30 years of Cancer Care in the Brazilian National Health System

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A Assistência Oncológica e os 30 Anos do Sistema Único de Saúde 30 años de Asistencia Oncológica en el Sistema Único de Salud en Brasil

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INTRODUCTION

Thirty years ago, on October 5, 1988, Brazil enacted a new National Constitution¹, in which Article 6 proclaims health as a fundamental social right, with articles 196 to 200 setting the guidelines for establishing a single, unified national health system.

The Article 198 clearly states the constitutional guidelines for organizing this system:

> Public health actions and services are part of a regionalized and hierarchical network, and constitute a single system, organized according to the following guidelines: I - decentralization, with a single direction at each level of government; II - comprehensive care, with priority for preventive activities alongside healthcare services; III community participation.

Although the 1988 Constitution received 99 amendments from March 1992 to December 2017, three of which pertaining to health, the basic guidelines have remained.

Two years after the Constitution was enacted, on September 19, 1990, the Organic Health Law was published under the number 8.080³, of which article 7 provides:

> Public health actions and services and private services under contract or agreement as part of a unified national health system (SUS, in Portuguese) are developed according to the guidelines established in article 198 of the National Constitution, in compliance with the following principles: I universal access to health services at all levels of care; II - comprehensive care, defined as an integrated and continuous set of actions and services, both preventive and curative, individual and collective,

as required by each case at all levels of the system's complexity; III – preservation of persons' autonomy in the defense of their physical and moral integrity; IV - equality of healthcare, without prejudices or privileges of any kind; V – for persons so assisted, the right to information about their health; VI - dissemination of information on the potential of health services and their utilization by users; VII – use of epidemiology for priority-setting, resource allocation, and program orientation; VIII - community participation; IX - policy and administrative decentralization with a single direction at each level of government: a) emphasis on decentralization of services to the municipalities; b) regionalization and hierarchical organization of the health services network; X - integration, at the executive level, of actions in health, environment, and basic sanitation; XI – combination of financial, technological, material, and human resources from the federal, state, Federal District, and municipal governments in the provision of healthcare services to the population; XII - case-resolution capacity in services at all levels of care; and XIII - organization of public services so as to avoid duplication of means for identical ends.

From 2013 to 2017, an item XIV was added through specific laws, providing for the organization of specific and specialized public care for women and victims of domestic violence in general, guaranteeing care, psychological follow-up, and reconstructive plastic surgeries, among others.

As with the National Constitution, the Law 8.080 received more than 60 amendments through different laws from 1999 to 20174, but none of them altered the underlying principles of the SUS, namely universal care, comprehensiveness, equal access, community participation, administrative and services decentralization, hierarchical organization, and regionalization.

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However, this law was not properly regulated until 2011, through Act 7.508, which rules on the organization of the SUS, health planning and health care, and interfederative articulation⁵. In the meantime, the SUS had been structured on the basis of Operational Norms, Rulings, and Resolutions, providing the system with a normative, conceptual, and functional framework that exists to this day (with updates and improvements).

In 1991, through the Brazilian National Cancer Institute (INCA, in Portuguese), under the Ministry of Health, a discussion was launched on cancer control in the SUS (ranging from prevention to palliative care, including the detection and diagnosis of malignant neoplasms and treatment and recovery of patients). This initiative continued with the actions and programs under way since the late 1980s, through the Oncology Program (Pro-Onco), associated with the National Institute of Medical Care and Social Security (INAMPS). Administrative decentralization gave impetus to the need to organize divisions in the state and municipal health departments to implement the corresponding actions and services. Four areas were identified as immediate priorities, without ruling out others: 1) national cervical and breast cancer control programs⁶⁻⁹; 2) tobacco control^{6,7,10}; 3) cancer registries; and 4) training for control and assessment in oncology^{6,7,11,12}.

Meanwhile, efforts were made to develop palliative care in Brazil^{13,14} and to implement education for cancer control in medical and nursing schools^{6,7,15-17}.

In relation to cancer care, the specific norms for its organization, functioning, and financing in the SUS were published in 1993, with Rulings SAS/MS no. 170 and no. 171 (high complexity care and oncological surgery with its respective procedures), culminating in 1998 with Rulings GM/MS no. 3.535 (organization and qualification of high-complexity cancer services) and no. 3.536 (an update, with major expansion of radiotherapy and chemotherapy, with specific procedures for outpatient and inpatient care)12.

