

unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assess the sufficiency of any safeguards in place to control these risks;

3. Design and implement reasonable safeguards to control the risks identified through risk assessment, and regularly test or monitor the effectiveness of the safeguards' key controls, systems, and procedures;

4. Develop and use reasonable steps to retain service providers capable of appropriately safeguarding personal information they receive from respondents and requiring service providers by contract to implement and maintain appropriate safeguards; and

5. Evaluate and adjust respondents' information security program in light of the results of the testing and monitoring, any material changes to respondents' operations or business arrangements, or any other circumstances that respondents know or have reason to know may have a material impact on the effectiveness of their information security program.

Part III of the proposed order requires that respondents, in connection with the online advertising, marketing, promotion, offering for sale, or sale of any product or service to consumers, obtain within 180 days, and on a biennial bases thereafter for a period of ten (10) years, an assessment and report from a qualified, objective, independent third-party professional, certifying, among other things, that respondents have in place a security program that provides protections that meet or exceed the protections required by Part II of the proposed order; and (2) respondents' security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumers' personal information is protected.

Parts IV through VIII of the proposed order are reporting and compliance provisions. Part IV requires respondents to retain documents relating to their compliance with the order. For most records, the order requires that the documents be retained for a five-year period. For the third-party assessments and supporting documents, respondents must retain the documents for a period of three years after the date that each assessment is prepared. Part V requires dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part VI ensures notification to the FTC of changes in corporate status. Part VII mandates that respondents submit an initial compliance report to the FTC, and make

available to the FTC subsequent reports. Part VIII is a provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of the analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark

Secretary

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BILLING CODE 6750-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Kazuhiro Tanaka, M.D., Ph.D., National Institute of Dental and Craniofacial Research, National Institutes of Health: Based on the report of an investigation conducted by the National Institutes of Health (NIH) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Kazuhiro Tanaka, former Visiting Postdoctoral Fellow, Molecular Biology Section, Craniofacial Developmental and Biology and Regeneration Branch (CDBRB), National Institute of Dental and Craniofacial Research (NIDCR), NIH, engaged in scientific misconduct in research supported by PHS funds from the NIDCR, NIH Intramural Program.

PHS found that Respondent engaged in scientific misconduct by falsifying data that were included in three published papers: Kazuhiro Tanaka, Yoshihiro Matsumoto, Fumihiko Nakatani, Yukihide Iwamoto, and Yoshihiko Yamada, "A zinc finger transcription α A-crystallin binding protein 1, is a negative regulator of the chondrocyte-specific enhancer of the α 1(II) collagen gene," *Molecular and Cellular Biology (MCB)* 20:4428-4435, 2000; Kazuhiro Tanaka, Noriyuki Tsumaki, Christine A. Kozak, Yoshihiro Matsumoto, Fumihiko Nakatani, Yukihide Iwamoto, and Yoshihiko Yamada, "A Krüppel-associated box-zinc finger protein, NT2, represses cell-type-specific promoter activity of the

α 2(XI) collagen gene," *Molecular and Cellular Biology* 22:4256-4267, 2002; and Ying Liu, Haochuan Li, Kazuhiro Tanaka, Noriyuki Tsumaki, and Yoshihiko Yamada, "Identification of an enhancer sequence with the first intron required for cartilage-specific transcription of the α 2(XI) collagen gene," *Journal of Biological Chemistry (JBC)* 275:12712-12718, 2000.

Specifically, PHS found that Respondent:

- Falsified the results for CRYBP1 or Sox9 binding to the Col2a1 DNA sequence in electrophoretic mobility shift assays in Figure 1D and Figure 7 in *MCB* 20:4428-4435, 2000. He used duplicate copies of bands or duplicate copies of parts of lanes to falsely represent results from reportedly different experimental conditions;

- Falsified the results for NT2 binding to the Col11a2 DNA sequence in electrophoretic mobility shift assays in Figures 2D and 6B, and falsified the Western blot for NT2 mutant proteins in Figure 8B in *MCB* 22:4256-4267, 2002. He used duplicate copies of bands, parts of bands, or duplicate copies of parts of lanes to falsely represent results from reportedly different experimental conditions in Figures 2D and 6B; and falsely represented results for the Figure 8B Western blot by using duplicate copies of bands to represent NT2 Δ 1 (lane 2) and NT2 Δ 4 (lane 5) mutant proteins;

- Falsified the Western blot for Sox9 protein expression in Figure 4B, *JBC* 275:12712-12718, 2000, by using duplicate copies of lanes 1 and 2 to represent the Sox9 expression in cell extracts from both Balb 3T3 and undifferentiated ATDC5 cells; and

- Falsified the Northern blots in multiple panels of Figure 3, *MCB* 20:4428-4435, 2000. He used duplicate copies of bands for CRYBP1, for Type II collagen, for Type X collagen, and for GAPDH and 18S EtBr stained control bands to falsely represent results of RNA expression from these different genes in ATDC5 cells. He also used duplicate copies of bands to falsely represent the RNA expression in ATDC5 cells grown under different conditions for either collagen Type II in Figure 3, *MCB* 2000 or collagen α 1(X) in Figure 5 in *MCB* 22:4256-4267, 2002. Similarly, duplicate copies of 18S EtBr stained control bands were used in both figures with reportedly different experimental conditions.

