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UPDATE OF THE DUTCH MANUAL FOR COSTING IN ECONOMIC EVALUATIONS

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Objectives: In 2000, the first "Dutch Manual for Costing: Methods and Reference Prices for Economic Evaluations in Healthcare" was published, followed by an updated version in 2004. The purpose of the Manual is to facilitate the implementation and assessment of costing studies in economic evaluations. New developments necessitated the publication of a thoroughly updated version of the Manual in 2010. The present study aims to describe the main changes of the 2010 Manual compared with earlier editions of the Manual.
Methods: New and updated topics of the Manual were identified. The recommendations of the Manual were compared with the health economic guidelines of other countries, eliciting strengths and limitations of alternative methods.
Results: New topics in the Manual concern medical costs in life-years gained, the database of the Diagnosis Treatment Combination (DBC) casemix System, reference prices for the mental healthcare sector and the costs borne by informal care-givers. Updated topics relate to the friction cost method, discounting future effects and options for transferring cost results from international studies to the Dutch situation.
Conclusions: The Action Plan is quite similar to many health economic guidelines in healthcare. However, the recommendations on particular aspects may differ between national guidelines in some respects. Although the Manual may serve as an example to countries intending to develop a manual of this kind, it should always be kept in mind that preferred methods predominantly depend on a country's specific context.

Keywords: Costing manual, Standardization, Costing methodology, Data sources, Reference prices

Economic evaluations provide healthcare decision makers with valuable information on the relative efficiency of alternative healthcare services, healthcare services offered by different healthcare providers and healthcare services in different countries (22). However, due to the wide range of costing methodologies applied and the in- or exclusion of certain costs, cost estimates of different healthcare services are often not readily comparable or cannot be adjusted to a different context (11;15).

The application of a standardized costing methodology encourages comparability and enables a meaningful comparison of actual cost differences between healthcare services. This way, cost differences can be attributed to the healthcare services under consideration, rather than to differences in the methodology (12;17). However, published guidelines on the conduct of economic evaluations provide little guidance regarding standardized use and potential bias of different costing methodologies (14;15). In general, guidelines furnish only general information about costing methodologies and considerable differences between guidelines exist (12;14).

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In 2000, the first "Dutch Manual for Costing: Methods and Reference Prices for Economic Evaluations in Healthcare" (further referred to as "the Manual") was published for use together with the Dutch "Guidelines for Pharmacoeconomic Research" (19). An updated version of the Manual was published in 2004. The Manual has been issued by the Dutch Healthcare Insurance Board and approved by the Ministry of Public Health, Welfare, and Sports.

The purpose of the Manual is to provide a cost study Action Plan to researchers and policy makers to facilitate the implementation and assessment of costing studies in economic evaluations. The Action Plan treats cost studies as a seven-step process relating to the (i) perspective of the economic evaluation, (ii) choice of cost categories, (iii) identification of resource quantities, (iv) measuring resource quantities, (v) valuing resource quantities, (vi) dealing with uncertainty and (vii) cost reporting. However, the Manual recognizes that economic evaluations are performed in different settings, have different aims, and differ with respect to the disease and treatment investigated. As there is no single standardized approach that is applicable to all economic evaluations, a balance was sought between standardization and the need to tailor the approach to a specific study setting (15;22). Therefore, each step in the Action Plan involves choices that have significant consequences for the way the next steps are performed. The choices are made based on the objective of the economic evaluation, the disease or treatment under consideration, and the choices made in earlier steps.

Table 1. Cost Categories in Economic Evaluations

	Healthcare sector	Outside healthcare sector
Direct costs	Medical costs (for prevention, diagnostics, therapy, rehabilitation and care)	Patient costs (time and travelling costs)
Indirect costs	Medical costs in life-years gained	Productivity costs, legal costs, special education

Source: Rutten-van Molken M. Van kosten tot effecten: een handleiding voor evaluatiestudies in de gezondheidszorg. second edition, Elsevier gezondheidszorg: Maarssen; 2010 (20).

