-que supone que el desempeño de Sánchez era normal, que el dicente nunca escuchó ninguna queja.-

ESTA AFIRMACION ECHA POR TIERRA LOS COMENTARIOS DE QUE HABIA MALESTAR ENTRE OTROS SECTORES Y SANCHEZ DENIS.

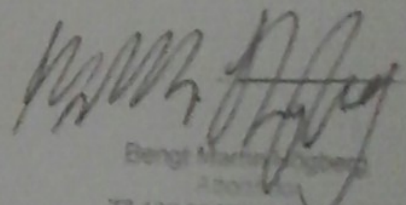
III. PETICIONA

Por lo expuesto solicito a V.S. tenga presente este alegato sobre la idoneidad de los testigo Alejandro Sergio Zwaryez y Carlos Horacio Duarte al momento de dictar sentencia.

Proveer de conformidad,

SERÁ JUSTICIA

SANCHEZ


Bengi Martínez
Abogado
T. 130 P. 50 C. P. 12 C. F.
T. LXV P. 12 CALP.