These rulings, subsequently replaced, were followed by others that updated and added to them¹², seeking to expand health actions and services for cancer prevention and control, in a continuous endeavor to confront the disease, with growing incidence in Brazil.

This article aims to provide a historical summary of cancer care in the 30 years since SUS was created constitutionally and the 28 years since it has been regulated by specific legislation, seeking to share with future generations the challenges for improvement and progress in dealing with new knowledge and diagnostic and therapeutic technologies, not always effective or costeffective, and which steadily and progressively present themselves for cancer prevention and control.

FROM 1988 TO 1997

Since 1986, even before the enactment of Brazil's 1988 National Constitution and the Organic Health Law in 1990, the Ministry of Health, through INCA and in partnership with INAMPS, had been implementing national cancer control programs¹⁸, such as oncology training in medical schools, control and assessment in oncology, and cancer registries, besides others such as tobacco control and cervical and breast cancer awareness.

Until 1992, cancer care in the SUS maintained the same departments from INAMPS, with its Integrated System for Endowment, Administration, and Contracts (SIPAC-Cancer), including their surgical procedures in various specialties, radiotherapy (5), and chemotherapy (10). There were few hospitals and professionals providing cancer care. The Central of Medicines (CEME, in Portuguese) had already been extinguished, still under the INAMPS, and cancer chemotherapy was already the responsibility of providers, most of which were independent chemotherapy services or services outsourced by the hospitals and reimbursed for the procedures.

Affiliation with SIPAC-Cancer, an accreditation system for specific hospitals providing high-complexity cancer care, gave the hospital the right to receive so-called hospital valuation indices and outpatient valuation indices (IVH and IVA, respectively, in Portuguese), as with other SIPACs (e.g., orthopedics and neurosurgery).

The Hospital Information System (SIH, in Portuguese)19, created in 1981 to replace the GIH system (Hospital Admission Form) in 1982, was maintained in the SUS with its Authorization for Hospital Admission (AIH). The Outpatient Information System (SIA)20 was created in 1992 and implemented starting in July 1995.

Thus, SUS succeeded in absorbing and expanding the management instruments from the extinct INAMPS.

The first major change in high-complexity cancer care in the SUS was in 1993, with the publication of procedures in Oncological Surgery performed exclusively by hospitals enrolled in SIPAC-Cancer and totaling 119. With the extinction of the valuation indices, these procedures were priced higher than the corresponding medium-complexity surgical procedures, but without compatibility with sequential procedures, braces, prostheses, and special materials. However, this list of procedures gave rise to the mistaken view (frequently repeated) that Oncological Surgery was priced higher than the other surgical specialties, since the comparison was only made with the values for the corresponding procedures, but not between values on the AIH recorded in the SIH-SUS.

However, there was no change in radiotherapy and chemotherapy, both of which continued to have duplicate procedures and tables (SIH-SUS and SIA-SUS), a multiplicity of providers (counted according to the services and not the hospitals with their services), outsourcing, and fragmented care. Additionally, there was difficulty in developing cancer registries based on individual data (data on radiotherapy and chemotherapy were recorded on the Bulletins on Outpatient Production, or BPA, in the SIA-SUS).

However, the Program for Control and Assessment in Oncology, conducted by Pro-Onco/INCA/Ministry of Health, first launched in the Municipal Health Department in Campos, Rio de Janeiro State¹¹, in 1993, revealed the distortions in recording and billing, especially in radiotherapy and chemotherapy. Methods were developed to assess the procedures provided in these two areas, and audits were performed in hospitals in various cities of Brazil, including both state capitals and smaller cities, the results of which proved that there was double billing for the same patient in the same month and for the same treatment.

In Campos, a city in the state of Rio de Janeiro, where authorization for radiotherapy and chemotherapy procedures was conceived, as with the AIH, the work in control and assessment was manual and painstaking, but the need to computerize it soon became evident (as in fact happened). This led to the limitation of billing to just one information system in the SUS (either SIH or SIA) for the same month¹¹.