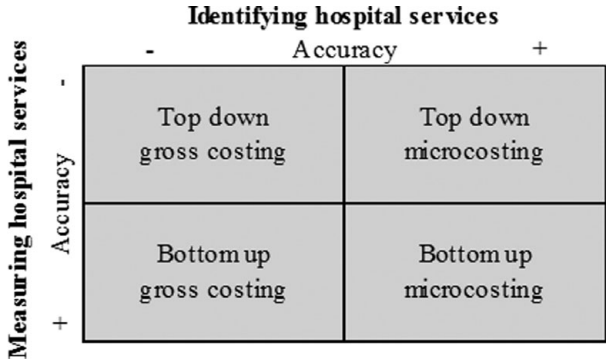

Figure 1. Methods for the cost estimation of healthcare services.
Source: Tan SS, Rutten FF, van Ineveld BM, Redekop WK & Hakkaart-van Roijen L. Comparing methodologies for the cost estimation of hospital services. *Eur J Health Econ.* 2009;10: 39-45 (24)

Since its introduction, the Manual has been widely used by Dutch health economic and clinical researchers and policy makers. A survey distributed to a representative sample of users of the 2004 Manual in 2009 revealed that 66 percent of the users were employed at university or university-affiliated hospitals, 24 percent at (pharmaceutical) for-profit organizations, and 9 percent at national institutes regulating the healthcare system. The reference prices published in the Manual are used by 4 of 5 users, of which 89 percent believe that these reference prices are reliable. Only one-third of the users indicated that pharmacoeconomic studies as part of a reimbursement file was the main purpose of consulting the Manual. From the survey it was concluded that the Manual lacked topics on (i) medical costs in life-years gained, (ii) the database of the Diagnosis Treatment Combination (DBC) casemix System, (iii) reference prices for the mental healthcare sector, and (iv) the costs borne by informal care-givers.

In addition, new insights and developments necessitated the update of existing topics, such as (v) the friction cost method to account for absence from paid work, (vi) discounting future effects, and (vii) options for transferring cost results from international studies to the Dutch situation. Therefore, a second, thoroughly reworked and updated version of the Manual was published in 2010 (9). The present study aims to describe the main changes of the 2010 Manual compared with earlier editions of the Manual. The next section briefly discusses the cost study Action Plan, which steps have not been changed over the revisions of the Manual. Subsequently, the new topics (section 3) and some of the updated topics (section 4) are described. Finally, the recommendations of the Manual are compared with the health economic guidelines of other countries and the alternative methods are discussed (section 5).

THE COST STUDY ACTION PLAN

The cost study Action Plan comprises seven chronological steps for conducting cost studies in economic evaluations. A cost study starts by choosing the perspective of the economic evaluation (step 1) and cost categories (step 2). Table 1 presents the four cost categories which may be relevant (20). The Manual requires economic evaluations to proceed from the societal perspective in which direct and indirect costs within the healthcare sector and indirect costs outside the healthcare sector are considered. Still, the societal perspective has not been commonly adopted in costing studies. For example, it is estimated that only 9 percent of pharmacoeconomic studies consider indirect costs outside the healthcare sector (*unpublished data*).

Next, resource quantities need to be identified (step 3), measured (step 4), and valued (step 5). Resource quantities may be identified in as much detail as is appropriate for the economic evaluation. In this context, a distinction is made between the very detailed "microcosting" and the less precise "gross-costing" method (21;24). Depending on their relevance for the economic evaluation, resource quantities may be measured either for individual patients ("bottom up approach") or for average patients ("top down approach") (24;28). The valuation of resource quantities may be based on existing unit costs (e.g., reference prices, section 3) or own unit cost calculations. The four available methods for the cost estimation of healthcare services are shown in Figure 1. Bottom-up microcosting allows for the identification of costs directly used for a patient and for insight in patient subgroups. As this methodology is lengthy and expensive, it has not been widely used in economic evaluations. Top-down microcosting is more feasible, but fails to trace costs directly to specific patients who incur costs. Gross costing identifies cost components at a highly aggregated level and should be considered only when data on individual cost components are lacking (24).

Finally, the Action Plan describes some options for dealing with uncertainty (step 6) and minimum standards for the presentation of methods and results (step 7).