Both Respondent and PHS are desirous of concluding this matter without further expense of time and other resources, and the parties have entered into a Voluntary Exclusion Agreement (Agreement). The settlement

is not an admission of liability on the part of the Respondent. Respondent neither admits nor denies ORI's finding of scientific misconduct. Respondent acknowledges that original data relating to the above referenced falsified figures are missing.

Dr. Tanaka has voluntarily agreed, for a period of three (3) years, beginning on January 14, 2009:

(1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 CFR Part 376 *et seq.*) of OMB Guidelines to Agencies on Government wide Debarment and Suspension (2 CFR, Part 180); and

(2) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8800.

Chris B. Pascal,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project:

"Evaluation of Phase I Demonstrations of the Pharmacy Quality Alliance." In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by April 13, 2009.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz,

Reports Clearance Officer, AHRQ, by e-mail at doris.lefkowitz@ahrq.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at doris.lefkowitz@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Evaluation of Phase I Demonstrations of the Pharmacy Quality Alliance

AHRQ proposes to conduct an independent evaluation of five Phase I demonstrations undertaken by the Pharmacy Quality Alliance (PQA). The PQA launched the five demonstration projects to test the feasibility of implementing a pharmacy provider report card system, which will be used to provide feedback to pharmacies on their performance. The goals of the demonstrations are to obtain feedback from pharmacists on the credibility of the performance reports and their utility in performance improvement, and to identify the most efficient and useful ways to implement a performance-based quality reporting system. The evaluation will be conducted for AHRQ by its contractor, the CNA Corporation and Thomas Jefferson Medical College.

The purpose of this evaluation is to identify problems associated with the implementation of a performance-based quality reporting system. The evaluation of the Phase I demonstrations will:

- Test the feasibility and utility of (1) using 15 PQA claims-based measures on pharmacy performance and (2) a survey of consumers about their experience with pharmacy services, which was developed by the PQA;
- Determine the resource (time and cost) requirements for collecting the data and generating the pharmacy performance reports; and
- Provide a base of knowledge that enables the PQA to improve the implementation process, increase operational efficiency, reduce operational costs, and enhance the utility and validity of the performance measures.

This project is being conducted pursuant to AHRQ's statutory authority to conduct and support research and evaluations on health care and on systems for the delivery of such care, including activities with respect to (1) the quality, effectiveness, efficiency, appropriateness and value of health care services and (2) quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

The project will include the following three data collections: (1) On-site interviews with key personnel involved in the demonstration; (2) a pre-interview questionnaire for the on site interview participants; and (3) a survey of pharmacy staff. The data will be collected to obtain the following types of information necessary for the evaluation:

- Organizational background related to quality measurement, organizational resources for quality measurement;
- Measurement methodology;
- Opinions on the performance measures;
- The process for disseminating the performance measures;
- Incentives and penalties for participation in pharmacy quality improvement;
- Usability of the performance reports;
- Future directions for quality measurement in the organization; and
- Respondent characteristics.

Onsite Interviews With Key Demonstration Participants

On-site interviews will be conducted with up to six persons at each of the five demonstration sites. The study will try to interview representatives from the following job functions: (1) Pharmacy operations management; (2) clinical pharmacy staff; (3) quality-improvement; (4) utilization management; (5) analytics management responsible for oversight of performance report analyses; (6) analytics staff assigned to complete the performance reports; (7) information technology (IT) staff responsible for developing and/or coordinating Internet components of the project; and (8) senior management (executive leadership, *i.e.*, Vice President level and above).

Pre-Interview Questionnaire

In addition to the on-site interview, a brief written questionnaire will be used to collect information from interview participants prior to the interview. There will be two different versions of this questionnaire, one for the demonstration project leaders and one for all on-site interview participants.

Survey of Pharmacy Staff

A pharmacy staff survey will be developed to yield additional quantitative data about the demonstration projects. The sample will consist of practicing pharmacists who are participating in the demonstration sites and who received one or more of the performance reports. It will also include field managers and supervisors.