Thus, the Municipal Health Department in Belo Horizonte, Minas Gerais, took up the program, which made great progress in administrative and operational terms, including computerization. The progress continued in the Municipal Health Department in Curitiba, Paraná, which further developed the integration of authorization with assessment and payment for radiotherapy and chemotherapy procedures.

The process was sufficiently mature to extend it to other cities and states of Brazil. This was done by training the control and assessment divisions in the municipal and state health departments¹¹. It was also conceptually prepared to become standard procedure in the SUS, that is, to be implemented at the national level.

The conditions were ripe for creating a subsystem in the SIA-SUS, based on the Authorization for High-Complexity Procedures (APAC, in Portuguese) in Oncology [The first implementation of the APAC ended up being done in dialysis following the tragic death of 60 chronic dialysis patients in Caruaru, Pernambuco, in 1996].

FROM 1998 TO 2004

A second major change in cancer care in the SUS came on September 2, 1998, when two disruptive rulings were

issued¹². The first, Ruling GM/MS no. 3.535, concerning the structuring of care and accreditation and qualification of hospitals as High-Complexity Cancer Care Centers (CACON in Portuguese) levels I, II, and III. Moreover, Ruling GM/MS no. 3.536, also issued, concerning the creation and authorization via APAC of radiotherapy and chemotherapy procedures, valid for inpatient and outpatient care, exclusively in the SIA/SUS.

Ruling GM/MS no. 3.535 created criteria and parameters for the integration of cancer services (surgery, radiotherapy, and chemotherapy) and estimation of oncology-accredited hospitals' needs based on the expected annual number of cancer cases per state of Brazil. All the existing inpatient and outpatient services had to adjust and qualify under the new criteria, and the hospitals were classified according to their technological size as CACON I, II, or III.

These measures gave local administrators of the SUS the technical and legal backing to organize cancer care in the public system, in terms of the need for hospitals and the supply and demand of hospital-based cancer services, with no more place in the SUS for stand-alone radiotherapy or chemotherapy services.

Ruling GM/MS no. 3.536 not only unified the radiotherapy and chemotherapy procedures, but also laid the foundations for the APAC-SIA-SUS subsystem, which allows upgrading information, planning, and programming, organization of cancer care, production of epidemiological data, estimating the demand (met and unmet), assessment of results, and research output^{21,22}.

Ruling GM/MS no. 3.536 created 25 new radiotherapy procedures (there are now 31) and 100 new chemotherapy procedures (there are now 168) and their respective codes in the SIA/SUS table, that is, without duplication in the SIH-SUS table.

As for the procedures in high-complexity oncological surgery, the 119 procedures specified under Ruling SAS/ MS no. 171/1993 remained, and today there are 457 surgical procedures consistent with the codes of the International Classification of Diseases for Oncology (ICD-O), of which 274 are high-complexity.

The data obtained from the records of oncological procedures in the SUS began to be used to estimate the needs for services and planning of cancer care²³. The planning model has been used thus far with improvements to estimate the need for hospitals qualified in oncology and to monitor their specific production.

Oncology, together with cardiology, orthopedics, and neurology, formed the four pioneering specialties in the National Clearinghouse for Regulation of High-Complexity Care (CNRAC)²⁴, created in 2001 and still in operation today, with updates.

In 2004, oncology was also included in the National Program for Health Services Assessment, together with general surgery, obstetrics, intensive care, and renal replacement therapy²⁵. Since then, with a few years of interruption, indicators to assess the production of oncological procedures in the SUS are calculated yearly by the Ministry of Health and sent to municipal health departments (for cities with hospitals accredited in oncology) and state and district departments, as well as to health councils and external oversight bodies.

Importantly, in 2000 the Ministry of Health had issued six rulings²⁶⁻³¹ that regulated the National Transplantation System in terms of histocompatibility tests, accreditation of laboratories, hematopoietic stem cell transplantation (HSCT), the National Registry of Bone Marrow Donors (REDOME), and searches for national and international donors. Although these rulings do not pertain exclusively to cancer, since they also cover histocompatibility tests for solid organ transplantation, they gave major impetus to HSCT in cases of leukemias and lymphomas, besides aplastic anemia. Its indications were updated for cancer starting in 2009, when autologous HSCT was also included in the treatment of neuroblastoma³².