NEW TOPICS IN THE 2010 MANUAL

Medical Costs in Life-Years Gained

One of the new topics in the 2010 Manual involves the indirect costs within the healthcare sector. Indirect costs within the

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healthcare sector arise as a secondary effect of the disease or treatment and are often referred to as medical costs in life-years gained. Although the inclusion of medical costs in life-years gained is not required in the Netherlands, the Manual provides methods for estimating these costs. A distinction is made between the costs of related and non-related diseases. With respect to related diseases, the Manual recommends to valuing life-years gained in the same way resource quantities in the direct cost category are valued. Regarding the costs of non-related diseases, the software package called "Practical Application to Include future Disease costs" (PAID 1.0) is suggested (25). PAID assumes that healthcare expenditure can be explained by age, sex, and time to death, while the relationship between costs and these three variables differs per disease. Dutch cost-of-illness data were used to estimate values for age- and sex-specific per capita health expenditure stratified to 107 disease categories, 8 healthcare provider categories, and time to death. PAID enables researchers to discard those disease categories that were already included in their own analysis and to estimate future healthcare costs of all other diseases for incorporation in their economic evaluation.

The Database of the DBC Casemix System

A second new topic in the 2010 Manual concerns the database of the DBC casemix system. In February 2005, a casemix system based on Diagnosis Related Group (DRG)-like DBCs was introduced for the registration and reimbursement of treatments provided by medical specialists and hospitals (23). Because DBC tariff setting was observed to be infeasible without the availability of resource quantities, the resource quantities consumed by each patient admitted to any hospital are systematically collected in the database of the DBC casemix system. This national database has not yet been used for the conduct of economic evaluations, because data from the database is not (yet) publicly accessible. To acquire data from the database, researchers need to get approval of the foundation Dutch Hospital Data. However, the database may serve as a unique data source for the conduct of economic evaluations in the (near) future, because it allows for detailed bottom-up microcosting studies, the collection of resource quantities from a single data source and comparability of health economic outcomes.

The database of the DBC casemix system does not contain the unit costs of resource quantities, but national DBC tariffs and charges of several resource quantities are published by the NZa. However, the Manual cautions strongly against the use of DBC tariffs for economic evaluations, because patients are classified into more or less homogenous groups in terms of diagnoses and treatments, the average cost distribution may vary considerably within DBCs and between hospitals. Although the DBC tariffs and charges must always be interpreted with caution, they may be still be recommended in some instances, for example, when no huge differences in the costs of resource quantities between patients are expected, when the resource quantities are not expected to have a large share in the total and incremental costs, in the case of a relatively homogenous production or if individual patient data are unavailable.

Table 2. Reference Prices for Direct Costs Within the Healthcare Sector (Euro 2009)

Standard resource quantity	Reference price
Inpatient day	
· General hospital	€ 435
· University hospital	€ 575
Intensive care unit day	€ 2.183
Daycare treatment	€ 251
Outpatient visit	
· General hospital	€ 64
· University hospital	€ 129
Emergency room visit	€ 151
Primary care physician (session)	€ 28
Paramedical care	
· Physical therapy	€ 36
· Exercise therapy (session)	€ 35
· Speech therapy (session)	€ 33
· Occupational therapy (hour)	€ 22
· Dietary advice (hour)	€ 27
Mental healthcare	
· Primary care psychiatrist (session)	€ 80
· Social worker (session)	€ 65
· Primary care physician (session)	€ 57
· Independent psychiatrist (session)	€ 103
· Independent psychotherapist (session)	€ 77
· Ambulatory consultation	€ 172
· Inpatient day	€ 232
· Daycare treatment	€ 154
· Residential care (day)	€ 151

Source: Hakkaart-van Roijen L, Tan SS, & Bouwmans-Frijters CAM. Handleiding voor kostenonderzoek: Methoden en referentieprijzen voor economische evaluaties in de gezondheidszorg, geactualiseerde versie 2010. 2010; www.cvz.nl/ (9).