FROM 2005 TO 2018

With the constant demands that led to evolution in the structure, administration, and care in the SUS, Rulings GM/MS no. 3.535 and no. 3.536 were updated in 2005, resulting in the National Policy for Cancer Care (promotion, prevention, diagnosis, treatment, rehabilitation, and palliative care). This policy was established under Ruling GM/MS no. 2.439/2005 (replaced by Ruling GM/MS no. 2.439/2013) and the reformulation, by Ruling SAS/MS no. 741/2005, of the criteria and parameters for accreditation in highcomplexity cancer care 12,33,34.

As in all high-complexity areas, the hospitals began to be accredited as High-Complexity Care Centers (CACONs, in the case of oncology) and High-Complexity Care Units (UNACONs, in the case of oncology). Different categories of UNACONs were created^{12,34}, and accreditation was established for General Hospitals with Oncological Surgery, besides orientation and creation of a technical advisory group for health departments for cancer care planning in the SUS. The same ruling also provided for the drafting and publication of National Guidelines for Cancer Care, covering the most prevalent malignant neoplasms in Brazil. This contributed to compliance by hospitals accredited as CACONs and UNACONs, as well as setting the criteria for a hospital accredited as a CACON to be authorized to assist the local SUS administrator as a Referral Center for High-Complexity Cancer Care.

Of all the provisions in Ruling SAS/MS no. 741/2005, only one failed to materialize, due to lack of indication, that of authorization as Referral Center.

The procedures of the SIA-SUS and SIH-SUS^{12,35} tables were unified in 2007, except those of radiotherapy and chemotherapy because they had already been unified since 1998.

Oncology in Brazil was updated continuously and specifically from 2005 to 2018, but it also underwent structural and conceptual enhancements, such as overall updating of radiotherapy and chemotherapy procedures 12,36. The overall updating of procedures in oncological surgery composed these enhancements, including the creation of "sequential procedures in oncology" and the inclusion of compatibilities between sequential procedures and between procedures and braces, prostheses, and special materials^{12,37}. It also considered the updating of Ruling SAS/MS no. 140/2015 (which replaced SAS no. 741/2005) as to criteria and parameters for the organization of oncology in the SUS and the accreditation of hospitals and their specialized services 12,38; and d) drafting and publication of clinical protocols and diagnostic and therapeutic guidelines in oncology^{12,39}.

Thus far, we have mentioned the main milestones in the history of cancer care in the SUS, since many activities, projects, programs, and rulings occurred between them and cannot be forgotten. Illustrations 1 to 5 summarize, respectively: (1) the most relevant rulings; (2) the evolution in accreditations from September 1999 to October 2018; (3) the accreditations in oncology according to state of Brazil and typology in 2018; (4) federal expenditures on cancer treatment in 1999, 2009, and 2017; and (5) the clinical protocols and diagnostic and therapeutic guidelines from 2012 to 2018 (a total of 23, of which five have already been updated).

Studies currently underway include updating radiotherapy in the SUS, with a conceptual and operational change in the authorization, recording, and billing for procedures in treatment format, and no longer equipment format. Also taken into consideration are the revision of procedures in oncological surgery, with improvement in the descriptions and compatibilities of procedures and discussion aimed at a proposal for the incorporation of new technologies and the updating of clinical protocols and diagnostic and therapeutic guidelines.

There has been intense discussion in the tripartite administration of SUS and in the INCA Advisory Board (CONSINCA) on the model Brazil should adopt to improve cancer diagnosis and treatment, based on the unswerving defense of comprehensive care via the integration of specialized services to guarantee better treatment outcomes.

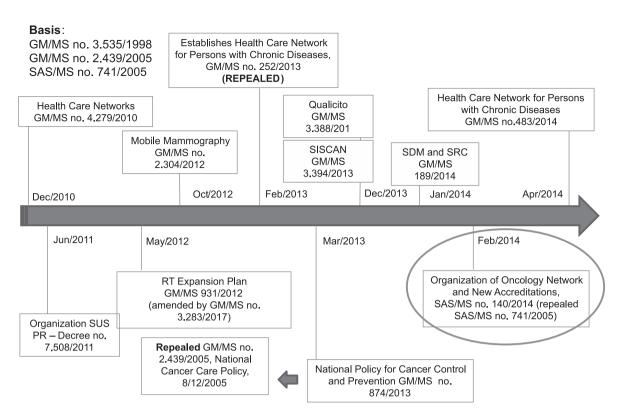


Figure 1. Principal strategies and norms

Chart 1. Evolution in cancer care in Brazil from September 1998 to October 2018

Classification	Sept/1998	Dec/2009	Jan/2014	Feb/2015	Nov/2017	Oct/2018	Obs.
Cacon	181 *	41**	44**	44**	43**	44	Until 2014, only Cacon
Unacon with RT	-	83	101	102	113	111	Evolution to Cacon and new services
Unacon without RT	-	125	126	130	137	144	Integration of stand-alone and new services
GH-SO	-	9	7	7	6	6	
Stand-alone RT or CT service	91	21	0	0	0	0	
Stand-alone RT service	-	15∞	11	10	9	8	Extended until Integration in hospital complex or exclusion from SUS
Stand-alone CT service	-	8∞	0	0	0	0	
Establishments	272	275	299	304	325	336	Unification of registries, Integration of stand-alone and new services
Accreditations	-	258	278	283	299	305	

Key: RT = Radiotherapy; CT = Chemotherapy; GH-SO = General Hospital with Surgical Oncology

Source: CGAE/DAET/SAS/MS - NOVEMBER/2018.

^{*} Without or without RT. Included standalone RT or CT services.

^{**} RT mandatory.

^{∞ 2} RT eand QT (dec/09)

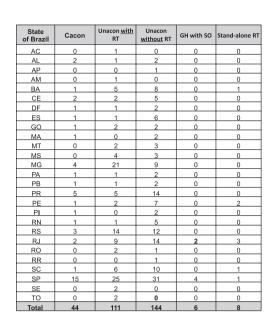




Figure 2. Hospitals accredited in High-Complexity Oncology in states of Brazil, October 2018

Chart 2. Federal expenditures in oncology services in SUSBRASIL, 1999 – 2009 – 2017

	1999	2009	2017
Surgical Oncology	BRL 87 million	BRL 172.81 million	BRL 910,536,114.771,2
Radiotherapy	BRL 77 million	BRL 163.72 million	BRL 436,589,390,343
Chemotherapy	BRL 306 million	BRL 1,228.41 million	BRL 2,394,807,252.204
lodotherapy	BRL 0.048 million	BRL 4.15 million	BRL 4,443,595.685
Total	BRL 470.5 million	BRL 1.6 billion	BRL 3,746,376,352.99

Key: Exchange rates. Dec. 1999 U\$ 1.00 = BRL 1.78; Dec. 2009 U\$1.00 = BRL 1.74; Dec. 2017: U\$ 1.00 = BRL 3.30.

⁵Procedures recorded in organization form 03.04.09 (SIA and SIH) – Nuclear Medicine – cancer therapy.

Does not include federal expenses in 2017 on:

- · Surgical procedures with cancer ICD not recorded in subgroup 0416 (Surgical Oncology) and procedure 0415020050 Sequential Procedures in Oncology in accredited and non-accredited hospitals in high-complexity oncology (BRL 634,512,346.92).
- 03.04.10 General Hospitals in Oncology (BRL 178,508,947.21).
- Scleral, liver, and hematopoietic stem cell transplants in cancer treatment (BRL 142,107,980.00).

TOTAL - ONCOLOGY - 2017: BRL 4,742,643.81

CONCLUSION

Changes in Brazilian society have continued to demand major effort by various divisions in the Ministry of Health, such as its Healthcare Department and INCA, in terms of proposals for new activities and services for cancer prevention and control. The updating of rulings, training courses for auditors and supervisors from the municipal and state health departments, as well as the drafting and updating of technical manuals in oncology for the SIA-SUS are in the scope of these changes. Last but not least, the activities proposed included the distribution of expert reports to the health departments, presentation of university students, legal experts, specialists, and associations of users and service providers to the SUS.

The dynamics of this history can be seen in the publication and replacement of Ministry of Health rulings and is documented in the Technical Manual in Oncology (SIA/SUS – Outpatient Information System), now in its 23rd edition, having been published for the first time in 1999¹².

¹ Procedures in subgroup 0416 and procedure 0415020050 Sequential Procedures in Oncology.