Reference Prices for the Mental Healthcare Sector

A reference price is an average unit cost estimated on the basis of large, diverse populations that can be directly used to value resource quantities. Reference prices increase the comparability of medical treatments, in particular where healthcare services impact significantly on the conclusion to be drawn from the economic evaluation. Table 2 presents some of the reference prices that are included in the Manual (2009 Euro). Next to the traditional healthcare services, such as inpatient days, daycare treatments, and outpatient visits, the 2010 Manual contains nine new reference prices for healthcare services in the mental healthcare sector. These reference prices were established

by means of own unit cost calculations comprising personnel costs, the costs of medical staff, material costs, costs of medical equipment and supporting departments, accommodation, and overhead costs. For each reference price, the Manual briefly enumerates the data sources used. For example, the reference prices for a session with an independent psychiatrist are based on the total healthcare expenditures in 2007, production parameters collected by the Dutch Healthcare Insurance Board and reimbursement claims at health insurers. The reference prices are established in conformity with the recommendations in the Manual and are based on the most recent data available.

Costs Borne by Informal Care-Givers

Direct costs outside the healthcare sector are costs that have a direct bearing on the disease or treatment, but incur outside the scope of the formal healthcare system. Examples are patients' time and travel costs, the costs of special nutrition, a wig, child care, and medical aids. However, apart from healthcare providers and patients, possible informal care-givers also invest in the treatment process. The next topic in the 2010 Manual involves the inclusion of costs borne by informal care-givers.

The time spent on informal care specifically concerns the time, usually spent on something else, sacrificed to provide informal care. Measuring this time in a standardized way is challenging. A care-giver may indicate that s/he provides informal care 24/7 by keeping an eye on the patient and helping out when required. However, during that time, the care-giver is often able to perform usual activities. Therefore it is necessary to identify the exact tasks performed when measuring informal care. The Manual recommends patient self-report to measure the sacrificed time spent on informal care. This time should be valued with the replacement costs for housekeeping as issued by the Central Administration Office which organization plays an important role in the financial and administrative activities of the health and welfare sector in the Netherlands. In 2009, the replacement costs amounted to € 12.50 per hour (3).

When they are considered to be an important part of the total and incremental costs from a medical perspective, travel- or productivity costs of informal care-givers should also be included in the economic evaluation. It may even be decided to measure the health effects of informal care-givers by means of, for example, the EuroQol-5 Dimensions (EQ-5D) or CarerQol-instrument.

UPDATED TOPICS IN THE 2010 MANUAL

The Friction Cost Method

Indirect costs outside the healthcare sector incur outside the scope of the formal healthcare system and arise as a secondary consequence of the disease or treatment. Examples include productivity costs due to absence from or inefficiency at paid and unpaid work, police and legal costs, special education, and counseling. With respect to productivity costs due to absence from paid work (absenteeism), the Manual recommends the information systems of occupational health organizations or patient self-report to measure the time absent from work. This time should be valued by means of the friction cost method, which approach assumes that, ultimately, each worker is replaceable. Productivity costs occur solely during the friction cost period in which a job vacancy arising due to long-term absenteeism is expected to be filled (13;26). One of the updated topics in the 2010 Manual concerns the duration of the friction cost period and the productivity costs per hour within the friction cost period.

Table 3. Average Productivity Costs per Hour, Stratified to Sex and Corrected for the Elasticity of Labor Time (Euro 2009)

Age range	Total	Men	Women
15 to 19 years	9.27	9.65	8.76
20 to 24 years	17.51	17.75	17.18
25 to 29 years	23.93	24.19	23.62
30 to 35 years	28.80	29.65	27.54
35 to 40 years	32.25	34.03	29.25
40 to 45 years	33.92	36.67	29.06
45 to 50 years	34.87	38.32	28.91
50 to 55 years	35.61	39.06	29.25
55 to 60 years	36.37	39.38	29.50
60 to 65 years	36.41	39.13	28.67
Average	30.02	32.49	25.94

Source: statline.cbs.nl.

The duration of the friction cost period equals the average duration of vacancies increased with the expected number of weeks employers need before taking the decision to place a vacancy for temporary or permanent replacement of the worker (4 weeks). In the 2010 Manual, the average duration of vacancies was estimated at 19 weeks (compared with 18 weeks in the 2004 Manual and 14 weeks in the 2000 Manual). Consequently, the friction cost period was determined at 23 weeks (160 days).

The productivity costs per hour is reflected by the gross added value of the labour that a worker would have produced, including a correction for the elasticity of labour time. Where the 2000 Manual did not take the elasticity of labour time into account, it was estimated at 0.8 in both the 2004 and 2010 Manual (13). This means that the production decreases 8 percent when labor time decreases 10 percent. Table 3 presents the productivity costs per hour applicable to both short-term and long-term absence, stratified to sex (Euro 2009). It concerns the average productivity costs for all workers in the Netherlands, given the existing individual differences in wage and production.

Discounting Future Effects

Another updated topic of the 2010 Manual concerns discounting future effects. When costs and effects occur in different

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years, they cannot be summed up in a straightforward way because, in decision making, current costs and effects usually get a greater weight than future costs and effects. Therefore, future costs and effects need to be discounted. The most common method to unify costs and effects occurring in different years is the calculation of the net present value by means of constant discounting. Similar to the 2000 and 2004 Manual, the 2010 Manual recommends costs to be discounted at a constant rate of 4 percent. In contrast to earlier versions of the Manual, however, the 2010 Manual requires effects to be discounted at a lower discounting rate than costs. The latter recommendation is based on the assumption that the value of health gains increases over time and this increasing value is not accounted for in economic evaluations (2). The discounting rate for effects is determined at 1.5 percent (compared with 4 percent in the 2004 and 2000 Manual). It should be noted that the Netherlands is rather exceptional in this respect (section 5). Discounting at a uniform rate remains preferred abroad, although the desirability of differentiated discounting rates is increasingly recognized in the literature.

Transferring Cost Results From International Studies

Where the effects of treatments are generally assumed to be equal in neighboring countries, their corresponding costs may significantly diverge as a result of the availability of resources, differences in medical treatment patterns and financial incentives, absolute and relative price differences between countries, and health economic guidelines. Therefore, treatment costs cannot simply be converted between countries (20). When it is not feasible to empirically derive Dutch data, cost results from international studies need to be transferred to and validated for the Dutch situation.

The Manual describes several options to transfer cost results from international studies. The 2004 Manual recommended to always use sophisticated decision analytic models to transfer cost results, but earlier studies have not revealed significantly different results when using less advanced alternatives. Therefore, the 2010 Manual allows naive methods or regression approaches to be used when resource quantities of individual patients are available. Naive methods assume that costs do not affect the health gains of the treatment. *Naive splitting* is currently the most common method to transfer cost results to a specific country (1). A multinational average is determined by multiplying the resource quantities of individual patients with the unit costs of each single country participating in a multinational trial. However, the method fails to take country-specific treatment patterns into account which may compromise the representativeness of the cost estimates.

Regression approaches do assume that costs affect the health gains of the treatment. There is a trend toward the use of the *multi-level regression approach* (8). Multi-level models deduct information from the multinational average of each single country to reduce the variability that results from analyzing sub-populations within or across countries. The approach allows for estimating the effects of determinants, even if they are measured at a different level of aggregation. Moreover, the multi-level approach enables lower aggregation effects to be conditionalized on higher aggregation effects. The drawback of regression approaches, however, is that a large population per country is needed to assure enough statistical power.

Similar to the 2004 Manual, the 2010 Manual recommends the use of *decision analytic models*, such as decision trees, Markov-models or micro-simulations, when the resource quantities of individual patients are not available. The key advantage of these models is that each health state and event in the model may be linked to country-specific resource quantities, unit costs, and health gains. This results in country-specific cost and cost-effectiveness estimates (27).

DISCUSSION

The present study aimed to describe the main changes of the 2010 Manual compared with earlier editions of the Manual. The cost study Action Plan forms the backbone of the Manual and comprises a seven-step process that is quite similar to many health economic guidelines in healthcare. However, the recommendations on particular aspects may differ between national guidelines in some respects. In this concluding section, the recommendations of the Manual are compared with the health economic guidelines of other countries and the alternative methods are briefly described.

The Manual requires economic evaluations to proceed from the societal perspective in which direct and indirect costs within the healthcare sector and indirect costs outside the healthcare sector are considered. This recommendation is in agreement with the guidelines of most health economic guidelines issued in Europe, North America, and Australia. Still, some countries favor the healthcare payer's perspective (e.g., the United Kingdom). In Belgium and Poland, the healthcare payer's perspective is preferred but other perspectives may be presented separately when considered significant for decision makers (10).