² Not including expenditures in Orthopedics, Neurosurgery, and Ophthalmology with ICD of cancer, amounting to BRL 41,257,016.69.

³ Procedures recorded in organization form 03.04.01 (SIA and SIH) – Radiotherapy.

⁴ Procedures recorded in organization forms 03.04.02 - Palliative chemotherapy - adult; 03.04.03 - Chemotherapy for temporary control of disease - adult; 03.04.04 - Prior chemotherapy (neoadjuvant/cytoreductive) - adult; 03.04.05 - Adjuvant chemotherapy (prophylactic) - adult; 03.04.06

⁻ Curative chemotherapy - adult; 03.04.07 - Chemotherapy for tumors in children and adolescents; 03.04.08 - Special procedures and amounts spent on cancer medications, total of BRL 570,938,963.55.

Chart 3. Clinical Protocols / Diagnostic and Therapeutic Guidelines in Oncology, Brazil

N°	CPTG / DTGO	Prevailing Ruling	
1	Ovarian Cancer	SAS/MS Ruling no. 458, of 21/5/2012	
2	Stomach Cancer	Joint Ruling no. 3 of 15/1/2018	
3	Cutaneous melanoma	SAS/MS Ruling no. 357 of 8/4/2013	
4	Gastrointestinal stromal tumor (GIST)	SAS/MS Ruling no. 494 of 18/6/2014	
5	Prostate cancer	SAS/MS Ruling no. 498 of 11/5/2016	
6	Esophageal cancer	SAS/MS Ruling no. 1.439 of 16/12/2014	
7	Breast cancer	Joint Ruling no. 19 of 3/7/2018	
8	Colorectal cancer	SAS/MS Ruling no. 601 of 26/6/2012	
9	Liver cancer, adults	SAS/MS Ruling no. 602 of 26/6/2012	
10	Lung cancer	SAS/MS Ruling no. 600 of 26/6/2012	
11	Brain tumor, adult	SAS/MS Ruling no. 599 of 26/6/2012	
12	Head and neck cancer	SAS/MS Ruling no. 516 of 17/6/2015	
13	Renal cancer	SAS/MS Ruling no. 1.440 of 16/12/2014	
14	Follicular lymphoma	SAS/MS Ruling no. 1.501 of 10/10/2014	
15	Chronic myeloid leukemia	SAS/MS Ruling no. 1.219 of 4/11/2013	
16	Multiple myeloma	SAS/MS Ruling no. 708 of 6/8/2015	
17	Acute myeloid leukemia, children and adolescents	SAS/MS Ruling no. 840 of 10/9/2014	
18	Acute myeloid leukemia, adults	SAS/MS Ruling no. 705 of 12/8/2014 (*)	
19	Well-differentiated thyroid carcinoma	SAS/MS Ruling no. 7 of 3/1/2014	
20	Ph+ acute lymphocytic leukemia, adults	SAS/MS Ruling no. 312 of 27/3/2013	
21	Diffuse large B-cell lymphoma	SAS/MS Ruling no. 621 of 5/7/2012	
22	Chronic myeloid leukemia, children and adolescents	SAS/MS Ruling no. 114 of 10/2/2012	
23	Ph+ acute lymphocytic leukemia, children and adolescents	SAS/MS Ruling no. 115 of 10/2/2012	

Key: SAS/MS = Health Care Secretariat, Brazilian Ministry of Health; (*) Republished. CPTG = Clinical Protocols and Therapeutic Guidelines; DTGO -Diagnostic and Therapeutic Guidelines in Oncology.

Since 1986, INCA, and since 1991 with its Advisory Board (CONSINCA), have consistently played a relevant role throughout this history. The technical groups from the Tripartite Administrators' Commission (CIT) and state, district, and municipal health departments, joined the Advisory Board, which have tirelessly conceived and implemented programs, projects, and management processes and continue in their quest for on-going improvement.

Challenges have been overcome, and new ones constantly emerge. That is why recording and publicizing the ways that ideas, conflicts, and solutions have been managed in the past and the transition to the present are always bridges from the present to the future. Thus, they become important tools for future generations to raise cancer care to a more integrated level with the health system to which it belongs, closer to the population that needs it.

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CONFLICT OF INTEREST:

None.

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