The health economic guidelines of only three countries specifically refer to medical costs in life-years gained. Where the inclusion of this cost category is required in Sweden, it is not required in Poland and the Netherlands. The inclusion of costs in life-years gained remains an area of much controversy (18). One of the main arguments for exclusion of costs in life-years gained is that these costs are difficult to estimate in a standardized manner and should always be explicitly modeled. However, others argue that costs in life-years gained are important from a societal perspective and the accurate estimation of these costs becomes increasingly conceivable (18;25).

DRGs have become the principal means of reimbursing hospitals in many developed countries. Because DRG tariff setting was observed to be infeasible without the availability of detailed resource quantities, many countries started to

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systematically collect resource quantities in national databases (16). For example, the British national database contains the resource quantities and unit costs of all inpatient admissions (6). These data are publicly accessible and serve as a basis to determine treatment costs in the United Kingdom. Due to the "fast track" activity and data collection from all public hospitals, resource quantities and unit costs in the British database are argued to be severely flawed (7). However, the data collection process is currently being reviewed to improve the accuracy and usefulness of the database. Similar developments are taking place in Australia, Germany, and the Netherlands (5;14;23). The database of the DBC casemix system is not yet publicly accessible, but may serve as a unique data source for the conduct of future economic evaluations. The potential role and validity of the Dutch database for determining treatment costs, establishing references prices, assessing the compliance to clinical practice guidelines and tracking treatment patterns over time is currently being investigated (unpublished data).

Standardization plays an important role in the field of health economic guidelines developed in recent years. In an attempt to standardize costing methodologies for economic evaluations, the establishment of reference prices has been the object of growing attention in many developed countries. However, reference prices for healthcare services in the mental healthcare sector are not (yet) widely adopted. One exception is the British Manual which presents an extensive list of reference prices for mental health problems. These reference prices were calculated by means of own unit cost calculations and generally comprise the cost items as the Dutch reference prices (section 3; Table 2). British reference prices in the mental healthcare sector include the primary care psychiatrist (€ 83 versus € 80 in the 2010 Manual), inpatient days (€ 260 versus € 232), daycare treatments (€ 59 versus € 154), and residential care (€ 72 versus € 151) (6). The reference prices for daycare treatments and residential care are higher in the Netherlands because they include daycare activities and counseling.

There is no consensus on the preferred method to account for productivity costs due to absence from paid work. Some countries (e.g., Austria, Belgium, Italy, and Sweden) favor the Human Capital Approach in which all lost time arising due to long-term absenteeism is valued, even until the retirement age where applicable (10). The approach is argued to proceed from the patient's- rather than the societal or healthcare payer's perspective. This argument stimulated the development of the friction cost method which assumes that productivity costs solely occur during the friction cost period in which a job vacancy is expected to be filled (13;26). Similar to health economic guidelines in France and Germany, the 2010 Manual recommends valuing the number of hours absent from work by means of the friction cost method (10).

Although there is a wide consensus on the necessity of discounting in economic evaluations, the discounting rate for effects is subject to discussion. Internationally, effects are most commonly discounted at the same discounting rate as costs. This practical agreement appears to be predominantly based on the consistency argument. This argument entails that consistency requires two identical treatments, which only differ in terms of timing, to get the same priority because they have the same ratio of costs and effects. However, a crucial assumption of this argument is that the value of health gains remains constant over time. The Manual recommends to discount effects at a lower discounting rate than costs, because it assumes that the value of health gains is likely to increase over time and not accounted for in economic evaluations (2). The discounting rate is determined at 1.5 percent (compared with between 3 and 5 percent in most developed countries) (4).

As new insights, developments, and data sources become available, the Manual is subject to periodic updating to reflect current practice and unit prices. The process of improvement also concerns the introduction of new reference prices, such as for target populations (e.g., children and elderly) and specific medical specialties (e.g., hemato-oncological diseases). However, the timing of the next update is still to be determined.

The Manual describes the starting points to be used in economic evaluations, the available methods for measuring and valuing costs and important criteria when choosing between methods. Although it may serve as an example to countries intending to develop a manual of this kind, it should always be kept in mind that preferred methods predominantly depend on a country's specific context.

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CONFLICTS OF INTEREST

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